REFERENCE MATERIALS
for Bailiwick News Collections
Version 1 - April 2025

Reference materials to accompany the subject-matter books assembled so far.

Book 1 – Biological product non-regulation contains the 1798-1972 series researched and written with Lydia Hazel; some posts about scientific and mathematical frauds (virus 'isolation,' antibodies, probability units); and posts from a series about FDA-directed biological product non-regulation acts and omissions since 1972. Reporting in this collection is focused on the 1902 Virus-Toxin law (also known as Biologics Control Act), 1906 Pure Food and Drug Act, 1938 Food Drug and Cosmetic Act, and 1944 Public Health Service Act, and the main implementing regulations prior to 1973: 42 CFR 22; 42 CFR 73; 21 CFR 273; and since 1973: 21 CFR 600-680.

Book 2 – PREP Act, public health emergency, and EUA countermeasure law contains reporting on federal PREP Act, public health emergency and EUA countermeasure law, focused on Public Health Service Act Section 319 (codified at 42 USC 247d-6d), Food Drug and Cosmetic Act Section 564 (21 USC 360bbb), PREP Act, Project Bioshield Act and a few others.

Book 3 - Communicable disease control, quarantine, habeas corpus law contains reporting on federal communicable disease control and quarantine law, focused on Public Health Service Act Section 351 (codified at 42 USC 264) and two implementing regulations: 42 CFR 70, 42 CFR 71

Version 1 of reference collection includes federal statutes. It includes only two relevant regulations (domestic quarantine and select agents and toxins) because regulation documents are much longer documents.

Readers interested in the reading biological product regulations will find most of the versions promulgated between 1902 and 1972 uploaded at the Bailiwick News archives page here and the current version of 21 CFR 600-680 here.

Contents

1902 Virus-Toxin law, also known as Biologics Control Act

Aiding and abetting.

SEC. 2. That any person who shall counsel, aid, abet, and assist in the perpetration of any of the offenses set forth in the preceding section shall be deemed to be principals therein.

Proofs.

SEC. 3. That upon the trial of any person charged with any offense set forth in this Act it shall not be necessary to set forth or prove the particular person against whom it was intended to commit the offense, or that it was intended to commit such offense against any particular person.

Approved, July 1, 1902.

July 1, 1902.
[Public, No. 243.]

CHAP. 1377.—An Act Providing for the resurvey of certain townships in San Diego County, California.

San Diego County, Cal.
Resurvey of certain townships.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That the Secretary of the Interior be, and he is hereby, authorized to cause to be made a resurvey of the lands in San Diego County, in the State of California, embraced in and consisting of the tier of townships thirteen, fourteen, fifteen, and sixteen south, of ranges eleven, twelve, thirteen, fourteen, fifteen, and sixteen east, and the fractional township seventeen south, of ranges fifteen and sixteen east, all of San Bernardino base and meridian; and all rules and regulations of the Interior Department requiring petitions from all settlers of said townships asking for resurvey and agreement to abide by the result of the same so far as these lands are concerned are hereby abrogated: *Provided*, That nothing herein contained shall be so construed as to impair the present bona fide claim of any actual occupant of any of said lands to the lands so occupied.

Proviso.
Bona fide claims of actual occupants.

Approved, July 1, 1902.

July 1, 1902.
[Public, No. 244.]

CHAP. 1378.—An Act To regulate the sale of viruses, serums, toxins, and analogous products in the District of Columbia, to regulate interstate traffic in said articles, and for other purposes.

District of Columbia.
Regulation of sale of and interstate traffic in viruses, serums, etc.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That from and after six months after the promulgation of the regulations authorized by section four of this Act no person shall sell, barter, or exchange, or offer for sale, barter, or exchange in the District of Columbia, or send, carry, or bring for sale, barter, or exchange from any State, Territory, or the District of Columbia into any State, Territory, or the District of Columbia, or from any foreign country into the United States, or from the United States into any foreign country, any virus, therapeutic serum, toxin, antitoxin, or analogous product applicable to the prevention and cure of diseases of man, unless (a) such virus, serum, toxin, antitoxin, or product has been propagated and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Secretary of the Treasury as hereinafter authorized, to propagate and prepare such virus, serum, toxin, antitoxin, or product for sale in the District of Columbia, or for sending, bringing, or carrying from place to place aforesaid; nor (b) unless each package of such virus, serum, toxin, antitoxin, or product is plainly marked with the proper name of the article contained therein, the name, address, and license number of the manufacturer, and the date beyond which the contents can not be expected beyond reasonable doubt to yield their specific results: *Provided*, That the suspension or revocation of any license shall not pre-

Proviso.
Revocation of licenses.

vent the sale, barter, or exchange of any virus, serum, toxin, antitoxin, or product aforesaid which has been sold and delivered by the licentiate prior to such suspension or revocation, unless the owner or custodian of such virus, serum, toxin, antitoxin, or product aforesaid has been notified by the Secretary of the Treasury not to sell, barter, or exchange the same.

False labels, etc.

SEC. 2. That no person shall falsely label or mark any package or container of any virus, serum, toxin, antitoxin, or product aforesaid; nor alter any label or mark on any package or container of any virus, serum, toxin, antitoxin, or product aforesaid so as to falsify such label or mark.

Inspection.

SEC. 3. That any officer, agent, or employee of the Treasury Department, duly detailed by the Secretary of the Treasury for that purpose, may during all reasonable hours enter and inspect any establishment for the propagation and preparation of any virus, serum, toxin, antitoxin, or product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State, Territory, or the District of Columbia into any other State or Territory or the District of Columbia, or from the United States into any foreign country, or from any foreign country into the United States.

Board created to prescribe regulations for licenses.

SEC. 4. That the Surgeon-General of the Army, the Surgeon-General of the Navy, and the supervising Surgeon-General of the Marine-Hospital Service, be, and they are hereby, constituted a board with authority, subject to the approval of the Secretary of the Treasury, to promulgate from time to time such rules as may be necessary in the judgment of said board to govern the issue, suspension, and revocation of licenses for the maintenance of establishments for the propagation and preparation of viruses, serums, toxins, antitoxins, and analogous products, applicable to the prevention and cure of diseases of man, intended for sale in the District of Columbia, or to be sent, carried or brought for sale from any State, Territory, or the District of Columbia, into any other State, Territory, or the District of Columbia, or from the United States into any foreign country, or from any foreign country into the United States: *Provided*, That all licenses issued for the maintenance of establishments for the propagation and preparation in any foreign country of any virus, serum, toxin, antitoxin, or product aforesaid; for sale, barter, or exchange in the United States, shall be issued upon condition that the licentiates will permit the inspection of the establishments where said articles are propagated and prepared, in accordance with section three of this Act.

Proviso. Conditions.

Enforcement of regulations, etc.

SEC. 5. That the Secretary of the Treasury be, and he is hereby, authorized and directed to enforce the provisions of this Act and of such rules and regulations as may be made by authority thereof; to issue, suspend, and revoke licenses for the maintenance of establishments aforesaid, and to detail for the discharge of such duties such officers, agents, and employees of the Treasury Department as may in his judgment be necessary.

Interference with officers, etc., prohibited.

SEC. 6. That no person shall interfere with any officer, agent, or employee of the Treasury Department in the performance of any duty imposed upon him by this Act or by regulations made by authority thereof.

Punishment for violation.

SEC. 7. That any person who shall violate, or aid or abet in violating, any of the provisions of this Act shall be punished by a fine not exceeding five hundred dollars or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

Repeal.

SEC. 8. That all Acts and parts of Acts inconsistent with the provisions of this Act be, and the same are hereby, repealed.

Approved, July 1, 1902.

1906 Pure Food and Drug Act (products other than biologics)

Report on expenditures.

That all moneys appropriated by this Act which the Jamestown Tercentennial Commission is authorized to expend shall be drawn out of the Treasury in such manner and under such regulations as such Commission may determine, subject to the approval of the Secretary of the Treasury; and at the close of the exposition period, and after the work of such Commission is completed, such Commission shall make a complete report of their actions hereunder and a complete statement of all expenditures for each of the purposes herein specified to the President of the United States for transmission to Congress.

Approved, June 30, 1906.

June 30, 1906.
[S. 88.]
[Public, No. 384.]

CHAP. 3915.—An Act For preventing the manufacture, sale, or transportation of adulterated or misbranded or poisonous or deleterious foods, drugs, medicines, and liquors, and for regulating traffic therein, and for other purposes.

Pure food act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That it shall be unlawful for any person to manufacture within any Territory or the District of Columbia any article of food or drug which is adulterated or misbranded, within the meaning of this Act; and any person who shall violate any of the provisions of this section shall be guilty of a misdemeanor, and for each offense shall, upon conviction thereof, be fined not to exceed five hundred dollars or shall be sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court, and for each subsequent offense and conviction thereof shall be fined not less than one thousand dollars or sentenced to one year's imprisonment, or both such fine and imprisonment, in the discretion of the court.

Manufacture of adulterated, etc., food or drugs in Territories and District of Columbia unlawful.
Penalty.

Interstate, etc., commerce of adulterated or misbranded goods prohibited.

SEC. 2. That the introduction into any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or from any foreign country, or shipment to any foreign country of any article of food or drugs which is adulterated or misbranded, within the meaning of this Act, is hereby prohibited; and any person who shall ship or deliver for shipment from any State or Territory or the District of Columbia to any other State or Territory or the District of Columbia, or to a foreign country, or who shall receive in any State or Territory or the District of Columbia from any other State or Territory or the District of Columbia, or foreign country, and having so received, shall deliver, in original unbroken packages, for pay or otherwise, or offer to deliver to any other person, any such article so adulterated or misbranded within the meaning of this Act, or any person who shall sell or offer for sale in the District of Columbia or the Territories of the United States any such adulterated or misbranded foods or drugs, or export or offer to export the same to any foreign country, shall be guilty of a misdemeanor, and for such offense be fined not exceeding two hundred dollars for the first offense, and upon conviction for each subsequent offense not exceeding three hundred dollars or be imprisoned not exceeding one year, or both, in the discretion of the court: *Provided*, That no article shall be deemed misbranded or adulterated within the provisions of this Act when intended for export to any foreign country and prepared or packed according to the specifications or directions of the foreign purchaser when no substance is used in the preparation or packing thereof in conflict with the laws of the foreign country to which said article is intended to be shipped; but if said article shall be in fact sold or offered for sale for domestic use or consumption, then this proviso shall not exempt said article from the operation of any of the other provisions of this Act.

Penalty.

Proviso.
Articles for export.

Domestic consumption.

Rules and regulations to be made.

SEC. 3. That the Secretary of the Treasury, the Secretary of Agriculture, and the Secretary of Commerce and Labor shall make uniform

rules and regulations for carrying out the provisions of this Act, including the collection and examination of specimens of foods and drugs manufactured or offered for sale in the District of Columbia, or in any Territory of the United States, or which shall be offered for sale in unbroken packages in any State other than that in which they shall have been respectively manufactured or produced, or which shall be received from any foreign country, or intended for shipment to any foreign country, or which may be submitted for examination by the chief health, food, or drug officer of any State, Territory, or the District of Columbia, or at any domestic or foreign port through which such product is offered for interstate commerce, or for export or import between the United States and any foreign port or country. Scope.

SEC. 4. That the examinations of specimens of foods and drugs shall be made in the Bureau of Chemistry of the Department of Agriculture, or under the direction and supervision of such Bureau, for the purpose of determining from such examinations whether such articles are adulterated or misbranded within the meaning of this Act; and if it shall appear from any such examination that any of such specimens is adulterated or misbranded within the meaning of this Act, the Secretary of Agriculture shall cause notice thereof to be given to the party from whom such sample was obtained. Any party so notified shall be given an opportunity to be heard, under such rules and regulations as may be prescribed as aforesaid, and if it appears that any of the provisions of this Act have been violated by such party, then the Secretary of Agriculture shall at once certify the facts to the proper United States district attorney, with a copy of the results of the analysis or the examination of such article duly authenticated by the analyst or officer making such examination, under the oath of such officer. After judgment of the court, notice shall be given by publication in such manner as may be prescribed by the rules and regulations aforesaid. Chemical examinations. Notice of result. Hearings. Certificate of violations to district attorney.

SEC. 5. That it shall be the duty of each district attorney to whom the Secretary of Agriculture shall report any violation of this Act, or to whom any health or food or drug officer or agent of any State, Territory, or the District of Columbia shall present satisfactory evidence of any such violation, to cause appropriate proceedings to be commenced and prosecuted in the proper courts of the United States, without delay, for the enforcement of the penalties as in such case herein provided. Legal proceedings.

SEC. 6. That the term "drug," as used in this Act, shall include all medicines and preparations recognized in the United States Pharmacopœia or National Formulary for internal or external use, and any substance or mixture of substances intended to be used for the cure, mitigation, or prevention of disease of either man or other animals. The term "food," as used herein, shall include all articles used for food, drink, confectionery, or condiment by man or other animals, whether simple, mixed, or compound. Terms defined. "Drugs." "Food."

SEC. 7. That for the purposes of this Act an article shall be deemed to be adulterated: Adulterations defined.

In case of drugs: Drugs.

First. If, when a drug is sold under or by a name recognized in the United States Pharmacopœia or National Formulary, it differs from the standard of strength, quality, or purity, as determined by the test laid down in the United States Pharmacopœia or National Formulary official at the time of investigation: *Provided*, That no drug defined in the United States Pharmacopœia or National Formulary shall be deemed to be adulterated under this provision if the standard of strength, quality, or purity be plainly stated upon the bottle, box, or other container thereof although the standard may differ from that determined by the test laid down in the United States Pharmacopœia or National Formulary. Difference from recognized standards. *Proviso.* Exception.

Below professed standard.

Second. If its strength or purity fall below the professed standard or quality under which it is sold.

Confectionery.

In the case of confectionery:

Deleterious ingredients, narcotics, etc.

If it contain terra alba, barytes, talc, chrome yellow, or other mineral substance or poisonous color or flavor, or other ingredient deleterious or detrimental to health, or any vinous, malt or spirituous liquor or compound or narcotic drug.

Food.

In the case of food:

Injurious mixtures.

First. If any substance has been mixed and packed with it so as to reduce or lower or injuriously affect its quality or strength.

Substitutes.

Second. If any substance has been substituted wholly or in part for the article.

Constituents abstracted.

Third. If any valuable constituent of the article has been wholly or in part abstracted.

Damage, etc., concealed.

Fourth. If it be mixed, colored, powdered, coated, or stained in a manner whereby damage or inferiority is concealed.

Deleterious additions.

Fifth. If it contain any added poisonous or other added deleterious ingredient which may render such article injurious to health: *Provided*,

Proviso.

Preservatives for shipment allowed.

That when in the preparation of food products for shipment they are preserved by any external application applied in such manner that the preservative is necessarily removed mechanically, or by maceration in water, or otherwise, and directions for the removal of said preservative shall be printed on the covering or the package, the provisions of this Act shall be construed as applying only when said products are ready for consumption.

Compositions prohibited.

Sixth. If it consists in whole or in part of a filthy, decomposed, or putrid animal or vegetable substance, or any portion of an animal unfit for food, whether manufactured or not, or if it is the product of a diseased animal, or one that has died otherwise than by slaughter.

Misbranding defined.

SEC. 8. That the term "misbranded," as used herein, shall apply to all drugs, or articles of food, or articles which enter into the composition of food, the package or label of which shall bear any statement, design, or device regarding such article, or the ingredients or substances contained therein which shall be false or misleading in any particular, and to any food or drug product which is falsely branded as to the State, Territory, or country in which it is manufactured or produced.

That for the purposes of this Act an article shall also be deemed to be misbranded:

Drugs.

In case of drugs:

False name.

First. If it be an imitation of or offered for sale under the name of another article.

False contents.

Second. If the contents of the package as originally put up shall have been removed, in whole or in part, and other contents shall have been placed in such package, or if the package fail to bear a statement on the label of the quantity or proportion of any alcohol, morphine, opium, cocaine, heroin, alpha or beta eucaine, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any such substances contained therein.

Failure to state narcotics, etc., used.

Foods.

In the case of food:

Imitations.

First. If it be an imitation of or offered for sale under the distinctive name of another article.

False label, etc.

Second. If it be labeled or branded so as to deceive or mislead the purchaser, or purport to be a foreign product when not so, or if the contents of the package as originally put up shall have been removed in whole or in part and other contents shall have been placed in such package, or if it fail to bear a statement on the label of the quantity or proportion of any morphine, opium, cocaine, heroin, alpha or beta eucane, chloroform, cannabis indica, chloral hydrate, or acetanilide, or any derivative or preparation of any of such substances contained therein.

Failure to state narcotics, etc., used.

Third. If in package form, and the contents are stated in terms of weight or measure, they are not plainly and correctly stated on the outside of the package. Incorrect weight or measure.

Fourth. If the package containing it or its label shall bear any statement, design, or device regarding the ingredients or the substances contained therein, which statement, design, or device shall be false or misleading in any particular: *Provided*, That an article of food which does not contain any added poisonous or deleterious ingredients shall not be deemed to be adulterated or misbranded in the following cases: Misleading ingredients. *Proviso.* Exceptions.

First. In the case of mixtures or compounds which may be now or from time to time hereafter known as articles of food, under their own distinctive names, and not an imitation of or offered for sale under the distinctive name of another article, if the name be accompanied on the same label or brand with a statement of the place where said article has been manufactured or produced. Compounds under distinctive names.

Second. In the case of articles labeled, branded, or tagged so as to plainly indicate that they are compounds, imitations, or blends, and the word "compound," "imitation," or "blend," as the case may be, is plainly stated on the package in which it is offered for sale: *Provided*, That the term blend as used herein shall be construed to mean a mixture of like substances, not excluding harmless coloring or flavoring ingredients used for the purpose of coloring and flavoring only: *And provided further*, That nothing in this Act shall be construed as requiring or compelling proprietors or manufacturers of proprietary foods which contain no unwholesome added ingredient to disclose their trade formulas, except in so far as the provisions of this Act may require to secure freedom from adulteration or misbranding. If "compound," etc. plainly stated. *Provisos.* Meaning of blend. Trade formulas.

SEC. 9. That no dealer shall be prosecuted under the provisions of this Act when he can establish a guaranty signed by the wholesaler, jobber, manufacturer, or other party residing in the United States, from whom he purchases such articles, to the effect that the same is not adulterated or misbranded within the meaning of this Act, designating it. Said guaranty, to afford protection, shall contain the name and address of the party or parties making the sale of such articles to such dealer, and in such case said party or parties shall be amenable to the prosecutions, fines, and other penalties which would attach, in due course, to the dealer under the provisions of this Act. Guaranty from manufacturer. Contents.

SEC. 10. That any article of food, drug, or liquor that is adulterated or misbranded within the meaning of this Act, and is being transported from one State, Territory, District, or insular possession to another for sale, or, having been transported, remains unloaded, unsold, or in original unbroken packages, or if it be sold or offered for sale in the District of Columbia or the Territories, or insular possessions of the United States, or if it be imported from a foreign country for sale, or if it is intended for export to a foreign country, shall be liable to be proceeded against in any district court of the United States within the district where the same is found, and seized for confiscation by a process of libel for condemnation. And if such article is condemned as being adulterated or misbranded, or of a poisonous or deleterious character, within the meaning of this Act, the same shall be disposed of by destruction or sale, as the said court may direct, and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States, but such goods shall not be sold in any jurisdiction contrary to the provisions of this Act or the laws of that jurisdiction: *Provided, however*, That upon the payment of the costs of such libel proceedings and the execution and delivery of a good and sufficient bond to the effect that such articles shall not be sold or otherwise disposed of contrary to the provisions of this Act, or the laws of any State, Territory, District, or insular possession, the court may by order direct that such articles be delivered to the owner thereof. The Seizure of original packages in interstate and foreign commerce. Disposal, if condemned. *Proviso.* Delivery to owner if not to be sold, etc. Proceedings.

proceedings of such libel cases shall conform, as near as may be, to the proceedings in admiralty, except that either party may demand trial by jury of any issue of fact joined in any such case, and all such proceedings shall be at the suit of and in the name of the United States.

Examination of imported foods and drugs.

SEC. 11. The Secretary of the Treasury shall deliver to the Secretary of Agriculture, upon his request from time to time, samples of foods and drugs which are being imported into the United States or offered for import, giving notice thereof to the owner or consignee, who may appear before the Secretary of Agriculture, and have the right to introduce testimony, and if it appear from the examination of such samples that any article of food or drug offered to be imported into the United States is adulterated or misbranded within the meaning of this Act, or is otherwise dangerous to the health of the people of the United States, or is of a kind forbidden entry into, or forbidden to be sold or restricted in sale in the country in which it is made or from which it is exported, or is otherwise falsely labeled in any respect, the said article shall be refused admission, and the Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any goods refused delivery which shall not be exported by the consignee within three months from the date of notice of such refusal under such regulations as the Secretary of the Treasury may prescribe: *Provided*, That the Secretary of the Treasury may deliver to the consignee such goods pending examination and decision in the matter on execution of a penal bond for the amount of the full invoice value of such goods, together with the duty thereon, and on refusal to return such goods for any cause to the custody of the Secretary of the Treasury, when demanded, for the purpose of excluding them from the country, or for any other purpose, said consignee shall forfeit the full amount of the bond: *And provided further*, That all charges for storage, cartage, and labor on goods which are refused admission or delivery shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future importation made by such owner or consignee.

Admission denied adulterated or misbranded goods.

Destruction, etc.

Provisos.
Delivery pending examination.
Bond required.

Charges.

Insular possessions included.
"Person" defined.

SEC. 12. That the term "Territory" as used in this Act shall include the insular possessions of the United States. The word "person" as used in this Act shall be construed to import both the plural and the singular, as the case demands, and shall include corporations, companies, societies and associations. When construing and enforcing the provisions of this Act, the act, omission, or failure of any officer, agent, or other person acting for or employed by any corporation, company, society, or association, within the scope of his employment or office, shall in every case be also deemed to be the act, omission, or failure of such corporation, company, society, or association as well as that of the person.

Liability of corporations, etc.

In effect January 1, 1907.

SEC. 13. That this Act shall be in force and effect from and after the first day of January, nineteen hundred and seven.

Approved, June 30, 1906.

June 30, 1906.
[H. R. 20410.]
[Public, No. 385.]

CHAP. 3916.—An Act To increase the limit of cost of certain public buildings, to authorize the purchase of sites for public buildings, to authorize the erection and completion of public buildings, and for other purposes.

Omnibus public buildings act.
Limit of cost increased.
Post, p. 1236.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That to enable the Secretary of the Treasury of the United States to give effect to and execute the provisions of existing legislation authorizing the purchase of sites and erection thereon of public buildings in the several cities hereinafter enumerated, the limit of cost heretofore fixed by Congress therefor

1913 Virus, Serum, Toxin Act (veterinary products, for use on animals)

hour law, the inspection and quarantine of imported animals, including the establishment and maintenance of quarantine stations and the alteration of buildings thereon, the inspection work relative to the existence of contagious diseases and the tuberculin and mallein testing of animals, $654,000: *Provided*, That of this sum not less than $75,000 shall be set aside for demonstrating the best method of preventing and eradicating hog cholera;

Proviso. Eradicating hog cholera.

Southern cattle ticks.

For all necessary expenses for the eradication of southern cattle ticks, $325,000: *Provided, however*, That no part of this appropriation shall be used in the purchase of materials for or in the construction of dipping vats upon land not owned solely by the United States, except at fairs or expositions where the Department of Agriculture makes exhibits or demonstrations; nor shall any part of this appropriation be used in the purchase of materials or mixtures for use in dipping vats except in experimental or demonstration work carried on by the officials or agents of the Bureau of Animal Industry;

Proviso. Limitation on purchase of materials, etc.

Dairy industry.

For all necessary expenses for investigations and experiments in dairy industry, cooperative investigations of the dairy industry in the various States, inspection of renovated butter factories and markets, $177,900;

Animal husbandry.

For all necessary expenses for investigations and experiments in animal husbandry, $52,180;

Animal diseases.

For all necessary expenses for scientific investigations in diseases of animals, including the maintenance and improvement of the bureau experiment station at Bethesda, Maryland, and the necessary alterations of buildings thereon, and the necessary expenses for investigations of tuberculin, serums, antitoxins, and analogous products, $78,680;

Viruses, toxins, etc. Trade in harmful, etc., unlawful.

That from and after July first, nineteen hundred and thirteen, it shall be unlawful for any person, firm, or corporation to prepare, sell, barter, or exchange in the District of Columbia, or in the Territories, or in any place under the jurisdiction of the United States, or to ship or deliver for shipment from one State or Territory or the District of Columbia to any other State or Territory or the District of Columbia, any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product intended for use in the treatment of domestic animals, and no person, firm, or corporation shall prepare, sell, barter, exchange, or ship as aforesaid any virus, serum, toxin, or analogous product manufactured within the United States and intended for use in the treatment of domestic animals, unless and until the said virus, serum, toxin, or analogous product shall have been prepared, under and in compliance with regulations prescribed by the Secretary of Agriculture, at an establishment holding an unsuspended and unrevoked license issued by the Secretary of Agriculture as hereinafter authorized. That the importation into the United States, without a permit from the Secretary of Agriculture, of any virus, serum, toxin, or analogous product for use in the treatment of domestic animals, and the importation of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, are hereby prohibited. The Secretary of Agriculture is hereby authorized to cause the Bureau of Animal Industry to examine and inspect all viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, which are being imported or offered for importation into the United States, to determine whether such viruses, serums, toxins, and analogous products are worthless, contaminated, dangerous, or harmful, and if it shall appear that any such virus, serum, toxin, or analogous product, for use in the treatment of domestic animals, is worthless, contaminated, dangerous, or harmful, the same shall be denied entry and shall be destroyed or returned at the expense of the owner or importer. That the Secretary of

Trade in virus, etc., restricted to licensed establishments.

Importation of harmful virus, etc., prohibited.

Inspection to determine quality.

Denied entry, etc.

Agriculture be, and hereby is, authorized to make and promulgate from time to time such rules and regulations as may be necessary to prevent the preparation, sale, barter, exchange, or shipment as aforesaid of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals, and to issue, suspend, and revoke licenses for the maintenance of establishments for the preparation of viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, intended for sale, barter, exchange, or shipment as aforesaid. The Secretary of Agriculture is hereby authorized to issue permits for the importation into the United States of viruses, serums, toxins, and analogous products, for use in the treatment of domestic animals, which are not worthless, contaminated, dangerous, or harmful. All licenses issued under authority of this Act to establishments where such viruses, serums, toxins, or analogous products are prepared for sale, barter, exchange, or shipment as aforesaid, shall be issued on condition that the licensee shall permit the inspection of such establishments and of such products and their preparation; and the Secretary of Agriculture may suspend or revoke any permit or license issued under authority of this Act, after opportunity for hearing has been granted the licensee or importer, when the Secretary of Agriculture is satisfied that such license or permit is being used to facilitate or effect the preparation, sale, barter, exchange, or shipment as aforesaid, or the importation into the United States of any worthless, contaminated, dangerous, or harmful virus, serum, toxin, or analogous product for use in the treatment of domestic animals. That any officer, agent, or employee of the Department of Agriculture duly authorized by the Secretary of Agriculture for the purpose may, at any hour during the daytime or nighttime, enter and inspect any establishment licensed under this Act where any virus, serum, toxin, or analogous product for use in the treatment of domestic animals is prepared for sale, barter, exchange, or shipment as aforesaid. That any person, firm, or corporation who shall violate any of the provisions of this Act shall be deemed guilty of a misdemeanor, and shall, upon conviction, be punished by a fine of not exceeding $1,000 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court. That there is hereby appropriated, out of any moneys in the Treasury not otherwise appropriated, to be expended as the Secretary of Agriculture may direct, for the purposes and objects of this Act, the sum of $25,000, which appropriation shall become available on July first, nineteen hundred and thirteen, and may be expended at any time before July first, nineteen hundred and fourteen;

Regulations, etc., to be issued.

Permits for importation.

Inspection of establishments.

Suspension of license.

Inspection, etc., by officers.

Punishment for violations.

Amount for expenses.

For construction of buildings at bureau experiment station at Bethesda, Maryland, and bureau experiment farm at Beltsville, Maryland, $16,500;

Buildings, experiment station, and farm.

For general administrative work, including traveling expenses and salaries of employees engaged in such work, rent outside of the District of Columbia, office fixtures and supplies, express, freight, telegraph, telephone, and other necessary expenses, $40,186;

Administrative work.

For all necessary expenses for experiments in the feeding and breeding of ostriches and for investigations and experiments in the study of the ostrich industry, $2,500;

Ostrich breeding.

In all, for general expenses, $1,371,946.

And hereafter the Secretary of Agriculture is authorized to prepare and sell at cost such pathological and zoological specimens as he may deem of scientific or educational value to scientists or others engaged in the work of hygiene and sanitation: *Provided*, That all moneys received from the sale of such specimens shall be deposited in the Treasury as miscellaneous receipts.

Sale of specimens etc., permitted.

Proviso. Receipts.

1938 Federal Food, Drug and Cosmetic Act (FDCA)

and two-tenths feet; run thence northerly across the United States Hot Springs Reservation in a straight line to the place of beginning.

Appropriation authorized for land acquisition.

SEC. 3. There is hereby authorized to be appropriated for the acquisition of lands described in section 1 hereof such sums as the Congress may from time to time determine.

Approved, June 24, 1938.

[CHAPTER 653]

AN ACT

June 25, 1938
[H. R. 9881]
[Public, No. 716]

To amend section 23 of the Act to create the California Débris Commission, as amended.

California Débris Commission.
27 Stat. 510; 48 Stat. 1118.
33 U. S. C. § 683.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 23 of the Act approved March 1, 1893, entitled "An Act to create the California Débris Commission and regulate hydraulic mining in the State of California", as amended by the Act approved June 19, 1934, is hereby further amended by adding at the end thereof the following: "The Secretary of War is authorized to enter into contracts to supply storage for water and use of outlet facilities from débris storage reservoirs, for domestic and irrigation purposes and power development upon such conditions of delivery, use, and payment as he may approve: *Provided*, That the moneys received from such contracts shall be deposited to the credit of the reservoir project from which the water is supplied, and the total capital cost of said reservoir, which is to be repaid by tax on mining operations as herein provided, shall be reduced in the amount so received".

Contracts to supply storage for water, etc., authorized.

Proviso.
Deposit of receipts from contracts.
Reduction of total capital cost.

Approved, June 25, 1938.

[CHAPTER 675]

AN ACT

June 25, 1938
[S. 5]
[Public, No. 717]

To prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes.

Federal Food, Drug, and Cosmetic Act.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Chapter I—Short title.

CHAPTER I—SHORT TITLE

SECTION 1. This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

Chapter II—Definitions.

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

"Territory."

(a) The term "Territory" means any Territory or possession of the United States, including the District of Columbia and excluding the Canal Zone.

"Interstate commerce."

(b) The term "interstate commerce" means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

"Department."

(c) The term "Department" means the Department of Agriculture of the United States.

"Secretary."

(d) The term "Secretary" means the Secretary of Agriculture.

"Person."

(e) The term "person" includes individual, partnership, corporation, and association.

"Food."

(f) The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

"Drug."

(g) The term "drug" means (1) articles recognized in the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories.

"Device"; exceptions. *Post*, pp. 1042, 1047, 1050, 1054.

(h) The term "device" (except when used in paragraph (n) of this section and in sections 301 (i), 403 (f), 502 (c), and 602 (c)) means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

"Cosmetic."

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

"Official compendium."

(j) The term "official compendium" means the official United States Pharmacopœia, official Homœopathic Pharmacopœia of the United States, official National Formulary, or any supplement to any of them.

"Label."

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

"Immediate container."

(l) The term "immediate container" does not include package liners.

"Labeling."

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

Determination as to whether article is misbranded because labeling misleading.

(n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

Drug represented as an antiseptic.

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

Term "new drug" construed.

(p) The term "new drug" means—

(1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe

for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

34 Stat. 768.
21 U. S. C. §§ 1–15; Supp. III, § 14a.

(2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

Chapter III—Prohibited acts and penalties.

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

Prohibited acts.

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404 or 505.

Post, pp. 1048, 1052.

(e) The refusal to permit access to or copying of any record as required by section 703.

Post, p. 1057.

(f) The refusal to permit entry or inspection as authorized by section 704.

Post, p. 1057.

(g) The manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 303 (c) (2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303 (c) (3), which guaranty or undertaking is false.

Post, p. 1043.

(i) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 404, 406 (b), 504, or 604.

Post, pp. 1048, 1049, 1052, 1055.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 505, or 704 concerning any method or process which as a trade secret is entitled to protection.

Post, pp. 1048, 1052, 1057.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale after shipment in interstate commerce and results in such article being misbranded.

(l) The using, on the labeling of any drug or in any advertising relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under section 505, or that such drug complies with the provisions of such section.

Post, p. 1052.

INJUNCTION PROCEEDINGS

Injunction proceedings.

SEC. 302. (a) The district courts of the United States and the United States courts of the Territories shall have jurisdiction, for cause shown, and subject to the provisions of section 17 (relating to notice to opposite party) of the Act entitled "An Act to supplement existing laws against unlawful restraints and monopolies, and for other purposes", approved October 15, 1914, as amended (U. S. C., 1934 ed., title 28, sec. 381), to restrain violations of section 301, except paragraphs (e), (f), (h), (i), and (j).

Jurisdiction.

38 Stat. 737.
28 U. S. C. § 381.

(b) In case of violation of an injunction or restraining order issued under this section, which also constitutes a violation of this Act, trial shall be by the court, or, upon demand of the accused, by a jury. Such trial shall be conducted in accordance with the practice and procedure applicable in the case of proceedings subject to the provisions of section 22 of such Act of October 15, 1914, as amended (U. S. C., 1934 ed., title 28, sec. 387).

Violations of injunctions or restraining orders, proceedings.

38 Stat. 738.
28 U. S. C. § 387.

PENALTIES

SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

Penalties.

(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or a fine of not more than $10,000, or both such imprisonment and fine.

Fraud.

(c) No person shall be subject to the penalties of subsection (a) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301 (a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act, or to the effect, in case of an alleged violation of section 301 (d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce; or (3) for having violated section 301 (a), where the violation exists because the article is adulterated by reason of containing a coal-tar color not from a batch certified in accordance with regulations promulgated by the Secretary under this Act, if such person establishes a guaranty or

Exceptions.

Post, pp. 1048, 1052.

undertaking signed by, and containing the name and address of, the manufacturer of the coal-tar color, to the effect that such color was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this Act.

SEIZURE

Seizure of articles.

SEC. 304. (a) Any article of food, drug, device, or cosmetic that is adulterated or misbranded when introduced into or while in interstate commerce, or which may not, under the provisions of section 404 or 505, be introduced into interstate commerce, shall be liable to be proceeded against while in interstate commerce, or at any time thereafter, on libel of information and condemned in any district court of the United States within the jurisdiction of which the article is found: *Provided, however*, That no libel for condemnation shall be instituted under this Act, for any alleged misbranding if there is pending in any court a libel for condemnation proceeding under this Act based upon the same alleged misbranding, and not more than one such proceeding shall be instituted if no such proceeding is so pending, except that such limitations shall not apply (1) when such misbranding has been the basis of a prior judgment in favor of the United States, in a criminal, injunction, or libel for condemnation proceeding under this Act, or (2) when the Secretary has probable cause to believe from facts found, without hearing, by him or any officer or employee of the Department that the misbranded article is dangerous to health, or that the labeling of the misbranded article is fraudulent, or would be in a material respect misleading to the injury or damage of the purchaser or consumer. In any case where the number of libel for condemnation proceedings is limited as above provided the proceeding pending or instituted shall, on application of the claimant, seasonably made, be removed for trial to any district agreed upon by stipulation between the parties, or, in case of failure to so stipulate within a reasonable time, the claimant may apply to the court of the district in which the seizure has been made, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, to which the case shall be removed for trial.

Post, pp. 1048, 1052.

Proviso.
If libel for condemnation proceeding pending.

Exceptions.

Change of venue.

Procedure.

(b) The article shall be liable to seizure by process pursuant to the libel, and the procedure in cases under this section shall conform, as nearly as may be, to the procedure in admiralty; except that on demand of either party any issue of fact joined in any such case shall be tried by jury. When libel for condemnation proceedings under this section, involving the same claimant and the same issues of adulteration or misbranding, are pending in two or more jurisdictions, such pending proceedings, upon application of the claimant seasonably made to the court of one such jurisdiction, shall be consolidated for trial by order of such court, and tried in (1) any district selected by the claimant where one of such proceedings is pending; or (2) a district agreed upon by stipulation between the parties. If no order for consolidation is so made within a reasonable time, the claimant may apply to the court of one such jurisdiction, and such court (after giving the United States attorney for such district reasonable notice and opportunity to be heard) shall by order, unless good cause to the contrary is shown, specify a district of reasonable proximity to the claimant's principal place of business, in which all such pending proceedings shall be consolidated for trial and tried. Such order of consolidation shall not apply so as to require the removal of any case the date for trial of which has been fixed. The court granting such

When proceedings are pending in two or more jurisdictions.

Consolidation for trial.

order shall give prompt notification thereof to the other courts having jurisdiction of the cases covered thereby.

Party to condemnation proceeding allowed a representative sample of article seized, etc.

(c) The court at any time after seizure up to a reasonable time before trial shall by order allow any party to a condemnation proceeding, his attorney or agent, to obtain a representative sample of the article seized, and as regards fresh fruits or fresh vegetables, a true copy of the analysis on which the proceeding is based and the identifying marks or numbers, if any, of the packages from which the samples analyzed were obtained.

Disposal of condemned articles after entry of decree.

(d) Any food, drug, device, or cosmetic condemned under this section shall, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, shall be paid into the Treasury of the United States; but such article shall not be sold under such decree contrary to the provisions of this Act or the laws of the jurisdiction in which sold: *Provided*, That after entry of the decree and upon the payment of the costs of such proceedings and the execution of a good and sufficient bond conditioned that such article shall not be sold or disposed of contrary to the provisions of this Act or the laws of any State or Territory in which sold, the court may by order direct that such article be delivered to the owner thereof to be destroyed or brought into compliance with the provisions of this Act under the supervision of an officer or employee duly designated by the Secretary, and the expenses of such supervision shall be paid by the person obtaining release of the article under bond. Any article condemned by reason of its being an article which may not, under section 404 or 505, be introduced into interstate commerce, shall be disposed of by destruction.

Proviso. Delivery to owner if not to be sold.

Destruction of designated articles. *Post*, pp. 1048, 1052.

Court costs, fees, etc.

(e) When a decree of condemnation is entered against the article, court costs and fees, and storage and other proper expenses, shall be awarded against the person, if any, intervening as claimant of the article.

Powers and duties of court in cases of removal.

(f) In the case of removal for trial of any case as provided by subsection (a) or (b)—

(1) The clerk of the court from which removal is made shall promptly transmit to the court in which the case is to be tried all records in the case necessary in order that such court may exercise jurisdiction.

(2) The court to which such case was removed shall have the powers and be subject to the duties, for purposes of such case, which the court from which removal was made would have had, or to which such court would have been subject, if such case had not been removed.

HEARING BEFORE REPORT OF CRIMINAL VIOLATION

Hearing before report of criminal violation.

SEC. 305. Before any violation of this Act is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

REPORT OF MINOR VIOLATIONS

Report of minor violations.

SEC. 306. Nothing in this Act shall be construed as requiring the Secretary to report for prosecution, or for the institution of libel or injunction proceedings, minor violations of this Act whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

PROCEEDINGS IN NAME OF UNITED STATES; PROVISION AS TO SUBPENAS

Proceedings in name of United States; subpenas. R. S. § 876. 28 U. S. C. § 654.

SEC. 307. All such proceedings for the enforcement, or to restrain violations, of this Act shall be by and in the name of the United States. Notwithstanding the provisions of section 876 of the Revised Statutes, subpenas for witnesses who are required to attend a court of the United States, in any district, may run into any other district in any such proceeding.

Chapter IV—Food.

CHAPTER IV—FOOD

DEFINITIONS AND STANDARDS FOR FOOD

Definitions and standards; regulations by Secretary.

SEC. 401. Whenever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container: *Provided*, That no definition and standard of identity and no standard of quality shall be established for fresh or dried fruits, fresh or dried vegetables, or butter, except that definitions and standards of identity may be established for avocadoes, cantaloupes, citrus fruits, and melons. In prescribing any standard of fill of container, the Secretary shall give due consideration to the natural shrinkage in storage and in transit of fresh natural food and to need for the necessary packing and protective material. In the prescribing of any standard of quality for any canned fruit or canned vegetable, consideration shall be given and due allowance made for the differing characteristics of the several varieties of such fruit or vegetable. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Secretary shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. Any definition and standard of identity prescribed by the Secretary for avocadoes, cantaloupes, citrus fruits, or melons shall relate only to maturity and to the effects of freezing.

Proviso. Fresh or dried fruits, etc.

Exceptions.

Standard of fill of container.

Standard of quality of canned fruit, etc.

Class in which optional ingredients are permitted.

Limitation on definition as to avocadoes, cantaloupes, etc.

ADULTERATED FOOD

Adulterated food.

SEC. 402. A food shall be deemed to be adulterated—

Added substances, etc.

(a) (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2) if it bears or contains any added poisonous or added deleterious substance which is unsafe within the meaning of section 406; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

Post, p. 1049.

Omission, abstraction, substitution, etc., of any valuable constituent.

(b) (1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk

or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406: *Provided*, That this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this Act and such application has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this Act for the purpose of coloring citrus fruit.

Coal-tar color other than in accordance with regulations.
Post, p. 1049.
Proviso.
Citrus fruits.

(d) If it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except harmless coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, natural gum, and pectin: *Provided*, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.

Confectionery, containing alcohol, etc.

Proviso.
Exemptions.

MISBRANDED FOOD

Misbranded food.

SEC. 403. A food shall be deemed to be misbranded—

Definitions.

(a) If its labeling is false or misleading in any particular.

False labeling.

(b) If it is offered for sale under the name of another food.

Using name of another food.

(c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

Imitations not properly indicated.

(d) If its container is so made, formed, or filled as to be misleading.

Misleading containers.

(e) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

Package form provisions.

Proviso.
Variations.

(f) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Label or labeling.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

Representations as to identity; conformity provisions.
Ante, p. 1046.

(h) If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 401, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

Below standard; exception.

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 401, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

Below standard of fill of container; exception.

If not subject to foregoing provisions, without prescribed label, etc.

(i) If it is not subject to the provisions of paragraph (g) of this section unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each: *Provided*, That, to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

Proviso. Exemptions.

Represented to be for special dietary use; label requirements.

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

Artificial flavoring, coloring, etc.; label requirements.

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided*, That to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream.

Proviso. Exemptions.

EMERGENCY PERMIT CONTROL

Emergency permit control.

SEC. 404. (a) Whenever the Secretary finds after investigation that the distribution in interstate commerce of any class of food may, by reason of contamination with micro-organisms during the manufacture, processing, or packing thereof in any locality, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered interstate commerce, he then, and in such case only, shall promulgate regulations providing for the issuance, to manufacturers, processors, or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or packing of such class of food, for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulations, and during such temporary period, no person shall introduce or deliver for introduction into interstate commerce any such food manufactured, processed, or packed by any such manufacturer, processor, or packer unless such manufacturer, processor, or packer holds a permit issued by the Secretary as provided by such regulations.

Suspension upon finding of violation.

(b) The Secretary is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the Secretary shall, immediately after prompt hearing and an inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued or as amended.

Reinstatement.

Access to factories, etc., by employees designated by Secretary.

(c) Any officer or employee duly designated by the Secretary shall have access to any factory or establishment, the operator of which holds a permit from the Secretary, for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator.

REGULATIONS MAKING EXEMPTIONS

SEC. 405. The Secretary shall promulgate regulations exempting from any labeling requirement of this Act (1) small open containers of fresh fruits and fresh vegetables and (2) food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such food is not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment. Regulations making exemptions.

TOLERANCES FOR POISONOUS INGREDIENTS IN FOOD AND CERTIFICATION OF COAL-TAR COLORS FOR FOOD

SEC. 406. (a) Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a); but when such substance is so required or cannot be so avoided, the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2) of section 402 (a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402 (a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances. Tolerances for poisonous ingredients in food.

Ante, p. 1046.

(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents. Certification of coal-tar colors for food.

CHAPTER V—DRUGS AND DEVICES

Chapter V—Drugs and devices.

ADULTERATED DRUGS AND DEVICES

SEC. 501. A drug or device shall be deemed to be adulterated— Adulterated drugs and devices. Definition.

(a) (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (4) if it is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 504.

Post, p. 1052.

(b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of

assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopœia and the Homœopathic Pharmacopœia of the United States it shall be subject to the requirements of the United States Pharmacopœia unless it is labeled and offered for sale as a homœopathic drug, in which case it shall be subject to the provisions of the Homœopathic Pharmacopœia of the United States and not to those of the United States Pharmacopœia.

(c) If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(d) If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

MISBRANDED DRUGS AND DEVICES

Misbranded drugs and devices.
False, etc., labeling.

SEC. 502. A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

Labels, information required.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

Proviso.
Variations and exemptions.

Prominence of information required by Act.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Drugs which may be habit forming.

(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane; or any chemical derivative of such substance, which derivative has been by the Secretary, after investigation, found to be, and by regulations designated as, habit forming; unless its label bears the name, quantity, and percentage of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming".

Drug not designated solely by recognized name.

(e) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common

or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the quantity, kind, and proportion of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: *Provided*, That to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

Proviso. Exemptions.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

Directions for use; warnings, etc.

Proviso. Exemptions.

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: *Provided*, That the method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopœia and the Homœopathic Pharmacopœia of the United States, it shall be subject to the requirements of the United States Pharmacopœia with respect to packaging and labeling unless it is labeled and offered for sale as a homœopathic drug, in which case it shall be subject to the provisions of the Homœopathic Pharmacopœia of the United States, and not to those of the United States Pharmacopœia.

Purported to be recognized drug.

Proviso. Modification in method of packing.

(h) If it has been found by the Secretary to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Secretary shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Secretary shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

Drug liable to deterioration.

(i) (1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

Drug and container misleading, etc.

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

Dangerous to health.

EXEMPTIONS IN CASE OF DRUGS AND DEVICES

Exemptions in case of drugs and devices.

SEC. 503. (a) The Secretary is hereby directed to promulgate regulations exempting from any labeling or packaging requirement of this Act drugs and devices which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such drugs and devices are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

Processing, repacking, etc., at other than original establishment.

Drugs dispensed on written prescription.

(b) A drug dispensed on a written prescription signed by a physician, dentist, or veterinarian (except a drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail), shall if—

(1) such physician, dentist, or veterinarian is licensed by law to administer such drug, and

(2) such drug bears a label containing the name and place of business of the dispenser, the serial number and date of such prescription, and the name of such physician, dentist, or veterinarian,

Ante, p. 1050.

be exempt from the requirements of section 502 (b) and (e), and (in case such prescription is marked by the writer thereof as not refillable or its refilling is prohibited by law) of section 502 (d).

CERTIFICATION OF COAL-TAR COLORS FOR DRUGS

Certification of coal-tar colors for drugs.

SEC. 504. The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in drugs for purposes of coloring only and for the certification of batches of such colors, with or without harmless diluents.

New drugs.

NEW DRUGS

Application for introduction into interstate commerce.

SEC. 505. (a) No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an application filed pursuant to subsection (b) is effective with respect to such drug.

Filing of application; requirements.

(b) Any person may file with the Secretary an application with respect to any drug subject to the provisions of subsection (a). Such person shall submit to the Secretary as a part of the application (1) full reports of investigations which have been made to show whether or not such drug is safe for use; (2) a full list of the articles used as components of such drug; (3) a full statement of the composition of such drug; (4) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug; (5) such samples of such drug and of the articles used as components thereof as the Secretary may require; and (6) specimens of the labeling proposed to be used for such drug.

Effective date of application.

(c) An application provided for in subsection (b) shall become effective on the sixtieth day after the filing thereof unless prior to such day the Secretary by notice to the applicant in writing postpones the effective date of the application to such time (not more than one hundred and eighty days after the filing thereof) as the Secretary deems necessary to enable him to study and investigate the application.

Tests, etc.

(d) If the Secretary finds, after due notice to the applicant and giving him an opportunity for a hearing, that (1) the investigations, reports of which are required to be submitted to the Secretary pursuant to subsection (b), do not include adequate tests by all methods reasonably applicable to show whether or not such drug is safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof; (2) the results of such tests show that such drug is unsafe for use under such conditions or do not show that such drug is safe for use under such conditions; (3) the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug are inadequate to preserve its identity, strength, quality, and purity; or (4) upon the basis of the information submitted to him as part of the application, or upon the basis of any other information before him with respect to such drug, he has insufficient information to determine whether such drug is safe for use under such conditions, he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

Order refusing to permit application to become effective.

Suspension of application.

(e) The effectiveness of an application with respect to any drug shall, after due notice and opportunity for hearing to the applicant, by order of the Secretary be suspended if the Secretary finds (1) that clinical experience, tests by new methods, or tests by methods not deemed reasonably applicable when such application became effective show that such drug is unsafe for use under the conditions of use upon the basis of which the application became effective, or (2) that the application contains any untrue statement of a material fact. The order shall state the findings upon which it is based.

Revocation of order of refusal.

(f) An order refusing to permit an application with respect to any drug to become effective shall be revoked whenever the Secretary finds that the facts so require.

Service of Secretary's orders.

(g) Orders of the Secretary issued under this section shall be served (1) in person by any officer or employee of the department designated by the Secretary or (2) by mailing the order by registered mail addressed to the applicant or respondent at his last-known address in the records of the Secretary.

Appeals.

(h) An appeal may be taken by the applicant from an order of the Secretary refusing to permit the application to become effective, or suspending the effectiveness of the application. Such appeal shall be taken by filing in the district court of the United States within any district wherein such applicant resides or has his principal place of business, or in the District Court of the United States for the District of Columbia, within sixty days after the entry of such order, a written petition praying that the order of the Secretary be set aside. A copy of such petition shall be forthwith served upon the Secretary, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the record upon which the order complained of was entered. Upon the filing of such transcript such court shall have exclusive jurisdiction to affirm or set aside such order. No objection to the order of the Secretary shall be considered by the court unless such objection shall have been urged before the Secretary or unless there were reasonable grounds for failure so to do. The finding of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive. If any person shall apply to the court for leave to adduce additional evidence, and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts by reason of the additional evidence so taken, and he shall file with the court such modified findings which, if supported by substantial evidence, shall be conclusive, and his recommendation, if any, for the setting aside of the original order. The judgment and decree of the court affirming or setting aside any such order of the Secretary shall be final, subject to review as provided in sections 128, 239, and 240 of the Judicial Code, as amended (U. S. C., 1934 ed., title 28, secs. 225, 346, and 347), and in section 7, as amended, of the Act entitled "An Act to establish a Court of Appeals for the District of Columbia", approved February 9, 1893 (D. C. Code, title 18, sec. 26). The commencement of proceedings under this subsection shall not, unless specifically ordered by the court to the contrary, operate as a stay of the Secretary's order.

Finality of judgment and decree; review.

28 U. S. C. §§ 225, 346, 347.

18 D. C. Code § 26.

Drugs for investigational use, etc.

(i) The Secretary shall promulgate regulations for exempting from the operation of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety of drugs.

Chapter VI—Cosmetics.

CHAPTER VI—COSMETICS

ADULTERATED COSMETICS

Adulterated cosmetics defined.

SEC. 601. A cosmetic shall be deemed to be adulterated—

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual: *Provided*, That this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

Proviso. Coal-tar hair dye bearing informative legend.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

(e) If it is not a hair dye and it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 604.

MISBRANDED COSMETICS

Misbranded cosmetics defined.

SEC. 602. A cosmetic shall be deemed to be misbranded—

False, etc., labeling.

(a) If its labeling is false or misleading in any particular.

Labels, information required.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

Proviso. Variations and exemptions.

Prominence of information required by Act.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Containers.

(d) If its container is so made, formed, or filled as to be misleading.

REGULATIONS MAKING EXEMPTIONS

Regulations making exemptions.

SEC. 603. The Secretary shall promulgate regulations exempting from any labeling requirement of this Act cosmetics which are, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such cosmetics are not adulterated or misbranded under the provisions of this Act upon removal from such processing, labeling, or repacking establishment.

CERTIFICATION OF COAL-TAR COLORS FOR COSMETICS

SEC. 604. The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in cosmetics and for the certification of batches of such colors, with or without harmless diluents.

Certification of coal-tar colors for cosmetics.

CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

Chapter VII—General administrative provisions.

REGULATIONS AND HEARINGS

SEC. 701. (a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.

Regulations.

(b) The Secretary of the Treasury and the Secretary of Agriculture shall jointly prescribe regulations for the efficient enforcement of the provisions of section 801, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Agriculture shall determine.

Post, p. 1058.

(c) Hearings authorized or required by this Act shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

Hearings.

(d) The definitions and standards of identity promulgated in accordance with the provisions of this Act shall be effective for the purposes of the enforcement of this Act, notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

Definitions and standards of identity.

(e) The Secretary, on his own initiative or upon an application of any interested industry or substantial portion thereof stating reasonable grounds therefor, shall hold a public hearing upon a proposal to issue, amend, or repeal any regulation contemplated by any of the following sections of this Act: 401, 403 (j), 404 (a), 406 (a) and (b), 501 (b), 502 (d), 502 (h), 504, and 604. The Secretary shall give appropriate notice of the hearing, and the notice shall set forth the proposal in general terms and specify the time and place for a public hearing to be held thereon not less than thirty days after the date of the notice, except that the public hearing on regulations under section 404 (a) may be held within a reasonable time, to be fixed by the Secretary, after notice thereof. At the hearing any interested person may be heard in person or by his representative. As soon as practicable after completion of the hearing, the Secretary shall by order make public his action in issuing, amending, or repealing the regulation or determining not to take such action. The Secretary shall base his order only on substantial evidence of record at the hearing and shall set forth as part of the order detailed findings of fact on which the order is based. No such order shall take effect prior to the ninetieth day after it is issued, except that if the Secretary finds that emergency conditions exist necessitating an earlier effective date, then the Secretary shall specify in the order his findings as to such conditions and the order shall take effect at such earlier date as the Secretary shall specify therein to meet the emergency.

Public hearing upon proposal to issue, amend, or repeal any regulation.

Ante, pp. 1046, 1048, 1049, 1050, 1051, 1052.

Procedure.

(f) (1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such

Controversies over validity of orders.

Petition to proper Circuit Court of Appeals for review.

person resides or has his principal place of business, for a judicial review of such order. The summons and petition may be served at any place in the United States. The Secretary, promptly upon service of the summons and petition, shall certify and file in the court the transcript of the proceedings and the record on which the Secretary based his order.

Leave to adduce additional evidence.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

Court jurisdiction to affirm or set aside order.

(3) The court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action, with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

Finality of judgment; review.

28 U. S. C. §§ 346, 347.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 239 and 240 of the Judicial Code, as amended.

Survival of action.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

Remedies deemed additional.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

Certified copies of transcript of record and proceedings.

(g) A certified copy of the transcript of the record and proceedings under subsection (e) shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, libel for condemnation, exclusion of imports, or other proceeding arising under or in respect to this Act, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f).

Admissibility.

EXAMINATIONS AND INVESTIGATIONS

Examinations and investigations.

SEC. 702. (a) The Secretary is authorized to conduct examinations and investigations for the purposes of this Act through officers and employees of the Department or through any health, food, or drug officer or employee of any State, Territory, or political subdivision thereof, duly commissioned by the Secretary as an officer of the Department. In the case of food packed in a Territory the Secretary shall attempt to make inspection of such food at the first point of entry within the United States when, in his opinion and with due regard to the enforcement of all the provisions of this Act, the facilities at his disposal will permit of such inspection. For the purposes

of this subsection the term "United States" means the States and the District of Columbia.

(b) Where a sample of a food, drug, or cosmetic is collected for analysis under this Act the Secretary shall, upon request, provide a part of such official sample for examination or analysis by any person named on the label of the article, or the owner thereof, or his attorney or agent; except that the Secretary is authorized, by regulations, to make such reasonable exceptions from, and impose such reasonable terms and conditions relating to, the operation of this subsection as he finds necessary for the proper administration of the provisions of this Act.

(c) For purposes of enforcement of this Act, records of any department or independent establishment in the executive branch of the Government shall be open to inspection by any official of the Department of Agriculture duly authorized by the Secretary to make such inspection.

RECORDS OF INTERSTATE SHIPMENT

Records of interstate shipment.

Access to carrier's, etc., records.

SEC. 703. For the purpose of enforcing the provisions of this Act, carriers engaged in interstate commerce, and persons receiving food, drugs, devices, or cosmetics in interstate commerce or holding such articles so received, shall, upon the request of an officer or employee duly designated by the Secretary, permit such officer or employee, at reasonable times, to have access to and to copy all records showing the movement in interstate commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper, and consignee thereof; and it shall be unlawful for any such carrier or person to fail to permit such access to and copying of any such record so requested when such request is accompanied by a statement in writing specifying the nature or kind of food, drug, device, or cosmetic to which such request relates: *Provided*, That evidence obtained under this section shall not be used in a criminal prosecution of the person from whom obtained: *Provided further*, That carriers shall not be subject to the other provisions of this Act by reason of their receipt, carriage, holding, or delivery of food, drugs, devices, or cosmetics in the usual course of business as carriers.

Provisos.
Use in certain criminal prosecutions forbidden.

Waiver of other provisions.

FACTORY INSPECTION

Factory inspection.

SEC. 704. For purposes of enforcement of this Act, officers or employees duly designated by the Secretary, after first making request and obtaining permission of the owner, operator, or custodian thereof, are authorized (1) to enter, at reasonable times, any factory, warehouse, or establishment in which food, drugs, devices, or cosmetics are manufactured, processed, packed, or held, for introduction into interstate commerce or are held after such introduction, or to enter any vehicle being used to transport or hold such food, drugs, devices, or cosmetics in interstate commerce; and (2) to inspect, at reasonable times, such factory, warehouse, establishment, or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein.

PUBLICITY

Publicity.

SEC. 705. (a) The Secretary shall cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Act, including the nature of the charge and the disposition thereof.

Dissemination of information regarding food, drugs, etc.

(b) The Secretary may also cause to be disseminated information regarding food, drugs, devices, or cosmetics in situations involving, in the opinion of the Secretary, imminent danger to health or gross deception of the consumer. Nothing in this section shall be construed to prohibit the Secretary from collecting, reporting, and illustrating the results of the investigations of the Department.

COST OF CERTIFICATION OF COAL-TAR COLORS

Cost of certification of coal-tar colors.

SEC. 706. The admitting to listing and certification of coal-tar colors, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

Chapter VIII—Imports and exports.

CHAPTER VIII—IMPORTS AND EXPORTS

Examination of imported foods, etc.

SEC. 801. (a) The Secretary of the Treasury shall deliver to the Secretary of Agriculture, upon his request, samples of food, drugs, devices, and cosmetics which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may appear before the Secretary of Agriculture and have the right to introduce testimony. If it appears from the examination of such samples or otherwise that (1) such article has been manufactured, processed, or packed under insanitary conditions, or (2) such article is forbidden or restricted in sale in the country in which it was produced or from which it was exported, or (3) such article is adulterated, misbranded, or in violation of section 505, then such article shall be refused admission. This paragraph shall not be construed to prohibit the admission of narcotic drugs the importation of which is permitted under section 2 of the Act of May 26, 1922, as amended (U. S. C., 1934 edition, title 21, sec. 173).

Articles manufactured, etc., under insanitary conditions.

Sale forbidden in exporting, etc., country.

Adulterated, misbranded, etc.

Ante, p. 1052.

Admission of narcotic drugs.

42 Stat. 596.
21 U. S. C. § 173.

Destruction of inadmissible articles; exception.

(b) The Secretary of the Treasury shall refuse delivery to the consignee and shall cause the destruction of any such article refused admission, unless such article is exported by the consignee within three months from the date of notice of such refusal, under such regulations as the Secretary of the Treasury may prescribe: *Provided*, That the Secretary of the Treasury may deliver to the consignee any such article pending examination and decision in the matter on execution of a bond as liquidated damages for the amount of the full invoice value thereof together with the duty thereon and on refusing for any cause to return such article or any part thereof to the custody of the Secretary of the Treasury when demanded for the purpose of excluding it from the country or for any other purpose, such consignee shall forfeit the full amount of the bond as liquidated damages.

Provisos.
Delivery pending examination.

Bond.

Charges.

(c) All charges for storage, cartage, and labor on any article which is refused admission or delivery shall be paid by the owner or consignee and in default of such payment shall constitute a lien against any future importations made by such owner or consignee.

Food, etc., for export; when deemed not adulterated, etc.

(d) A food, drug, device, or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it (1) accords to the specifications of the foreign purchaser, (2) is not in conflict with the laws of the country to which it is intended for export, and (3) is labeled on the outside of the shipping package to show that it is intended for export. But if such article is sold or offered for sale in domestic commerce, this subsection shall not exempt it from any of the provisions of this Act.

CHAPTER IX—MISCELLANEOUS

Chapter IX—Miscellaneous.

SEPARABILITY CLAUSE

Separability clause.

SEC. 901. If any provision of this Act is declared unconstitutional, or the applicability thereof to any person or circumstances is held invalid, the constitutionality of the remainder of the Act and the applicability thereof to other persons and circumstances shall not be affected thereby.

EFFECTIVE DATE AND REPEALS

Effective date and repeals.
34 Stat. 768.
21 U. S. C. §§ 1–15; Supp. III, § 14a.

SEC. 902. (a) This Act shall take effect twelve months after the date of its enactment. The Federal Food and Drugs Act of June 30, 1906, as amended (U. S. C., 1934 ed., title 21, secs. 1–15), shall remain in force until such effective date, and, except as otherwise provided in this subsection, is hereby repealed effective upon such date: *Provided*, That the provisions of section 701 shall become effective on the enactment of this Act, and thereafter the Secretary is authorized hereby to (1) conduct hearings and to promulgate regulations which shall become effective on or after the effective date of this Act as the Secretary shall direct, and (2) designate prior to the effective date of this Act food having common or usual names and exempt such food from the requirements of clause (2) of section 403 (i) for a reasonable time to permit the formulation, promulgation, and effective application of definitions and standards of identity therefor as provided by section 401: *Provided further*, That sections 502 (j), 505, and 601 (a), and all other provisions of this Act to the extent that they may relate to the enforcement of such sections, shall take effect on the date of the enactment of this Act, except that in the case of a cosmetic to which the proviso of section 601 (a) relates, such cosmetic shall not, prior to the ninetieth day after such date of enactment, be deemed adulterated by reason of the failure of its label to bear the legend prescribed in such proviso: *Provided further*, That the Act of March 4, 1923 (U. S. C., 1934 ed., title 21, sec. 6; 42 Stat. 1500, ch. 268), defining butter and providing a standard therefor; the Act of July 24, 1919 (U. S. C., 1934 ed., title 21, sec. 10; 41 Stat. 271, ch. 26), defining wrapped meats as in package form; and the amendment to the Food and Drugs Act, section 10A, approved August 27, 1935 (U. S. C., 1934 ed., Sup. III, title 21, sec. 14a), shall remain in force and effect and be applicable to the provisions of this Act.

Provisos.
Regulations and hearings.
Ante, p. 1055.

Ante, p. 1048.

Ante, p. 1046.
Designated provisions immediately in force; exceptions.
Ante, pp. 1051, 1052, 1054.

Applicability of designated Acts.
Definition of butter.
42 Stat. 1500.
21 U. S. C. § 6.
Wrapped meats in package form.
41 Stat. 271.
21 U. S. C. § 10.
Sea food regulation.
49 Stat. 871.
21 U. S. C., Supp. III, § 14a.

(b) Meats and meat food products shall be exempt from the provisions of this Act to the extent of the application or the extension thereto of the Meat Inspection Act, approved March 4, 1907, as amended (U. S. C., 1934 ed., title 21, secs. 71–91; 34 Stat. 1260 et seq.).

Meats and meat food products.
34 Stat. 1260.
21 U. S. C. §§ 71–91.

(c) Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the virus, serum, and toxin Act of July 1, 1902 (U. S. C., 1934 ed., title 42, chap. 4); the Filled Cheese Act of June 6, 1896 (U. S. C., 1934 ed., title 26, ch. 10), the Filled Milk Act of March 4, 1923 (U. S. C., 1934 ed., title 21, ch. 3, secs. 61–63); or the Import Milk Act of February 15, 1927 (U. S. C., 1934 ed., title 21, ch. 4, secs. 141–149).

Virus, serum, and toxin Act.
32 Stat. 728.
42 U. S. C. ch. 4.

Filled Cheese Act.
29 Stat. 253.
26 U. S. C., ch. 10.
Filled Milk Act.
42 Stat. 1486.
21 U. S. C., ch. 3.
Import Milk Act.
44 Stat. 1101.
21 U. S. C., §§ 141–149.

(d) In order to carry out the provisions of this Act which take effect prior to the repeal of the Food and Drugs Act of June 30, 1906, as amended, appropriations available for the enforcement of such Act of June 30, 1906, are also authorized to be made available to carry out such provisions.

Appropriations available.
Ante, p. 742.

Approved, June 25, 1938.

1944 Public Health Service Act, excerpts incl.
Part F, Regulation of biological products (PHSA Sec. 351 = 42 USC 262-263) and
Part G, Quarantine and inspection (PHSA Sec. 361 = 42 USC 264-272)

(56 Stat. 147), as amended (56 Stat. 1093; 50 App., U. S. C., Supp. III, 1015), and payments under the retroactive provisions of such amendments are authorized to be paid from appropriations currently available.

Approved July 1, 1944.

[CHAPTER 372]

AN ACT

July 1, 1944
[H. R. 4466]
[Public Law 409]

To amend section 18 of the Pay Readjustment Act of 1942 to provide additional pay for personnel who are required to participate in regular and frequent glider flights.

56 Stat. 368.
37 U. S. C., Supp. III, § 118.
Post, p. 730.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That section 18 of the Pay Readjustment Act of 1942, as amended, is hereby amended by adding a new paragraph at the end thereof to read as follows:

Personnel making glider flights.
Additional pay.

"Any officer, warrant officer, nurse, or enlisted man of any of the services mentioned in the title of this Act, not in flying-pay or parachute-jumping-pay status, who is required by orders of competent authority to participate in regular and frequent glider flights as an essential part of his military or naval duty and training, as defined under such regulations as may be prescribed by the President, shall receive an increase of 50 per centum of their pay when in consequence of such orders they do participate in such flights: *Provided*, That such increase shall not exceed $100 per month in the case of any such officer, warrant officer or nurse, nor $50 per month in the case of any such enlisted man."

Limitation.

Approved July 1, 1944.

[CHAPTER 373]

AN ACT

July 1, 1944
[H. R. 4624]
[Public Law 410]

To consolidate and revise the laws relating to the Public Health Service, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

TITLE I—SHORT TITLE AND DEFINITIONS

SHORT TITLE

Public Health Service Act.

SECTION 1. Titles I to V, inclusive, of this Act may be cited as the "Public Health Service Act".

DEFINITIONS

SEC. 2. When used in this Act—

"Service."

(a) The term "Service" means the Public Health Service;

"Surgeon General."

(b) The term "Surgeon General" means the Surgeon General of the Public Health Service;

"Administrator."

(c) The term "Administrator" means the Federal Security Administrator;

"Regulations."

(d) The term "regulations", except when otherwise specified, means rules and regulations made by the Surgeon General with the approval of the Administrator;

"Executive department."

(e) The term "executive department" means any executive department, agency, or independent establishment of the United States or any corporation wholly owned by the United States;

"State."

(f) The term "State" means a State or the District of Columbia, Hawaii, Alaska, Puerto Rico, or the Virgin Islands, except that as

used in section 361 (d) such term means a State, the District of Columbia, or Alaska; *Post*, p. 704.

(g) The term "possession" includes, among other possessions, Puerto Rico and the Virgin Islands; "Possession."

(h) The term "seamen" includes any person employed on board in the care, preservation, or navigation of any vessel, or in the service, on board, of those engaged in such care, preservation, or navigation; "Seamen."

(i) The term "vessel" includes every description of watercraft or other artificial contrivance used, or capable of being used, as a means of transportation on water, exclusive of aircraft and amphibious contrivances; "Vessel."

(j) The term "habit-forming narcotic drug" or "narcotic" means opium and coca leaves and the several alkaloids derived therefrom, the best known of these alkaloids being morphia, heroin, and codeine, obtained from opium, and cocaine derived from the coca plant; all compounds, salts, preparations, or other derivatives obtained either from the raw material or from the various alkaloids; Indian hemp and its various derivatives, compounds, and preparations, and peyote in its various forms; and "Habit-forming narcotic drug"; "narcotic."

(k) The term "addict" means any person who habitually uses any habit-forming narcotic drugs so as to endanger the public morals, health, safety, or welfare, or who is or has been so far addicted to the use of such habit-forming narcotic drugs as to have lost the power of self-control with reference to his addiction. "Addict."

TITLE II—ADMINISTRATION

PUBLIC HEALTH SERVICE

SEC. 201. The Public Health Service in the Federal Security Agency shall be administered by the Surgeon General under the supervision and direction of the Administrator.

ORGANIZATION

SEC. 202. The Service shall consist of (1) the Office of the Surgeon General, (2) the National Institute of Health, (3) the Bureau of Medical Services, and (4) the Bureau of State Services. The Surgeon General is authorized and directed to assign to the Office of the Surgeon General, to the National Institute of Health, to the Bureau of Medical Services, and to the Bureau of State Services, respectively, the several functions of the Service, and to establish within them such divisions, sections, and other units as he may find necessary; and from time to time abolish, transfer, and consolidate divisions, sections, and other units and assign their functions and personnel in such manner as he may find necessary for efficient operation of the Service. No division shall be established, abolished, or transferred, and no divisions shall be consolidated, except with the approval of the Administrator. The National Institute of Health shall be administered as a part of the field service. The Surgeon General may delegate to any officer or employee of the Service such of his powers and duties under this Act, except the making of regulations, as he may deem necessary or expedient.

Assignment of functions.

National Institute of Health.

Delegation of powers.

COMMISSIONED CORPS

SEC. 203. There shall be in the Service a commissioned Regular Corps and, for the purpose of securing a reserve for duty in the Service in time of national emergency, a Reserve Corps. All commissioned officers shall be citizens and shall be appointed without

Regular Corps and Reserve Corps.

Citizenship requirement.

corps of the Service to be a military service. Upon such declaration, and during the period of such war or such part thereof as the President shall prescribe, the commissioned corps (1) shall constitute a branch of the land and naval forces of the United States, and (2) to the extent prescribed by regulations of the President, shall be subject to the Articles of War and to the Articles for the Government of the Navy: *Provided*, That during such period or part thereof the commissioned corps shall continue to operate as part of the Service except to the extent that the President may direct as Commander in Chief.

41 Stat. 787; 12 Stat. 600.
10 U. S. C. § 1471 *et seq.*; Supp. III, ch. 36; 34 U. S. C. § 1200; Supp. III, ch. 21.

NATIONAL ADVISORY HEALTH AND CANCER COUNCILS

SEC. 217. (a) The National Advisory Health Council shall consist of fourteen members. The Director of the National Institute of Health, and three experts, one each from the Army, the Navy, and the Bureau of Animal Industry, to be detailed by the Secretary of War, the Secretary of the Navy, and the Secretary of Agriculture, respectively, shall be ex officio members of the Council. The Surgeon General, with the approval of the Administrator, shall appoint, without regard to the civil-service laws, ten members of the Council who shall be persons, not otherwise in the employ of the United States, skilled in the sciences related to health. Each appointed member shall hold office for a term of five years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term. An appointed member shall not be eligible to serve continuously for more than five years but shall be eligible for reappointment if he has not served immediately preceding his reappointment.

National Advisory Health Council. Members.

(b) The National Advisory Health Council shall advise, consult with, and make recommendations to, the Surgeon General on matters relating to health activities and functions of the Service. The Surgeon General is authorized to utilize the services of any member or members of the Council, and where appropriate, any member or members of the National Advisory Cancer Council in connection with matters related to the work of the Service, for such periods, in addition to conference periods, as he may determine.

Duties.

(c) The National Advisory Cancer Council shall consist of the Surgeon General ex officio, who shall be Chairman, and of six members to be appointed without regard to the civil-service laws by the Surgeon General with the approval of the Administrator. The six appointed members shall be selected from leading medical or scientific authorities who are outstanding in the study, diagnosis, or treatment of cancer. Each appointed member shall hold office for a term of three years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which his predecessor was appointed shall be appointed for the remainder of such term. An appointed member shall not be eligible to serve continuously for more than three years but shall be eligible for reappointment if he has not served immediately preceding his reappointment.

National Advisory Cancer Council. Members.

TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

PART A—RESEARCH AND INVESTIGATIONS

IN GENERAL

SEC. 301. The Surgeon General shall conduct in the Service, and encourage, cooperate with, and render assistance to other appropriate

Duties and authority of Surgeon General.

public authorities, scientific institutions, and scientists in the conduct of, and promote the coordination of, research, investigations, experiments, demonstrations, and studies relating to the causes, diagnosis, treatment, control, and prevention of physical and mental diseases and impairments of man, including water purification, sewage treatment, and pollution of lakes and streams. In carrying out the foregoing the Surgeon General is authorized to—

Collection and dissemination of information.

(a) Collect and make available through publications and other appropriate means, information as to, and the practical application of, such research and other activities;

Research facilities.

(b) Make available research facilities of the Service to appropriate public authorities, and to health officials and scientists engaged in special study;

Research fellowships.

(c) Establish and maintain research fellowships in the Service with such stipends and allowances, including traveling and subsistence expenses, as he may deem necessary to procure the assistance of the most brilliant and promising research fellows from the United States and abroad;

Grants in aid to institutions and individuals.

(d) Make grants in aid to universities, hospitals, laboratories, and other public or private institutions, and to individuals for such research projects as are recommended by the National Advisory Health Council, or, with respect to cancer, recommended by the National Advisory Cancer Council;

Assistance of experts.

(e) Secure from time to time and for such periods as he deems advisable, the assistance and advice of experts, scholars, and consultants from the United States or abroad;

Admission of cases for study.

(f) For purposes of study, admit and treat at institutions, hospitals, and stations of the Service, persons not otherwise eligible for such treatment; and

Adoption of additional means for research and investigations.

(g) Adopt, upon recommendation of the National Advisory Health Council, or, with respect to cancer, upon recommendation of the National Advisory Cancer Council, such additional means as he deems necessary or appropriate to carry out the purposes of this section.

NARCOTICS

Studies and investigations.

SEC. 302. (a) In carrying out the purposes of section 301 with respect to narcotics, the studies and investigations shall include the use and misuse of narcotic drugs, the quantities of crude opium, coca leaves, and their salts, derivatives, and preparations, together with reserves thereof, necessary to supply the normal and emergency medicinal and scientific requirements of the United States. The results of studies and investigations of the quantities of crude opium, coca leaves, or other narcotic drugs, together with such reserves thereof, as are necessary to supply the normal and emergency medicinal and scientific requirements of the United States, shall be reported not later than the 1st day of September each year to the Secretary of the Treasury, to be used at his discretion in determining the amounts of crude opium and coca leaves to be imported under the Narcotic Drugs Import and Export Act, as amended.

Reports.

35 Stat. 614.
21 U. S. C. §§ 171–184.

(b) The Surgeon General shall cooperate with States for the purpose of aiding them to solve their narcotic drug problems and shall give authorized representatives of the States the benefit of his experience in the care, treatment, and rehabilitation of narcotic addicts to the end that each State may be encouraged to provide adequate facilities and methods for the care and treatment of its narcotic addicts.

Post, p. 721.
Cooperation with States.

PART B—FEDERAL-STATE COOPERATION

IN GENERAL

SEC. 311. The Surgeon General is authorized to accept from State and local authorities any assistance in the enforcement of quarantine regulations made pursuant to this Act which such authorities may be able and willing to provide. The Surgeon General shall also assist States and their political subdivisions in the prevention and suppression of communicable diseases, shall cooperate with and aid State and local authorities in the enforcement of their quarantine and other health regulations and in carrying out the purposes specified in section 314, and shall advise the several States on matters relating to the preservation and improvement of the public health.

Enforcement of quarantine regulations.

Prevention of communicable diseases.
Post, p. 857.

HEALTH CONFERENCES

SEC. 312. A conference of the health authorities of the several States shall be called annually by the Surgeon General. Whenever in his opinion the interests of the public health would be promoted by a conference, the Surgeon General may invite as many of such health authorities to confer as he deems necessary or proper. Upon the application of health authorities of five or more States it shall be the duty of the Surgeon General to call a conference of all State and Territorial health authorities joining in the request. Each State represented at any conference shall be entitled to a single vote.

COLLECTION OF VITAL STATISTICS

SEC. 313. To secure uniformity in the registration of mortality, morbidity, and vital statistics the Surgeon General shall prepare and distribute suitable and necessary forms for the collection and compilation of such statistics which shall be published as a part of the health reports published by the Surgeon General.

GRANTS AND SERVICES TO STATES

SEC. 314. (a) To enable the Surgeon General to carry out the purposes of section 301 with respect to developing more effective measures for the prevention, treatment, and control of venereal diseases, and to assist, through grants and as otherwise provided in this section, States, counties, health districts, and other political subdivisions of the States in establishing and maintaining adequate measures for the prevention, treatment, and control of such diseases, including the training of personnel for State and local health work, and to enable him to prevent and control the spread of the venereal diseases in interstate traffic, and to meet the cost of pay, allowances, and traveling expenses of commissioned officers and other personnel of the Service detailed to assist in carrying out the purposes of this section with respect to the venereal diseases, and to administer this section with respect to such diseases, there is hereby authorized to be appropriated for each fiscal year a sum sufficient to carry out the purposes of this subsection.

Control of venereal diseases.
Ante, p. 691.

Appropriations authorized.

(b) To enable the Surgeon General to carry out the purposes of section 301 with respect to developing more effective measures for the prevention, treatment, and control of tuberculosis, and to assist, through grants and as otherwise provided in this section, States, counties, health districts, and other political subdivisions of the States in establishing and maintaining adequate measures for the prevention, treatment, and control of such disease, including the

Control of tuberculosis.
Ante, p. 691.
Post, p. 857.

provision of appropriate facilities for care and treatment and including the training of personnel for State and local health work, and to enable him to prevent and control the spread of tuberculosis in interstate traffic, and to meet the cost of pay, allowances, and traveling expenses of commissioned officers and other personnel of the Service detailed to assist in carrying out the purposes of this section with respect to tuberculosis, and to administer this section with respect to such disease, there is hereby authorized to be appropriated for the fiscal year ending June 30, 1945, the sum of $10,000,000, and for each fiscal year thereafter a sum sufficient to carry out the purposes of this subsection.

Appropriation authorized.

State and local health services.

(c) To enable the Surgeon General to assist, through grants and as otherwise provided in this section, States, counties, health districts, and other political subdivisions of the States in establishing and maintaining adequate public health services, including grants for demonstrations and for the training of personnel for State and local health work, there is hereby authorized to be appropriated for each fiscal year a sum not to exceed $20,000,000. Of the sum appropriated for each fiscal year pursuant to this subsection there shall be available an amount, not to exceed $2,000,000, to enable the Surgeon General to provide demonstrations and to train personnel for State and local health work and to meet the cost of pay, allowances, and traveling expenses of commissioned officers and other personnel of the Service detailed to assist States in carrying out the purposes of this subsection.

Appropriation authorized.
Demonstrations and training of personnel.

Determination of State allotments.

(d) For each fiscal year, the Surgeon General, with the approval of the Administrator, shall determine the total sum from the appropriation under subsection (a), the total sum from the appropriation under subsection (b), and, within the limits specified in subsection (c), the total sum from the appropriation under that subsection which shall be available for allotment among the several States. He shall, in accordance with regulations, from time to time make allotments from such sums to the several States on the basis of (1) the population, (2) the size of the venereal-disease problem, the size of the tuberculosis problem, and the size of other special health problems, respectively, and (3) the financial need of the respective States. Upon making such allotments the Surgeon General shall notify the Secretary of the Treasury of the amounts thereof.

Certification and payment.

(e) The Surgeon General, with the approval of the Administrator, shall from time to time determine the amounts to be paid to each State from the allotments to such State, and shall certify to the Secretary of the Treasury, the amounts so determined, reduced or increased, as the case may be, by the amounts by which he finds that estimates of required expenditures with respect to any prior period were greater or less than the actual expenditures for such period. Upon receipt of such certification, the Secretary of the Treasury shall, through the Division of Disbursement of the Treasury Department and prior to audit or settlement by the General Accounting Office, pay in accordance with such certification.

Method of expenditure.

(f) The moneys so paid to any State shall be expended solely in carrying out the purposes specified in subsection (a), or subsection (b), or subsection (c) of this section, as the case may be, and in accordance with plans presented by the health authority of such State and approved by the Surgeon General.

Local contributions.

(g) Money so paid shall be paid upon the condition that there shall be spent in such State for the same general purpose from funds of such State and its political subdivisions an amount determined in accordance with regulations.

(h) Whenever the Surgeon General, after reasonable notice and opportunity for hearing to the health authority of the State, finds that, with respect to money paid to the State out of appropriations under subsection (a), or subsection (b), or subsection (c), as the case may be, there is a failure to comply substantially with either— Failure to comply with requirements.

(1) the provisions of this section;
(2) the plan submitted under subsection (f); or
(3) the regulations;

the Surgeon General shall notify such State health authority either that further payments will not be made to the State from appropriations under such subsection (or in his discretion that further payments will not be made to the State from such appropriations for activities in which there is such failure), until he is satisfied that there will no longer be any such failure. Until he is so satisfied the Surgeon General shall make no further certification for payment to such State from appropriations under such subsection, or shall limit payment to activities in which there is no such failure.

(i) All regulations and amendments thereto with respect to grants to States under this section shall be made after consultation with a conference of the State health authorities. Insofar as practicable, the Surgeon General shall obtain the agreement of the State health authorities prior to the issuance of any such regulations or amendments. Consultations with State health authorities.

(j) Funds appropriated under subsection (a) and funds appropriated under subsection (b), in addition to being available for payments to States, shall also be available for expenditure by the Surgeon General in otherwise carrying out the respective subsections, including expenditures for printing and binding of the findings of investigations, and for pay and allowances and traveling expenses of personnel of the Service engaged in activities authorized by the respective subsections. Expenditures by Surgeon General.

HEALTH EDUCATION AND INFORMATION

SEC. 315. From time to time the Surgeon General shall issue information related to public health, in the form of publications or otherwise, for the use of the public, and shall publish weekly reports of health conditions in the United States and other countries and other pertinent health information for the use of persons and institutions engaged in work related to the functions of the Service.

PART C—HOSPITALS, MEDICAL EXAMINATIONS, AND MEDICAL CARE

HOSPITALS

SEC. 321. The Surgeon General, pursuant to regulations, shall—

(a) Control, manage, and operate all institutions, hospitals, and stations of the Service, and provide for the care, treatment and hospitalization of patients, including the furnishing of prosthetic and orthopedic devices; and from time to time, with the approval of the President, select suitable sites for and establish such additional institutions, hospitals, and stations in the States and possessions of the United States as in his judgment are necessary to enable the Service to discharge its functions and duties; Functions and duties. General.

(b) Provide for the transfer of Public Health Service patients, in the care of attendants where necessary, between hospitals and stations operated by the Service or between such hospitals and stations and other hospitals and stations in which Public Health Transfer of patients.

Accomplices.

(c) Any person who procures the escape of any person admitted to a hospital of the Service at which addicts are treated and cared for, or who advises, connives at, aids, or assists in such escape, or who conceals any such inmate after such escape, shall be punished upon conviction in a United States court by imprisonment in the penitentiary for not more than three years.

PART F—BIOLOGICAL PRODUCTS

REGULATION OF BIOLOGICAL PRODUCTS

Sale, barter, or exchange in D. C., etc.

SEC. 351. (a) No person shall sell, barter, or exchange, or offer for sale, barter, or exchange in the District of Columbia, or send, carry, or bring for sale, barter, or exchange from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession, any virus, therapeutic serum, toxin, antitoxin, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man, unless (1) such virus, serum, toxin, antitoxin, or other product has been propagated or manufactured and prepared at an establishment holding an unsuspended and unrevoked license, issued by the Administrator as hereinafter authorized, to propagate or manufacture, and prepare such virus, serum, toxin, antitoxin, or other product for sale in the District of Columbia, or for sending, bringing, or carrying from place to place aforesaid; and (2) each package of such virus, serum, toxin, antitoxin, or other product is plainly marked with the proper name of the article contained therein, the name, address, and license number of the manufacturer, and the date beyond which the contents cannot be expected beyond reasonable doubt to yield their specific results. The suspension or revocation of any license shall not prevent the sale, barter, or exchange of any virus, serum, toxin, antitoxin, or other product aforesaid which has been sold and delivered by the licensee prior to such suspension or revocation, unless the owner or custodian of such virus, serum, toxin, antitoxin, or other product aforesaid has been notified by the Administrator not to sell, barter, or exchange the same.

Manufacturers of virus, etc. License requirement.

Package marking requirement.

Effect of license suspension, etc.

False labels, etc.

(b) No person shall falsely label or mark any package or container of any virus, serum, toxin, antitoxin, or other product aforesaid; nor alter any label or mark on any package or container of any virus, serum, toxin, antitoxin, or other product aforesaid so as to falsify such label or mark.

Inspection of establishments for manufacture of virus, etc.

(c) Any officer, agent, or employee of the Federal Security Agency, authorized by the Administrator for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any virus, serum, toxin, antitoxin, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession.

Issuance of licenses. Standards required.

(d) Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations made jointly by the Surgeon General, the Surgeon General of the Army, and the Surgeon General of the Navy, and approved by the Administrator,

and licenses for new products may be issued only upon a showing that they meet such standards. All such licenses shall be issued, suspended, and revoked as prescribed by regulations and all licenses issued for the maintenance of establishments for the propagation or manufacture and preparation, in any foreign country, of any such products for sale, barter, or exchange in any State or possession shall be issued upon condition that the licensees will permit the inspection of their establishments in accordance with subsection (c) of this section.

Conditions.

(e) No person shall interfere with any officer, agent, or employee of the Service in the performance of any duty imposed upon him by this section or by regulations made by authority thereof.

Interference with Service officer, etc.

(f) Any person who shall violate, or aid or abet in violating, any of the provisions of this section shall be punished upon conviction by a fine not exceeding $500 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

Punishment for violations.

(g) Nothing contained in this Act shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act (U. S. C., 1940 edition, title 21, ch. 9).

52 Stat. 1040. 21 U. S. C. § 301 *et seq.*; Supp. III, ch. 9.

PREPARATION OF BIOLOGICAL PRODUCTS

SEC. 352. (a) The Service may prepare for its own use any product described in section 351 and any product necessary to carrying out any of the purposes of section 301.

Ante, p. 702.

Ante, p. 691.

(b) The Service may prepare any product described in section 351 for the use of other Federal departments or agencies, and public or private agencies and individuals engaged in work in the field of medicine when such product is not available from establishments licensed under such section.

PART G—QUARANTINE AND INSPECTION

CONTROL OF COMMUNICABLE DISEASES

SEC. 361. (a) The Surgeon General, with the approval of the Administrator, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.

Regulations.

(b) Regulations prescribed under this section shall not provide for the apprehension, detention, or conditional release of individuals except for the purpose of preventing the introduction, transmission, or spread of such communicable diseases as may be specified from time to time in Executive orders of the President upon the recommendation of the National Advisory Health Council and the Surgeon General.

Limitation on apprehension, etc., of individuals.

(c) Except as provided in subsection (d), regulations prescribed under this section, insofar as they provide for the apprehension, detention, examination, or conditional release of individuals, shall be applicable only to individuals coming into a State or possession from a foreign country, the Territory of Hawaii, or a possession.

Applicability.

Interstate spread of diseases.

(d) On recommendation of the National Advisory Health Council, regulations prescribed under this section may provide for the apprehension and examination of any individual reasonably believed to be infected with a communicable disease in a communicable stage and (1) to be moving or about to move from a State to another State; or (2) to be a probable source of infection to individuals who, while infected with such disease in a communicable stage, will be moving from a State to another State. Such regulations may provide that if upon examination any such individual is found to be infected, he may be detained for such time and in such manner as may be reasonably necessary.

SUSPENSION OF ENTRIES AND IMPORTS FROM DESIGNATED PLACES

SEC. 362. Whenever the Surgeon General determines that by reason of the existence of any communicable disease in a foreign country there is serious danger of the introduction of such disease into the United States, and that this danger is so increased by the introduction of persons or property from such country that a suspension of the right to introduce such persons and property is required in the interest of the public health, the Surgeon General, in accordance with regulations approved by the President, shall have the power to prohibit, in whole or in part, the introduction of persons and property from such countries or places as he shall designate in order to avert such danger, and for such period of time as he may deem necessary for such purpose.

SPECIAL POWERS IN TIME OF WAR

SEC. 363. To protect the military and naval forces and war workers of the United States, in time of war, against any communicable disease specified in Executive orders as provided in subsection (b) of section 361, the Surgeon General, on recommendation of the National Advisory Health Council, is authorized to provide by regulations for the apprehension and examination, in time of war, of any individual reasonably believed (1) to be infected with such disease in a communicable stage and (2) to be a probable source of infection to members of the armed forces of the United States or to individuals engaged in the production or transportation of arms, munitions, ships, food, clothing, or other supplies for the armed forces. Such regulations may provide that if upon examination any such individual is found to be so infected, he may be detained for such time and in such manner as may be reasonably necessary.

QUARANTINE STATIONS

Control, etc.
40 Stat. 220.
50 U. S. C., Supp. III, § 192.

SEC. 364. (a) Except as provided in title II of the Act of June 15, 1917, as amended (U. S. C., 1940 edition, title 50, secs. 191–194), the Surgeon General shall control, direct, and manage all United States quarantine stations, grounds, and anchorages, designate their boundaries, and designate the quarantine officers to be in charge thereof. With the approval of the President he shall from time to time select suitable sites for and establish such additional stations, grounds, and anchorages in the States and possessions of the United States as in his judgment are necessary to prevent the introduction of communicable diseases into the States and possessions of the United States.

Additional stations.

Quarantine inspection.

(b) The Surgeon General shall establish the hours during which quarantine service shall be performed at each quarantine station, and, upon application by any interested party, may establish quar-

antine inspection during the twenty-four hours of the day, or any fraction thereof, at such quarantine stations as, in his opinion, require such extended service. He may restrict the performance of quarantine inspection to hours of daylight for such arriving vessels as cannot, in his opinion, be satisfactorily inspected during hours of darkness. No vessel shall be required to undergo quarantine inspection during the hours of darkness, unless the quarantine officer at such quarantine station shall deem an immediate inspection necessary to protect the public health. Uniformity shall not be required in the hours during which quarantine inspection may be obtained at the various ports of the United States.

CERTAIN DUTIES OF CONSULAR AND OTHER OFFICERS

Reports of health conditions.

SEC. 365. (a) Any consular or medical officer of the United States, designated for such purpose by the Administrator, shall make reports to the Surgeon General, on such forms and at such intervals as the Surgeon General may prescribe, of the health conditions at the port or place at which such officer is stationed.

Enforcement of regulations.

(b) It shall be the duty of the customs officers and of Coast Guard officers to aid in the enforcement of quarantine rules and regulations; but no additional compensation, except actual and necessary traveling expenses, shall be allowed any such officer by reason of such services.

BILLS OF HEALTH

Procurement by vessel at port of departure.

SEC. 366. (a) Except as otherwise prescribed in regulations, any vessel at any foreign port or place clearing or departing for any port or place in a State or possession shall be required to obtain from the consular officer of the United States or from the Public Health Service officer, or other medical officer of the United States designated by the Surgeon General, at the port or place of departure, a bill of health in duplicate, in the form prescribed by the Surgeon General. The President, from time to time, shall specify the ports at which a medical officer shall be stationed for this purpose. Such bill of health shall set forth the sanitary history and condition of said vessel, and shall state that it has in all respects complied with the regulations prescribed pursuant to subsection (c). Before granting such duplicate bill of health, such consular or medical officer shall be satisfied that the matters and things therein stated are true. The consular officer shall be entitled to demand and receive the fees for bills of health and such fees shall be established by regulation.

Contents.

Fees.

Delivery of originals and duplicates.

(b) Original bills of health shall be delivered to the collectors of customs at the port of entry. Duplicate copies of such bills of health shall be delivered at the time of inspection to quarantine officers at such port. The bills of health herein prescribed shall be considered as part of the ship's papers, and when duly certified to by the proper consular or other officer of the United States, over his official signature and seal, shall be accepted as evidence of the statements therein contained in any court of the United States.

Regulations.

(c) The Surgeon General shall from time to time prescribe regulations, applicable to vessels referred to in subsection (a) of this section for the purpose of preventing the introduction into the States or possessions of the United States of any communicable disease by securing the best sanitary condition of such vessels, their cargoes, passengers, and crews. Such regulations shall be observed by such vessels prior to departure, during the course of the voyage, and also during inspection, disinfection, or other quarantine procedure upon arrival at any United States quarantine station.

Excepted vessels.

(d) The provisions of subsections (a) and (b) of this section shall not apply to vessels plying between such foreign ports on or near the frontiers of the United States and ports of the United States as are designated by treaty.

Certificate of quarantine officer.

(e) It shall be unlawful for any vessel to enter any port in any State or possession of the United States to discharge its cargo, or land its passengers, except upon a certificate of the quarantine officer that regulations prescribed under subsection (c) have in all respects been complied with by such officer, the vessel, and its master. The master of every such vessel shall deliver such certificate to the collector of customs at the port of entry, together with the original bill of health and other papers of the vessel. The certificate required by this subsection shall be procurable from the quarantine officer, upon arrival of the vessel at the quarantine station and satisfactory inspection thereof, at any time within which quarantine services are performed at such station.

CIVIL AIR NAVIGATION AND CIVIL AIRCRAFT

SEC. 367. The Surgeon General is authorized to provide by regulations for the application to air navigation and aircraft of any of the provisions of sections 364, 365, and 366 and regulations prescribed thereunder (including penalties and forfeitures for violations of such sections and regulations), to such extent and upon such conditions as he deems necessary for the safeguarding of the public health.

PENALTIES

SEC. 368. (a) Any person who violates any regulation prescribed under sections 361, 362, or 363, or any provision of section 366 or any regulation prescribed thereunder, or who enters or departs from the limits of any quarantine station, ground, or anchorage in disregard of quarantine rules and regulations or without permission of the quarantine officer in charge, shall be punished by a fine of not more than $1,000 or by imprisonment for not more than one year, or both.

Unlawful entry or departure.

Forfeitures.

(b) Any vessel which violates section 366, or any regulations thereunder or under section 364, or which enters within or departs from the limits of any quarantine station, ground, or anchorage in disregard of the quarantine rules and regulations or without permission of the officer in charge, shall forfeit to the United States not more than $5,000, the amount to be determined by the court, which shall be a lien on such vessel, to be recovered by proceedings in the proper district court of the United States. In all such proceedings the United States district attorney shall appear on behalf of the United States; and all such proceedings shall be conducted in accordance with the rules and laws governing cases of seizure of vessels for violation of the revenue laws of the United States.

Proceedings.

Remission or mitigation.

(c) With the approval of the Administrator, the Surgeon General may, upon application therefor, remit or mitigate any forfeiture provided for under subsection (b) of this section, and he shall have authority to ascertain the facts upon all such applications.

ADMINISTRATION OF OATHS

SEC. 369. Medical officers of the United States, when performing duties as quarantine officers at any port or place within the United States, are authorized to take declarations and administer oaths in matters pertaining to the administration of the quarantine laws and regulations of the United States.

Title 42, PUBLIC HEALTH SERVICE ACT -
Chapter 6A - Public Health Service
PART B - Federal-State Cooperation
Sections 243 through 247d-12 as of April 15, 2025

1944 PHSA as of April 2025, highlighting addition, under Part B, of Public Health Emergencies, 42 USC 247d (added 1983, replaced 2000); Targeted liability protections/PREP Act, 42 USC 247d-6d (added 2005); Covered Countermeasure Process/ PREP Act, 42 USC 247d-6e (added 2005); BARDA, 42 USC 247d-7e (added 2006)

Highlighting:

42 USC 247d, Public health emergencies
42 USC 247d-6d. Targeted liability protections for pandemic and epidemic products and security countermeasures
42 USC 247d-6e. Covered countermeasure process
42 USC 247d–7e. Biomedical Advanced Research and Development Authority

42 USC 247d: Public health emergencies
Text contains those laws in effect on April 14, 2025

From Title 42-THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A-PUBLIC HEALTH SERVICE
SUBCHAPTER II-GENERAL POWERS AND DUTIES
Part B-Federal-State Cooperation

Jump To:

PHSA Sec 319 = 42 USC 247d, Public health emergencies.
Added 1983, 1983 version repealed and replaced in 2000.

§247d. Public health emergencies

(a) Emergencies

If the Secretary determines, after consultation with such public health officials as may be necessary, that-
(1) a disease or disorder presents a public health emergency; or
(2) a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists,

the Secretary may take such action as may be appropriate to respond to the public health emergency, including making grants, providing awards for expenses, and entering into contracts and conducting and supporting investigations into the cause, treatment, or prevention of a disease or disorder as described in paragraphs (1) and (2). Any such determination of a public health emergency terminates upon the Secretary declaring that the emergency no longer exists, or upon the expiration of the 90-day period beginning on the date on which the determination is made by the Secretary, whichever occurs first. Determinations that terminate under the preceding sentence may be renewed by the Secretary (on the basis of the same or additional facts), and the preceding sentence applies to each such renewal. Not later than 48 hours after making a determination under this subsection of a public health emergency (including a renewal), the Secretary shall submit to the Congress written notification of the determination.

(b) Public Health Emergency Fund

(1) In general

There is established in the Treasury a fund to be designated as the "Public Health Emergency Fund" to be made available to the Secretary without fiscal year limitation to carry out subsection (a) only if a public health emergency has been declared by the Secretary under such subsection or if the Secretary determines there is the significant potential for a public health emergency, to allow the Secretary to rapidly respond to the immediate needs resulting from such public health emergency or potential public health emergency. The Secretary shall plan for the expedited distribution of funds to appropriate agencies and entities. There is authorized to be appropriated to the Fund such sums as may be necessary.

(2) Uses

The Secretary may use amounts in the Fund established under paragraph (1), to-
(A) facilitate coordination between and among Federal, State, local, Tribal, and territorial entities and public and private health care entities that the Secretary determines may be affected by a public health emergency or potential public health emergency referred to in paragraph (1) (including communication of such entities with relevant international entities, as applicable);
(B) make grants, provide for awards, enter into contracts, and conduct supportive investigations pertaining to a public health emergency or potential public health emergency, including further supporting programs under section 247d–3a, 247d–3b, or 247d–3c of this title;
(C) facilitate and accelerate, as applicable, advanced research and development of security countermeasures (as defined in section 247d–6b of this title), qualified countermeasures (as defined in section 247d–6a of this title), or qualified pandemic or epidemic products (as defined in section 247d–6d of this title), that are applicable to the public health emergency or potential public health emergency under paragraph (1);
(D) strengthen biosurveillance capabilities and laboratory capacity to identify, collect, and analyze information regarding such public health emergency or potential public health emergency, including the systems under section 247d–4 of this title;
(E) support initial emergency operations and assets related to preparation and deployment of intermittent disaster response personnel under section 300hh–11 of this title and the Medical Reserve Corps under section 300hh–15 of this title;
(F) support the initial deployment and distribution of contents of the Strategic National Stockpile, as appropriate; and
(G) carry out other activities, as the Secretary determines applicable and appropriate.

(3) Report

Not later than 90 days after the end of each fiscal year, the Secretary shall prepare and submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Commerce and the Committee on Appropriations of the House of Representatives a report describing-
(A) the expenditures made from the Public Health Emergency Fund in such fiscal year, including-
(i) the amount obligated;
(ii) the recipient or recipients of such obligated funds;
(iii) the specific response activities such obligated funds will support; and
(iv) the declared or potential public health emergency for which such funds were obligated; and

(B) each public health emergency for which the expenditures were made and the activities undertaken with respect to each emergency which was conducted or supported by expenditures from the Fund.

(4) Review

Not later than 2 years after June 24, 2019, the Secretary, in coordination with the Assistant Secretary for Preparedness and Response, shall conduct a review of the Fund under this section and provide recommendations to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives on policies to improve such Fund for the uses described in paragraph (2).

(5) GAO report

Not later than 4 years after June 24, 2019, the Comptroller General of the United States shall-
(A) conduct a review of the Fund under this section, including its uses and the resources available in the Fund; and
(B) submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on such review, including recommendations related to such review, as applicable.

(c) Supplement not supplant

Funds appropriated under this section shall be used to rapidly respond to public health emergencies or potential public health emergencies and supplement and not supplant other Federal, State, and local public funds provided for activities under this chapter or funds otherwise provided for emergency response.

(d) Data submittal and reporting deadlines

In any case in which the Secretary determines that, wholly or partially as a result of a public health emergency that has been determined pursuant to subsection (a), individuals or public or private entities are unable to comply with deadlines for the submission to the Secretary of data or reports required under any law administered by the Secretary, the Secretary may, notwithstanding any other provision of law, grant such extensions of such deadlines as the circumstances reasonably require, and may waive, wholly or partially, any sanctions otherwise applicable to such failure to comply. Before or promptly after granting such an extension or waiver, the Secretary shall notify the Congress of such action and publish in the Federal Register a notice of the extension or waiver.

(e) Temporary reassignment of State and local personnel during a public health emergency

(1) Emergency reassignment of federally funded personnel

Notwithstanding any other provision of law, and subject to paragraph (2), upon request by the Governor of a State or a tribal organization or such Governor or tribal organization's designee, the Secretary may authorize the requesting State or Indian tribe to temporarily reassign, for purposes of immediately addressing a public health emergency in the State or Indian tribe, State and local public health department or agency personnel funded in whole or in part through programs authorized under this chapter, as appropriate.

(2) Activation of emergency reassignment

(A) Public health emergency

The Secretary may authorize a temporary reassignment of personnel under paragraph (1) only during the period of a public health emergency determined pursuant to subsection (a).

(B) Contents of request

To seek authority for a temporary reassignment of personnel under paragraph (1), the Governor of a State or a tribal organization shall submit to the Secretary a request for such reassignment flexibility and shall include in the request each of the following:
(i) An assurance that the public health emergency in the geographic area of the requesting State or Indian tribe cannot be adequately and appropriately addressed by the public health workforce otherwise available.
(ii) An assurance that the public health emergency would be addressed more efficiently and effectively through the requested temporary reassignment of State and local personnel described in paragraph (1).
(iii) An assurance that the requested temporary reassignment of personnel is consistent with any applicable All-Hazards Public Health Emergency Preparedness and Response Plan under section 247d–3a of this title.
(iv) An identification of-
(I) each Federal program from which personnel would be temporarily reassigned pursuant to the requested authority; and

(II) the number of personnel who would be so reassigned from each such program.

(v) Such other information and assurances upon which the Secretary and Governor of a State or tribal organization agree.

(C) Consideration

In reviewing a request for temporary reassignment under paragraph (1), the Secretary shall consider the degree to which the program or programs funded in whole or in part by programs authorized under this chapter would be adversely affected by the reassignment.

(D) Termination and extension

(i) Termination

A State or Indian tribe's temporary reassignment of personnel under paragraph (1) shall terminate upon the earlier of the following:
(I) The Secretary's determination that the public health emergency no longer exists.
(II) Subject to clause (ii), the expiration of the 30-day period following the date on which the Secretary approved the State or Indian tribe's request for such reassignment flexibility.

(ii) Extension of reassignment flexibility

The Secretary may extend reassignment flexibility of personnel under paragraph (1) beyond the date otherwise applicable under clause (i)(II) if the public health emergency still exists as of such date, but only if-
(I) the State or Indian tribe that submitted the initial request for a temporary reassignment of personnel submits a request for an extension of such temporary reassignment; and
(II) the request for an extension contains the same information and assurances necessary for the approval of an initial request for such temporary reassignment pursuant to subparagraph (B).

(3) Voluntary nature of temporary reassignment of State and local personnel

(A) In general

Unless otherwise provided under the law or regulation of the State or Indian tribe that receives authorization for temporary reassignment of personnel under paragraph (1), personnel eligible for reassignment pursuant to such authorization-
(i) shall have the opportunity to volunteer for temporary reassignment; and
(ii) shall not be required to agree to a temporary reassignment.

(B) Prohibition on conditioning Federal awards

The Secretary may not condition the award of a grant, contract, or cooperative agreement under this chapter on the requirement that a State or Indian tribe require that personnel eligible for reassignment pursuant to an authorization under paragraph (1) agree to such reassignment.

(4) Notice to Congress

The Secretary shall give notice to the Congress in conjunction with the approval under this subsection of-
(A) any initial request for temporary reassignment of personnel; and
(B) any request for an extension of such temporary reassignment.

(5) Guidance

The Secretary shall-
(A) not later than 6 months after March 13, 2013, issue proposed guidance on the temporary reassignment of personnel under this subsection; and
(B) after providing notice and a 60-day period for public comment, finalize such guidance.

(6) Report to Congress

Not later than 4 years after March 13, 2013, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the appropriate committees of the Congress a report, on temporary reassignment under this subsection, including-
(A) a description of how, and under what circumstances, such temporary reassignment has been used by States and Indian tribes;
(B) an analysis of how such temporary reassignment has assisted States and Indian tribes in responding to public health emergencies;
(C) an evaluation of how such temporary reassignment has improved operational efficiencies in responding to public health emergencies;
(D) an analysis of the extent to which, if any, Federal programs from which personnel have been temporarily reassigned have been adversely affected by the reassignment; and
(E) recommendations on how medical surge capacity could be improved in responding to public health emergencies and the impact of the reassignment flexibility under this section on such surge capacity.

(7) Definitions

In this subsection-
(A) the terms "Indian tribe" and "tribal organization" have the meanings given such terms in section 5304 of title 25; and
(B) the term "State" includes, in addition to the entities listed in the definition of such term in section 201 of this title, the Freely Associated States.

(8) Sunset

This subsection shall terminate on September 30, 2025.

(f) Determination with respect to Paperwork Reduction Act waiver during a public health emergency

(1) Determination

If the Secretary determines, after consultation with such public health officials as may be necessary, that-
(A)(i) the criteria set forth for a public health emergency under paragraph (1) or (2) of subsection (a) has been met; or
(ii) a disease or disorder, including a novel and emerging public health threat, is significantly likely to become a public health emergency; and
(B) the circumstances of such public health emergency, or potential for such significantly likely public health emergency, including the specific preparation for and response to such public health emergency or threat, necessitate a waiver from the requirements of subchapter I of chapter 35 of title 44 (commonly referred to as the Paperwork Reduction Act),

then the requirements of such subchapter I with respect to voluntary collection of information shall not be applicable during the immediate investigation of, and response to, such public health emergency during the period of such public health emergency or the period of time necessary to determine if a disease or disorder, including a novel and emerging public health threat, will become a public health emergency as provided for in this paragraph. The requirements of such subchapter I with respect to voluntary collection of information shall not be applicable during the immediate postresponse review regarding such public health emergency if such immediate postresponse review does not exceed a reasonable length of time.

(2) Transparency

If the Secretary determines that a waiver is necessary under paragraph (1), the Secretary shall promptly post on the Internet website of the Department of Health and Human Services a brief justification for such waiver, the anticipated period of time such waiver will be in effect, and the agencies and offices within the Department of Health and Human Services to which such waiver shall apply, and update such information posted on the Internet website of the Department of Health and Human Services, as applicable.

(3) Effectiveness of waiver

Any waiver under this subsection shall take effect on the date on which the Secretary posts information on the Internet website as provided for in this subsection.

(4) Termination of waiver

Upon determining that the circumstances necessitating a waiver under paragraph (1) no longer exist, the Secretary shall promptly update the Internet website of the Department of Health and Human Services to reflect the termination of such waiver.

(5) Limitations

(A) Period of waiver

The period of a waiver under paragraph (1) shall not exceed the period of time for the related public health emergency, including a public health emergency declared pursuant to subsection (a), and any immediate postresponse review regarding the public health emergency consistent with the requirements of this subsection.

(B) Subsequent compliance

An initiative subject to a waiver under paragraph (1) that is ongoing after the date on which the waiver expires, shall be subject to the requirements of subchapter I of chapter 35 of title 44 and the Secretary shall ensure that compliance with such requirements occurs in as timely a manner as possible based on the applicable circumstances, but not to exceed 30 calendar days after the expiration of the applicable waiver.

(g) Certain appointments to support public health emergency responses

(1) In general

In order to support the initial response to a public health emergency declared by the Secretary under this section, the Secretary may, subject to paragraph (2) and without regard to sections 3309 through 3318 of title 5, appoint individuals directly to positions in the Department of Health and Human Services for which the Secretary has provided public notice in order to-
(A) address a critical hiring need directly related to responding to a public health emergency declared by the Secretary under this section; or
(B) address a severe shortage of candidates that impacts the operational capacity of the Department of Health and Human Services to respond in the event of a public health emergency declared by the Secretary under this section.

(2) Number of appointments

Each fiscal year in which the Secretary makes a determination of a public health emergency under subsection (a) (not including a renewal), the Secretary may directly appoint not more than-
(A) 400 individuals under paragraph (1)(A); and
(B) 100 individuals under paragraph (1)(B).

(3) Compensation

The annual rate of basic pay of an individual appointed under this subsection shall be determined in accordance with chapter 51 and subchapter III of chapter 53 of title 5.

(4) Reporting

The Secretary shall establish and maintain records regarding the use of the authority under this subsection, including-
(A) the number of positions filled through such authority;
(B) the types of appointments of such positions;
(C) the titles, occupational series, and grades of such positions;
(D) the number of positions publicly noticed to be filled under such authority;
(E) the number of qualified applicants who apply for such positions;
(F) the qualification criteria for such positions; and
(G) the demographic information of individuals appointed to such positions.

(5) Notification to Congress

In the event the Secretary, within a single fiscal year, directly appoints more than 50 percent of the individuals allowable under either subparagraph (A) or (B) of paragraph (2), the Secretary shall, not later than 15 days after the date of such action, notify the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives. Such notification shall, in a manner that protects personal privacy, to the extent required by applicable Federal and State privacy law, at a minimum, include-
(A) information on each such appointment within such fiscal year;
(B) a description of how each such position relates to the requirements of subparagraph (A) or (B) of paragraph (1); and
(C) the additional number of personnel, if any, the Secretary anticipates to be necessary to adequately support a response to a public health emergency declared under this section using the authorities described in paragraph (1) within such fiscal year.

(6) Reports to Congress

Not later than September 30, 2023, and annually thereafter for each fiscal year in which the authority under this subsection is used, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report describing the total number of appointments filled under this subsection within the fiscal year and a description of how the positions relate to the requirements of subparagraph (A) or (B) of paragraph (1).

(7) Sunset

The authority under this subsection shall expire on September 30, 2028.

(h) Stockpile depletion reporting

The Secretary shall, not later than 30 days after the deployment of contents of the Strategic National Stockpile under section 247d–6b(a) of this title to respond to a public health emergency declared by the Secretary under this section or an emergency or major disaster declared by the President under the Robert T. Stafford Disaster Relief and Emergency Assistance Act [42 U.S.C. 5121 et seq.], and every 30 days thereafter until the expiration or termination of such public health emergency, emergency, or major disaster, submit a report to the Committee on Health, Education, Labor, and Pensions and the Committee on Appropriations of the Senate and the Committee on Energy and Commerce and the Committee on Appropriations of the House of Representatives on-
(1) the deployment of the contents of the stockpile in response to State, local, and Tribal requests;
(2) the amount of such products that remain within the stockpile following such deployment; and
(3) plans to replenish such products, as appropriate, including related timeframes and any barriers or limitations to replenishment.

(July 1, 1944, ch. 373, title III, §319, as added Pub. L. 106–505, title I, §102, Nov. 13, 2000, 114 Stat. 2315 ; amended Pub. L. 107–188, title I, §§141, 144(a), 158, June 12, 2002, 116 Stat. 626 , 630, 633; Pub. L. 113–5, title II, §201, Mar. 13, 2013, 127 Stat. 170 ; Pub. L. 114–255, div. A, title III, §3087, Dec. 13, 2016, 130 Stat. 1147 ; Pub. L. 116–22, title II, §206, title VII, §701(c), June 24, 2019, 133 Stat. 925 , 961; Pub. L. 117–328, div. FF, title II, §§2103(a), 2223(a), 2407, Dec. 29, 2022, 136 Stat. 5711 , 5747, 5788; Pub. L. 118–15, div. B, title III, §2332, Sept. 30, 2023, 137 Stat. 96 ; Pub. L. 118–22, div. B, title II, §203(a), Nov. 17, 2023, 137 Stat. 120 ; Pub. L. 118–35, div. B, title I, §103(a), Jan. 19, 2024, 138 Stat. 5 ; Pub. L. 118–42, div. G, title I, §103(a), Mar. 9, 2024, 138 Stat. 398 ; Pub. L. 118–158, div. C, title I, §3103(a), Dec. 21, 2024, 138 Stat. 1763 ; Pub. L. 119–4, div. B, title I, §2103(a), Mar. 15, 2025, 139 Stat. 41 .)

Editorial Notes

References in Text

The Robert T. Stafford Disaster Relief and Emergency Assistance Act, referred to in subsec. (h), is Pub. L. 93–288, May 22, 1974, 88 Stat. 143 , which is classified principally to chapter 68 (§5121 et seq.) of this title. For complete classification of this Act to the Code, see Short Title note set out under section 5121 of this title and Tables.

Prior Provisions

A prior section 247d, act July 1, 1944, ch. 373, title III, §319, as added Pub. L. 98–49, July 13, 1983, 97 Stat. 245 ; amended Pub. L. 100–607, title II, §256(a), Nov. 4, 1988, 102 Stat. 3110 ; Pub. L. 102–321, title I, §163(b)(2), July 10, 1992, 106 Stat. 376 ; Pub. L. 102–531, title III, §312(d)(2), Oct. 27, 1992, 106 Stat. 3504 , authorized the Secretary to take appropriate action relating to public health emergencies, prior to repeal by Pub. L. 106–505, title I, §102, Nov. 13, 2000, 114 Stat. 2315 .

Another prior section 247d, act July 1, 1944, ch. 373, title III, §319, formerly §310, as added Sept. 25, 1962, Pub. L. 87–692, 76 Stat. 592 , and amended and renumbered, which related to migrant health centers, was renumbered section 329 of act July 1, 1944, by Pub. L. 95–626, title I, §102(a), Nov. 10, 1978, 92 Stat. 3551 , and transferred to section 254b of this title, prior to being omitted in the general amendment of subpart I (§254b et seq.) of part D of this subchapter by Pub. L. 104–299, §2.

Amendments

2025-Subsec. (e)(8). Pub. L. 119–4 substituted "September 30, 2025" for "March 31, 2025".
2024-Subsec. (e)(8). Pub. L. 118–158 substituted "March 31, 2025" for "December 31, 2024".
Pub. L. 118–42 substituted "December 31, 2024" for "March 8, 2024".
Pub. L. 118–35 substituted "March 8, 2024" for "January 19, 2024".
2023-Subsec. (e)(8). Pub. L. 118–22 substituted "January 19, 2024" for "November 17, 2023".
Pub. L. 118–15 substituted "November 17, 2023" for "September 30, 2023".
2022-Subsec. (b)(2)(F), (G). Pub. L. 117–328, §2103(a)(1), added subpar. (F) and redesignated former subpar. (F) as (G).
Subsec. (b)(3)(A). Pub. L. 117–328, §2103(a)(2), amended subpar. (A) generally. Prior to amendment, subpar. (A) read as follows: "the expenditures made from the Public Health Emergency Fund in such fiscal year; and".
Subsec. (g). Pub. L. 117–328, §2223(a), added subsec. (g).
Subsec. (h). Pub. L. 117–328, §2407, added subsec. (h).
2019-Subsec. (b)(1). Pub. L. 116–22, §206(1)(A), substituted "under such subsection or if the Secretary determines there is the significant potential for a public health emergency, to allow the Secretary to rapidly respond to the immediate needs resulting from such public health emergency or potential public health emergency. The Secretary shall plan for the expedited distribution of funds to appropriate agencies and entities." for "under such subsection."
Subsec. (b)(2), (3). Pub. L. 116–22, §206(1)(B), (C), added par. (2) and redesignated former par. (2) as (3).
Subsec. (b)(4), (5). Pub. L. 116–22, §206(1)(D), added pars. (4) and (5).
Subsec. (c). Pub. L. 116–22, §206(2), inserted "rapidly respond to public health emergencies or potential public health emergencies and" after "used to" and substituted "activities under this chapter or funds otherwise provided for emergency response." for "activities under this section."
Subsec. (e)(8). Pub. L. 116–22, §701(c), substituted "2023" for "2018".
2016-Subsec. (f). Pub. L. 114–255 added subsec. (f).
2013-Subsec. (e). Pub. L. 113–5 added subsec. (e).
2002-Subsec. (a). Pub. L. 107–188, §158, substituted "grants, providing awards for expenses, and" for "grants and" in concluding provisions.
Pub. L. 107–188, §144(a), inserted at end of concluding provisions "Any such determination of a public health emergency terminates upon the Secretary declaring that the emergency no longer exists, or upon the expiration of the 90-day period beginning on the date on which the determination is made by the Secretary, whichever occurs first. Determinations that terminate under the preceding sentence may be renewed by the Secretary (on the basis of the same or additional facts), and the preceding sentence applies to each such renewal. Not later than 48 hours after making a determination under this subsection of a public health emergency (including a renewal), the Secretary shall submit to the Congress written notification of the determination."
Subsec. (d). Pub. L. 107–188, §141, added subsec. (d).

Statutory Notes and Related Subsidiaries

Change of Name

Committee on Commerce of House of Representatives changed to Committee on Energy and Commerce of House of Representatives, and jurisdiction over matters relating to securities and exchanges and insurance generally transferred to Committee on Financial Services of House of Representatives by House Resolution No. 5, One Hundred Seventh Congress, Jan. 3, 2001.

Effective Date of 2002 Amendment

Pub. L. 107–188, title I, §144(b), June 12, 2002, 116 Stat. 630 , provided that: "The amendment made by subsection (a) [amending this section] applies to any public health emergency under section 319(a) of the Public Health Service Act [42 U.S.C. 247d(a)], including any such emergency that was in effect as of the day before the date of the enactment of this Act [June 12, 2002]. In the case of such an emergency that was in effect as of such day, the 90-day period described in such section with respect to the termination of the emergency is deemed to begin on such date of enactment."

Consideration of Unique Challenges in Noncontiguous States and Territories

Pub. L. 117–328, div. FF, title II, §2115, Dec. 29, 2022, 136 Stat. 5726 , provided that: "During any public health emergency declared under section 319 of the Public Health Service Act (42 U.S.C. 247d), the Secretary of Health and Human Services shall conduct quarterly meetings or consultations, as applicable or appropriate, with noncontiguous States and territories with regard to addressing unique public health challenges in such States and territories associated with such public health emergency."

Funding for COVID–19 Vaccine Activities at the Centers for Disease Control and Prevention

Pub. L. 117–2, title II, §2301, Mar. 11, 2021, 135 Stat. 37 , provided that:

"(a) In General.-In addition to amounts otherwise available, there is appropriated to the Secretary of Health and Human Services (in this subtitle [subtitle D (§§2301–2305) of title II of Pub. L. 117–2, see Tables for classification] referred to as the 'Secretary') for fiscal year 2021, out of any money in the Treasury not otherwise appropriated, $7,500,000,000, to remain available until expended, to carry out activities to plan, prepare for, promote, distribute, administer, monitor, and track COVID–19 vaccines.

"(b) Use of Funds.-The Secretary, acting through the Director of the Centers for Disease Control and Prevention, and in consultation with other agencies, as applicable, shall, in conducting activities referred to in subsection (a)-

"(1) conduct activities to enhance, expand, and improve nationwide COVID–19 vaccine distribution and administration, including activities related to distribution of ancillary medical products and supplies related to vaccines; and

"(2) provide technical assistance, guidance, and support to, and award grants or cooperative agreements to, State, local, Tribal, and territorial public health departments for enhancement of COVID–19 vaccine distribution and administration capabilities, including-

"(A) the distribution and administration of vaccines licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) or authorized under section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3) and ancillary medical products and supplies related to vaccines;

"(B) the establishment and expansion, including staffing support, of community vaccination centers, particularly in underserved areas;

"(C) the deployment of mobile vaccination units, particularly in underserved areas;

"(D) information technology, standards-based data, and reporting enhancements, including improvements necessary to support standards-based sharing of data related to vaccine distribution and vaccinations and systems that enhance vaccine safety, effectiveness, and uptake, particularly among underserved populations;

"(E) facilities enhancements;

"(F) communication with the public regarding when, where, and how to receive COVID–19 vaccines; and

"(G) transportation of individuals to facilitate vaccinations, including at community vaccination centers and mobile vaccination units, particularly for underserved populations.

"(c) Supplemental Funding for State Vaccination Grants.-

"(1) Definitions.-In this subsection:

"(A) Base formula.-The term 'base formula' means the allocation formula that applied to the Public Health Emergency Preparedness cooperative agreement in fiscal year 2020.

"(B) Alternative allocation.-The term 'alternative allocation' means an allocation to each State, territory, or locality calculated using the percentage derived from the allocation received by such State, territory, or locality of the aggregate amount of fiscal year 2020 Public Health Emergency Preparedness cooperative agreement awards under section 319C–1 of the Public Health Service Act (42 U.S.C. 247d–3a).

"(2) Supplemental funding.-

"(A) In general.-Not later than 21 days after the date of enactment of this Act [Mar. 11, 2021], the Secretary shall, out of amounts described in subsection (a), provide supplemental funding to any State, locality, or territory that received less of the amounts that were appropriated under title III of division M of Public Law 116–260 [see Tables for classification] for vaccination grants to be issued by the Centers for Disease Control and Prevention than such State, locality, or territory would have received had such amounts been allocated using the alternative allocation.

"(B) Amount.-The amount of supplemental funding provided under this subsection shall be equal to the difference between-

"(i) the amount the State, locality, or territory received, or would receive, under the base formula; and

"(ii) the amount the State, locality, or territory would receive under the alternative allocation."

Funding for COVID–19 Testing, Contact Tracing, and Mitigation Activities

Pub. L. 117–2, title II, §2401, Mar. 11, 2021, 135 Stat. 40 , provided that:

"(a) In General.-In addition to amounts otherwise available, there is appropriated to the Secretary of Health and Human Services (in this subtitle [subtitle E (§§2401–2404) of title II of Pub. L. 117–2, see Tables for classification] referred to as the 'Secretary') for fiscal year 2021, out of any money in the Treasury not otherwise appropriated, $47,800,000,000, to remain available until expended, to carry out activities to detect, diagnose, trace, and monitor SARS–CoV–2 and COVID–19 infections and related strategies to mitigate the spread of COVID–19.

"(b) Use of Funds.-From amounts appropriated by subsection (a), the Secretary shall-

"(1) implement a national, evidence-based strategy for testing, contact tracing, surveillance, and mitigation with respect to SARS–CoV–2 and COVID–19, including through activities authorized under section 319(a) of the Public Health Service Act [42 U.S.C. 247d(a)];

"(2) provide technical assistance, guidance, and support, and award grants or cooperative agreements to State, local, and territorial public health departments for activities to detect, diagnose, trace, and monitor SARS–CoV–2 and COVID–19 infections and related strategies and activities to mitigate the spread of COVID–19;

"(3) support the development, manufacturing, procurement, distribution, and administration of tests to detect or diagnose SARS–CoV–2 and COVID–19, including through-

"(A) support for the development, manufacture, procurement, and distribution of supplies necessary for administering tests, such as personal protective equipment; and

"(B) support for the acquisition, construction, alteration, or renovation of non-federally owned facilities for the production of diagnostics and ancillary medical products and supplies where the Secretary determines that such an investment is necessary to ensure the production of sufficient amounts of such supplies;

"(4) establish and expand Federal, State, local, and territorial testing and contact tracing capabilities, including-

"(A) through investments in laboratory capacity, such as-

"(i) academic and research laboratories, or other laboratories that could be used for processing of COVID–19 testing;

"(ii) community-based testing sites and community-based organizations; or

"(iii) mobile health units, particularly in medically underserved areas; and

"(B) with respect to quarantine and isolation of contacts;

"(5) enhance information technology, data modernization, and reporting, including improvements necessary to support sharing of data related to public health capabilities;

"(6) award grants to, or enter into cooperative agreements or contracts with, State, local, and territorial public health departments to establish, expand, and sustain a public health workforce; and

"(7) to cover administrative and program support costs necessary to conduct activities related to subparagraph (a)."

Importance of the Blood Supply

Pub. L. 116–136, div. A, title III, §3226, Mar. 27, 2020, 134 Stat. 383 , provided that:

"(a) In General.-The Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall carry out a national campaign to improve awareness of, and support outreach to the public and health care providers about the importance and safety of blood donation and the need for donations for the blood supply during the public health emergency declared by the Secretary under section 319 of the Public Health Service Act (42 U.S.C. 247d) with respect to COVID–19.

"(b) Awareness Campaign.-In carrying out subsection (a), the Secretary may enter into contracts with one or more public or private nonprofit entities, to establish a national blood donation awareness campaign that may include television, radio, internet, and newspaper public service announcements, and other activities to provide for public and professional awareness and education.

"(c) Consultation.-In carrying out subsection (a), the Secretary shall consult with the Commissioner of Food and Drugs, the Assistant Secretary for Health, the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, and the heads of other relevant Federal agencies, and relevant accrediting bodies and representative organizations.

"(d) Report to Congress.-Not later than 2 years after the date of enactment of this Act [Mar. 27, 2020], the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives, a report that shall include-

"(1) a description of the activities carried out under subsection (a);

"(2) a description of trends in blood supply donations; and

"(3) an evaluation of the impact of the public awareness campaign, including any geographic or population variations."

Reporting by Laboratories of Results of Tests To Detect SARS–CoV–2 or To Diagnose COVID–19

Pub. L. 116–136, div. B, title VIII, §18115(a)–(c), Mar. 27, 2020, 134 Stat. 574 , provided that:

"(a) In General.-Every laboratory that performs or analyzes a test that is intended to detect SARS–CoV–2 or to diagnose a possible case of COVID–19 shall report the results from each such test, to the Secretary of Health and Human Services in such form and manner, and at such timing and frequency, as the Secretary may prescribe until the end of the Secretary's Public Health Emergency declaration with respect to COVID–19 or any extension of such declaration.

"(b) Laboratories Covered.-The Secretary may prescribe which laboratories must submit reports pursuant to this section.

"(c) Implementation.-The Secretary may make prescriptions under this section by regulation, including by interim final rule, or by guidance, and may issue such regulations or guidance without regard to the procedures otherwise required by section 553 of title 5, United States Code."

Executive Documents

Ex. Ord. No. 13987. Organizing and Mobilizing the United States Government To Provide a Unified and Effective Response To Combat COVID–19 and To Provide United States Leadership on Global Health and Security

Ex. Ord. No. 13987, Jan. 20, 2021, 86 F.R. 7019, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Purpose*. The Federal Government must act swiftly and aggressively to combat coronavirus disease 2019 (COVID–19). To that end, this order creates the position of Coordinator of the COVID–19 Response and Counselor to the President and takes other steps to organize the White House and activities of the Federal Government to combat COVID–19 and prepare for future biological and pandemic threats.

Sec. 2. *Organizing the White House to Combat COVID–19*. (a) In order to effectively, fully, and immediately respond to COVID–19, there is established within the Executive Office of the President the position of Coordinator of the COVID–19 Response and Counselor to the President (COVID–19 Response Coordinator) and the position of Deputy Coordinator of the

COVID–19 Response. The COVID–19 Response Coordinator shall report directly to the President; advise and assist the President and executive departments and agencies (agencies) in responding to the COVID–19 pandemic; coordinate all elements of the COVID–19 response; and perform such duties as the President may otherwise direct. These duties shall include:

(i) coordinating a Government-wide effort to reduce disparities in the response, care, and treatment of COVID–19, including racial and ethnic disparities;

(ii) coordinating the Federal Government's efforts to produce, supply, and distribute personal protective equipment, vaccines, tests, and other supplies for the Nation's COVID–19 response, including through the use of the Defense Production Act, as amended (50 U.S.C. 4501 et seq.);

(iii) coordinating the Federal Government's efforts to expand COVID–19 testing and the use of testing as an effective public health response;

(iv) coordinating the Federal Government's efforts to support the timely, safe, and effective delivery of COVID–19 vaccines to the United States population;

(v) coordinating the Federal Government's efforts to support the safe reopening and operation of schools, child care providers, and Head Start programs, and to help ensure the continuity of educational and other services for young children and elementary and secondary students during the COVID–19 pandemic; and

(vi) coordinating, as appropriate, with State, local, Tribal, and territorial authorities.

(b) The COVID–19 Response Coordinator shall have the authority to convene principals from relevant agencies, in consultation with the Assistant to the President for Domestic Policy (APDP) on matters involving the domestic COVID–19 response, and in consultation with the Assistant to the President for National Security Affairs (APNSA) on matters involving the global COVID–19 response. The COVID–19 Response Coordinator shall also coordinate any corresponding deputies and interagency processes.

(c) The COVID–19 Response Coordinator may act through designees in performing these or any other duties.

SEC. 3. *United States Leadership on Global Health and Security and the Global COVID–19 Response.*

(a) *Preparing to Respond to Biological Threats and Pandemics*. To identify, monitor, prepare for, and, if necessary, respond to emerging biological and pandemic threats:

(i) The APNSA shall convene the National Security Council (NSC) Principals Committee as necessary to coordinate the Federal Government's efforts to address such threats and to advise the President on the global response to and recovery from COVID–19, including matters regarding: the intersection of the COVID–19 response and other national security equities; global health security; engaging with and strengthening the World Health Organization; public health, access to healthcare, and the secondary impacts of COVID–19; and emerging biological risks and threats, whether naturally occurring, deliberate, or accidental.

(ii) Within 180 days of the date of this order [Jan. 20, 2021], the APNSA shall, in coordination with relevant agencies, the COVID–19 Response Coordinator, and the APDP, complete a review of and recommend actions to the President concerning emerging domestic and global biological risks and national biopreparedness policies. The review and recommended actions shall incorporate lessons from the COVID–19 pandemic and, among other things, address: the readiness of the pandemic supply chain, healthcare workforce, and hospitals; the development of a framework of pandemic readiness with specific triggers for when agencies should take action in response to large-scale biological events; pandemic border readiness; the development and distribution of medical countermeasures; epidemic forecasting and modeling; public health data modernization; bio-related intelligence; bioeconomic investments; biotechnology risks; the development of a framework for coordinating with and distributing responsibilities as between the Federal Government and State, local, Tribal, and territorial authorities; and State, local, Tribal, and territorial preparedness for biological events.

(b) *NSC Directorate on Global Health Security and Biodefense*. There shall be an NSC Directorate on Global Health Security and Biodefense, which shall be headed by a Senior Director for Global Health Security and Biodefense. The Senior Director shall be responsible for monitoring current and emerging biological threats, and shall report concurrently to the APNSA and to the COVID–19 Response Coordinator on matters relating to COVID–19. The Senior Director shall oversee the Global Health Security Agenda Interagency Review Council, which was established pursuant to Executive Order 13747 of November 4, 2016 (Advancing the Global Health Security Agenda To Achieve a World Safe and Secure From Infectious Disease Threats) [50 U.S.C. 3021 note], and is hereby reconvened as described in that order.

(c) *Responsibility for National Biodefense Preparedness*. Notwithstanding any statements in the National Security Presidential Memorandum–14 of September 18, 2018 (Support for National Biodefense), the APNSA shall be responsible for coordinating the Nation's biodefense preparedness efforts, and, as stated in sections 1 and 2 of this order, the COVID–19 Response Coordinator shall be responsible for coordinating the Federal Government's response to the COVID–19 pandemic.

SEC. 4. *Prompt Resolution of Issues Related to the United States COVID–19 Response*. The heads of agencies shall, as soon as practicable, bring any procedural, departmental, legal, or funding obstacle to the COVID–19 response to the attention of the COVID–19 Response Coordinator. The COVID–19 Response Coordinator shall, in coordination with relevant agencies, the APDP, and the APNSA, as appropriate, immediately bring to the President's attention any issues that require Presidential guidance or decision-making.

SEC. 5. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

J.R. BIDEN, JR.

[Positions of COVID–19 Response Coordinator and Deputy Coordinator of the COVID–19 Response, as established by section 2 of Ex. Ord. No. 13987, set out above, terminated, and responsibilities and duties transferred to Director of the Office of Pandemic Preparedness and Response Policy, by Ex. Ord. No. 14122, §3, Apr. 12, 2024, 89 F.R. 27355, set out in a note under section 300hh–3 of this title.]

EXECUTIVE ORDER NO. 13991

Ex. Ord. No. 13991, Jan. 20, 2021, 86 F.R. 7045, which required compliance with CDC guidelines with respect to wearing masks, maintaining physical distance, and other public health measures by Federal employees and contractors and all persons in Federal buildings or on Federal lands, and HHS promotion of public health best practices identified by the CDC, was revoked by Ex. Ord. No. 14122, §2, Apr. 12, 2024, 89 F.R. 27355, set out in a note under section 300hh–3 of this title.

EX. ORD. NO. 13994. ENSURING A DATA-DRIVEN RESPONSE TO COVID–19 AND FUTURE HIGH-CONSEQUENCE PUBLIC HEALTH THREATS

Ex. Ord. No. 13994, Jan. 21, 2021, 86 F.R. 7189, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Policy*. It is the policy of my Administration to respond to the coronavirus disease 2019 (COVID–19) pandemic through effective approaches guided by the best available science and data, including by building back a better public health infrastructure. This stronger public health infrastructure must help the Nation effectively prevent, detect, and respond to future biological threats, both domestically and internationally.

Consistent with this policy, the heads of all executive departments and agencies (agencies) shall facilitate the gathering, sharing, and publication of COVID–19-related data, in coordination with the Coordinator of the COVID–19 Response and Counselor to the President (COVID–19 Response Coordinator), to the extent permitted by law, and with appropriate protections for confidentiality, privacy, law enforcement, and national security. These efforts shall assist Federal, State, local, Tribal, and territorial authorities in developing and implementing policies to facilitate informed community decision-making, to further public understanding of the pandemic and the response, and to deter the spread of misinformation and disinformation.

SEC. 2. *Enhancing Data Collection and Collaboration Capabilities for High-Consequence Public Health Threats, Such as the COVID–19 Pandemic.* (a) The Secretary of Defense, the Attorney General, the Secretary of Commerce, the Secretary of Labor, the Secretary of Health and Human Services (HHS), the Secretary of Education, the Director of the Office of Management and Budget (OMB), the Director of National Intelligence, the Director of the Office of Science and Technology Policy (OSTP), and the Director of the National Science Foundation shall each promptly designate a senior official to serve as their agency's lead to work on COVID–19- and pandemic-related data issues. This official, in consultation with the COVID–19 Response Coordinator, shall take steps to make data relevant to high-consequence public health threats, such as the COVID–19 pandemic, publicly available and accessible.

(b) The COVID–19 Response Coordinator shall, as necessary, convene appropriate representatives from relevant agencies to coordinate the agencies' collection, provision, and analysis of data, including key equity indicators, regarding the COVID–19 response, as well as their sharing of such data with State, local, Tribal, and territorial authorities.

(c) The Director of OMB, in consultation with the Director of OSTP, the United States Chief Technology Officer, and the COVID–19 Response Coordinator, shall promptly review the Federal Government's existing approaches to open data, and shall issue supplemental guidance, as appropriate and consistent with applicable law, concerning how to de-identify COVID–19-related data; how to make data open to the public in human- and machine-readable formats as rapidly as possible; and any other topic the Director of OMB concludes would appropriately advance the policy of this order. Any guidance shall include appropriate protections for the information described in section 5 of this order.

(d) The Director of the Office of Personnel Management, in consultation with the Director of OMB, shall promptly:

(i) review the ability of agencies to hire personnel expeditiously into roles related to information technology and the collection, provision, analysis, or other use of data to address high-consequence public health threats, such as the COVID–19 pandemic; and

(ii) take action, as appropriate and consistent with applicable law, to support agencies in such efforts.

SEC. 3. *Public Health Data Systems*. The Secretary of HHS, in consultation with the COVID–19 Response Coordinator and the heads of relevant agencies, shall promptly:

(a) review the effectiveness, interoperability, and connectivity of public health data systems supporting the detection of and response to high-consequence public health threats, such as the COVID–19 pandemic;

(b) review the collection of morbidity and mortality data by State, local, Tribal, and territorial governments during high-consequence public health threats, such as the COVID–19 pandemic; and

(c) issue a report summarizing the findings of the reviews detailed in subsections (a) and (b) of this section and any recommendations for addressing areas for improvement identified in the reviews.

SEC. 4. *Advancing Innovation in Public Health Data and Analytics*. The Director of OSTP, in coordination with the National Science and Technology Council, as appropriate, shall develop a plan for advancing innovation in public health data and analytics in the United States.

SEC. 5. *Privileged Information*. Nothing in this order shall compel or authorize the disclosure of privileged information, law-enforcement information, national-security information, personal information, or information the disclosure of which is prohibited by law.

SEC. 6. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

J.R. BIDEN, JR.

[Position of COVID–19 Response Coordinator terminated, and responsibilities and duties of COVID–19 Response Coordinator specified in Ex. Ord. No. 13994, set out above, transferred to Director of the Office of Pandemic Preparedness and Response Policy, by Ex. Ord. No. 14122, §3, Apr. 12, 2024, 89 F.R. 27355, set out in a note under section 300hh–3 of this title.]

EX. ORD. NO. 13995. ENSURING AN EQUITABLE PANDEMIC RESPONSE AND RECOVERY

Ex. Ord. No. 13995, Jan. 21, 2021, 86 F.R. 7193, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, and in order to address the disproportionate and severe impact of coronavirus disease 2019 (COVID–19) on communities of color and other underserved populations, it is hereby ordered as follows:

SECTION 1. *Purpose*. The COVID–19 pandemic has exposed and exacerbated severe and pervasive health and social inequities in America. For instance, people of color experience systemic and structural racism in many facets of our society and are more likely to become sick and die from COVID–19. The lack of complete data, disaggregated by race and ethnicity, on COVID–19 infection, hospitalization, and mortality rates, as well as underlying health and social vulnerabilities, has further hampered efforts to ensure an equitable pandemic response. Other communities, often obscured in the data, are also disproportionately affected by COVID–19, including sexual and gender minority groups, those living with disabilities, and those living at the margins of our economy. Observed inequities in rural and Tribal communities, territories, and other geographically isolated communities require a place-based approach to data collection and the response. Despite increased State and local efforts to address these inequities, COVID–19's disparate impact on communities of color and other underserved populations remains unrelenting.

Addressing this devastating toll is both a moral imperative and pragmatic policy. It is impossible to change the course of the pandemic without tackling it in the hardest-hit communities. In order to identify and eliminate health and social inequities resulting in disproportionately higher rates of exposure, illness, and death, I am directing a Government-wide effort to address health equity. The Federal Government must take swift action to prevent and remedy differences in COVID–19 care and outcomes within communities of color and other underserved populations.

SEC. 2. *COVID–19 Health Equity Task Force*. There is established within the Department of Health and Human Services (HHS) a COVID–19 Health Equity Task Force (Task Force).

(a) *Membership*. The Task Force shall consist of the Secretary of HHS; an individual designated by the Secretary of HHS to Chair the Task Force (COVID–19 Health Equity Task Force Chair); the heads of such other executive departments, agencies, or offices (agencies) as the Chair may invite; and up to 20 members from sectors outside of the Federal Government appointed by the President.

(i) Federal members may designate, to perform the Task Force functions of the member, a senior-level official who is a part of the member's agency and a full-time officer or employee of the Federal Government.

(ii) Nonfederal members shall include individuals with expertise and lived experience relevant to groups suffering disproportionate rates of illness and death in the United States; individuals with expertise and lived experience relevant to equity in public health, health care, education, housing, and community-based services; and any other individuals with expertise the President deems relevant. Appointments shall be made without regard to political affiliation and shall reflect a diverse set of perspectives.

(iii) Members of the Task Force shall serve without compensation for their work on the Task Force, but members shall be allowed travel expenses, including per diem in lieu of subsistence, as authorized by law for persons serving intermittently in the Government service (5 U.S.C. 5701–5707).

(iv) At the direction of the Chair, the Task Force may establish subgroups consisting exclusively of Task Force members or their designees under this section, as appropriate.

(b) *Mission and Work.*

(i) Consistent with applicable law and as soon as practicable, the Task Force shall provide specific recommendations to the President, through the Coordinator of the COVID–19 Response and Counselor to the President (COVID–19 Response Coordinator), for mitigating the health inequities caused or exacerbated by the COVID–19 pandemic and for preventing such inequities in the future. The recommendations shall include:

(A) recommendations for how agencies and State, local, Tribal, and territorial officials can best allocate COVID–19 resources, in light of disproportionately high rates of COVID–19 infection, hospitalization, and mortality in certain communities and disparities in COVID–19 outcomes by race, ethnicity, and other factors, to the extent permitted by law;

(B) recommendations for agencies with responsibility for disbursing COVID–19 relief funding regarding how to disburse funds in a manner that advances equity; and

(C) recommendations for agencies regarding effective, culturally aligned communication, messaging, and outreach to communities of color and other underserved populations.

(ii) The Task Force shall submit a final report to the COVID–19 Response Coordinator addressing any ongoing health inequities faced by COVID–19 survivors that may merit a public health response, describing the factors that contributed to disparities in COVID–19 outcomes, and recommending actions to combat such disparities in future pandemic responses.

(c) *Data Collection*. To address the data shortfalls identified in section 1 of this order, and consistent with applicable law, the Task Force shall:

(i) collaborate with the heads of relevant agencies, consistent with the Executive Order entitled "Ensuring a Data-Driven Response to COVID–19 and Future High-Consequence Public Health Threats," [Ex. Ord. No. 13994, set out above] to develop recommendations for expediting data collection for communities of color and other underserved populations and identifying data sources, proxies, or indices that would enable development of short-term targets for pandemic-related actions for such communities and populations;

(ii) develop, in collaboration with the heads of relevant agencies, a set of longer-term recommendations to address these data shortfalls and other foundational data challenges, including those relating to data intersectionality, that must be tackled in order to better prepare and respond to future pandemics; and

(iii) submit the recommendations described in this subsection to the President, through the COVID–19 Response Coordinator.

(d) *External Engagement*. Consistent with the objectives set out in this order and with applicable law, the Task Force may seek the views of health professionals; policy experts; State, local, Tribal, and territorial health officials; faith-based leaders; businesses; health providers; community organizations; those with lived experience with homelessness, incarceration, discrimination, and other relevant issues; and other stakeholders.

(e) *Administration*. Insofar as the Federal Advisory Committee Act, as amended ([former] 5 U.S.C. App.) [see 5 U.S.C. 1001 et seq.], may apply to the Task Force, any functions of the President under the Act, except for those in section 6 of the Act, shall be performed by the Secretary of HHS in accordance with the guidelines that have been issued by the Administrator of General Services. HHS shall provide funding and administrative support for the Task Force to the extent permitted by law and within existing appropriations. The Chair shall convene regular meetings of the Task Force, determine its agenda, and direct its work. The Chair shall designate an Executive Director of the Task Force, who shall coordinate the work of the Task Force and head any staff assigned to the Task Force.

(f) *Termination*. Unless extended by the President, the Task Force shall terminate within 30 days of accomplishing the objectives set forth in this order, including the delivery of the report and recommendations specified in this section, or 2 years from the date of this order [Jan. 21, 2021], whichever comes first.

SEC. 3. *Ensuring an Equitable Pandemic Response*. To address the inequities identified in section 1 of this order, it is hereby directed that:

(a) The Secretary of Agriculture, the Secretary of Labor, the Secretary of HHS, the Secretary of Housing and Urban Development, the Secretary of Education, the Administrator of the Environmental Protection Agency, and the heads of all other agencies with authorities or responsibilities relating to the pandemic response and recovery shall, as appropriate and consistent with applicable law:

(i) consult with the Task Force to strengthen equity data collection, reporting, and use related to COVID–19;

(ii) assess pandemic response plans and policies to determine whether personal protective equipment, tests, vaccines, therapeutics, and other resources have been or will be allocated equitably, including by considering:

(A) the disproportionately high rates of COVID–19 infection, hospitalization, and mortality in certain communities; and

(B) any barriers that have restricted access to preventive measures, treatment, and other health services for high-risk populations;

(iii) based on the assessments described in subsection (a)(ii) of this section, modify pandemic response plans and policies to advance equity, with consideration to:

(A) the effect of proposed policy changes on the distribution of resources to, and access to health care by, communities of color and other underserved populations;

(B) the effect of proposed policy changes on agencies' ability to collect, analyze, and report data necessary to monitor and evaluate the impact of pandemic response plans and policies on communities of color and other underserved populations; and

(C) policy priorities expressed by communities that have suffered disproportionate rates of illness and death as a result of the pandemic;

(iv) strengthen enforcement of anti-discrimination requirements pertaining to the availability of, and access to, COVID–19 care and treatment; and

(v) partner with States, localities, Tribes, and territories to explore mechanisms to provide greater assistance to individuals and families experiencing disproportionate economic or health effects from COVID–19, such as by expanding access to food, housing, child care, or income support.

(b) The Secretary of HHS shall:

(i) provide recommendations to State, local, Tribal, and territorial leaders on how to facilitate the placement of contact tracers and other workers in communities that have been hardest hit by the pandemic, recruit such workers from those communities, and connect such workers to existing health workforce training programs and other career advancement programs; and

(ii) conduct an outreach campaign to promote vaccine trust and uptake among communities of color and other underserved populations with higher levels of vaccine mistrust due to discriminatory medical treatment and research, and engage with leaders within those communities.

SEC. 4. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

J.R. BIDEN, JR.

EX. ORD. NO. 13996. ESTABLISHING THE COVID–19 PANDEMIC TESTING BOARD AND ENSURING A SUSTAINABLE PUBLIC HEALTH WORKFORCE FOR COVID–19 AND OTHER BIOLOGICAL THREATS

Ex. Ord. No. 13996, Jan. 21, 2021, 86 F.R. 7197, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, it is hereby ordered as follows:

SECTION 1. *Policy*. It is the policy of my Administration to control coronavirus disease 2019 (COVID–19) by using a Government-wide, unified approach that includes: establishing a national COVID–19 testing and public health workforce strategy; working to expand the supply of tests; working to bring test manufacturing to the United States, where possible; working to enhance laboratory testing capacity; working to expand the public health workforce; supporting screening testing for schools and priority populations; and ensuring a clarity of

messaging about the use of tests and insurance coverage.

SEC. 2. *COVID–19 Pandemic Testing Board.*

(a) *Establishment and Membership*. There is established a COVID–19 Pandemic Testing Board (Testing Board), chaired by the Coordinator of the COVID–19 Response and Counselor to the President (COVID–19 Response Coordinator) or his designee. The Testing Board shall include representatives from executive departments and agencies (agencies) that are designated by the President. The heads of agencies so designated shall designate officials from their respective agencies to represent them on the Testing Board.

(b) *Mission and Functions*. To support the implementation and oversight of the policy laid out in section 1 of this order, the Testing Board shall:

(i) coordinate Federal Government efforts to promote COVID–19 diagnostic, screening, and surveillance testing;

(ii) make recommendations to the President with respect to prioritizing the Federal Government's assistance to State, local, Tribal, and territorial authorities, in order to expand testing and reduce disparities in access to testing;

(iii) identify barriers to access and use of testing in, and coordinate Federal Government efforts to increase testing for:

(A) priority populations, including healthcare workers and other essential workers;

(B) communities with major shortages in testing availability and use;

(C) at-risk settings, including long-term care facilities, correctional facilities, immigration custodial settings, detention facilities, schools, child care settings, and food processing and manufacturing facilities; and

(D) high-risk groups, including people experiencing homelessness, migrants, and seasonal workers;

(iv) identify methods to expand State, local, Tribal, and territorial capacity to conduct testing, contact tracing, and isolation and quarantine, in order for schools, businesses, and travel to be conducted safely;

(v) provide guidance on how to enhance the clarity, consistency, and transparency of Federal Government communication with the public about the goals and purposes of testing;

(vi) identify options for the Federal Government to maximize testing capacity of commercial labs and academic labs; and

(vii) propose short- and long-term reforms for the Federal Government to: increase State, local, Tribal, and territorial capacity to conduct testing; expand genomic sequencing; and improve the effectiveness and speed of the Federal Government's response to future pandemics and other biological emergencies.

(d) The Chair of the Testing Board shall coordinate with the Secretary of Health and Human Services (HHS) and the heads of other relevant agencies or their designees, as necessary, to ensure that the Testing Board's work is coordinated with the Public Health Emergency Countermeasures Enterprise within HHS.

SEC. 3. *Actions to Address the Cost of COVID–19 Testing*. (a) The Secretary of the Treasury, the Secretary of HHS, and the Secretary of Labor, in coordination with the COVID–19 Response Coordinator, shall promptly, and as appropriate and consistent with applicable law:

(i) facilitate the provision of COVID–19 testing free of charge to those who lack comprehensive health insurance; and

(ii) clarify group health plans' and health insurance issuers' obligations to provide coverage for COVID–19 testing.

(b) The Secretary of HHS, the Secretary of Education, and the Secretary of Homeland Security, through the Administrator of the Federal Emergency Management Agency (FEMA), in coordination with the COVID–19 Response Coordinator, shall promptly, and as appropriate and consistent with applicable law:

(i) provide support for surveillance tests for settings such as schools; and

(ii) expand equitable access to COVID–19 testing.

SEC. 4. *Establishing a Public Health Workforce Program*. (a) The Secretary of HHS and the Secretary of Labor shall promptly consult with State, local, Tribal, and territorial leaders to understand the challenges they face in pandemic response efforts, including challenges recruiting and training sufficient personnel to ensure adequate and equitable community-based testing, and testing in schools and high-risk settings.

(b) The Secretary of HHS shall, as appropriate and consistent with applicable law, as soon as practicable:

(i) provide technical support to State, local, Tribal, and territorial public health agencies with respect to testing and contact-tracing efforts; and

(ii) assist such authorities in the training of public health workers. This may include technical assistance to non-Federal public health workforces in connection with testing, contact tracing, and mass vaccinations, as well as other urgent public health workforce needs, such as combating opioid use.

(c) The Secretary of HHS shall submit to the President, through the COVID–19 Response Coordinator, the Assistant to the President for Domestic Policy (APDP), and the Assistant to the President for National Security Affairs (APNSA), a plan detailing:

(i) how the Secretary of HHS would deploy personnel in response to future high-consequence public health threats; and

(ii) five-year targets and budget requirements for achieving a sustainable public health workforce, as well as options for expanding HHS capacity, such as by expanding the U.S. Public Health Service Commissioned Corps and Epidemic Intelligence Service, so that the Department can better respond to future pandemics and other biological threats.

(d) The Secretary of HHS, the Secretary of Homeland Security, the Secretary of Labor, the Secretary of Education, and the Chief Executive Officer of the Corporation for National and Community Service, in coordination with the COVID–19 Response Coordinator, the APDP, and the APNSA, shall submit a plan to the President for establishing a national contact tracing and COVID–19 public health workforce program, to be known as the U.S. Public Health Job Corps, which shall be modeled on or developed as a component of the FEMA Corps program. Such plan shall include means by which the U.S. Public Health Job Corps can be part of the National Civilian Community Corps program, as well as recommendations about whether it would be appropriate for the U.S. Public Health Job Corps to immediately assign personnel from any of the agencies involved in the creation of the plan, including existing AmeriCorps members, to join or aid the U.S. Public Health Job Corps. The U.S. Public Health Job Corps will:

(i) conduct and train individuals in contact tracing related to the COVID–19 pandemic;

(ii) assist in outreach for vaccination efforts, including by administering vaccination clinics;

(iii) assist with training programs for State, local, Tribal, and territorial governments to provide testing, including in schools; and

(iv) provide other necessary services to Americans affected by the COVID–19 pandemic.

SEC. 5. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

J.R. BIDEN, JR.

[Position of COVID–19 Response Coordinator terminated, and responsibilities and duties of COVID–19 Response Coordinator specified in Ex. Ord. No. 13996, set out above, transferred to Director of the Office of Pandemic Preparedness and Response Policy, by Ex. Ord. No. 14122, §3, Apr. 12, 2024, 89 F.R. 27355, set out in a note under section 300hh–3 of this title.]

EX. ORD. NO. 13997. IMPROVING AND EXPANDING ACCESS TO CARE AND TREATMENTS FOR COVID–19

Ex. Ord. No. 13997, Jan. 21, 2021, 86 F.R. 7201, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Policy*. It is the policy of my Administration to improve the capacity of the Nation's healthcare systems to address coronavirus disease 2019 (COVID–19), to accelerate the development of novel therapies to treat COVID–19, and to improve all Americans' access to quality and affordable healthcare.

SEC. 2. *Accelerating the Development of Novel Therapies*. To enhance the Nation's ability to quickly develop the most promising COVID–19 interventions, the Secretary of Health and Human Services (HHS), in consultation with the Director of the National Institutes of Health, shall:

(a) develop a plan for supporting a range of studies, including large-scale randomized trials, for identifying optimal clinical management strategies, and for supporting the most promising treatments for COVID–19 and future high-consequence public health threats, that can be easily manufactured, distributed, and administered, both domestically and internationally;

(b) develop a plan, in consultation with non-governmental partners, as appropriate, to support research:

(i) in rural hospitals and other rural locations; and

(ii) that studies the emerging evidence concerning the long-term impact of COVID–19 on patient health; and

(c) consider steps to ensure that clinical trials include populations that have been historically underrepresented in such trials.

SEC. 3. *Improving the Capacity of the Nation's Healthcare Systems to Address COVID–19*. To bolster the capacity of the Nation's healthcare systems to support healthcare workers and patients:

(a) The Secretary of Defense, the Secretary of HHS, the Secretary of Veterans Affairs, and the heads of other relevant executive departments and agencies (agencies), in coordination with the Coordinator of the COVID–19 Response and Counselor to the President (COVID–19 Response Coordinator), shall promptly, as appropriate and consistent with applicable law, provide targeted surge assistance to critical care and long-term care facilities, including nursing homes and skilled nursing facilities, assisted living facilities, intermediate care facilities for individuals with disabilities, and residential treatment centers, in their efforts to combat the spread of COVID–19.

(b) The COVID–19 Response Coordinator, in coordination with the Secretary of Defense, the Secretary of HHS, the Secretary of Veterans Affairs, and the heads of other relevant agencies, shall review the needs of Federal facilities providing care to COVID–19 patients and develop recommendations for further actions such facilities can take to support active military personnel, veterans, and Tribal nations during this crisis.

(c) The Secretary of HHS shall promptly:

(i) issue recommendations on how States and healthcare providers can increase the capacity of their healthcare workforces to address the COVID–19 pandemic; and

(ii) through the Administrator of the Health Resources and Services Administration and the Administrator of the Substance Abuse and Mental Health Services Administration, take appropriate actions, as consistent with applicable law, to expand access to programs and services designed to meet the long-term health needs of patients recovering from COVID–19, including through technical assistance and support to community health centers.

SEC. 4. *Improving Access to Quality and Affordable Healthcare*. (a) To facilitate the equitable and effective distribution of therapeutics and bolster clinical care capacity where needed to support patient care, the Secretary of Defense, the Secretary of HHS, and the Secretary of Veterans Affairs, in coordination with the COVID–19 Response Coordinator, shall establish targets for the production, allocation, and distribution of COVID–19 treatments. To meet those targets, the Secretary of Defense, the Secretary of HHS, and the Secretary of Veterans Affairs shall consider prioritizing, including through grants for research and development, investments in therapeutics that can be readily administered and scaled.

(b) To facilitate the utilization of existing COVID–19 treatments, the Secretary of HHS shall identify barriers to maximizing the effective and equitable use of existing COVID–19 treatments and shall, as appropriate and consistent with applicable law, provide support to State, local, Tribal, and territorial authorities aimed at overcoming those barriers.

(c) To address the affordability of treatments and clinical care, the Secretary of HHS shall, promptly and as appropriate and consistent with applicable law:

(i) evaluate the COVID–19 Uninsured Program, operated by the Health Resources and Services Administration within HHS, and take any available steps to promote access to treatments and clinical care for those without adequate coverage, to support safety-net providers in delivering such treatments and clinical care, and to make the Program easy to use and accessible for patients and providers, with information about the Program widely disseminated; and

(ii) evaluate Medicare, Medicaid, group health plans, and health insurance issuers, and take any available steps to promote insurance coverage for safe and effective COVID–19 treatments and clinical care.

SEC. 5. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

J.R. BIDEN, JR.

EXECUTIVE ORDER NO. 13998

Ex. Ord. No. 13998, Jan. 21, 2021, 86 F.R. 7205, which related to promoting COVID–19 safety in domestic and international travel, was revoked by Ex. Ord. No. 14122, §2, Apr. 12, 2024, 89 F.R. 27355, set out in a note under section 300hh–3 of this title.

EX. ORD. NO. 13999. PROTECTING WORKER HEALTH AND SAFETY

Ex. Ord. No. 13999, Jan. 21, 2021, 86 F.R. 7211, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Policy*. Ensuring the health and safety of workers is a national priority and a moral imperative. Healthcare workers and other essential workers, many of whom are people of color and immigrants, have put their lives on the line during the coronavirus disease 2019 (COVID–19) pandemic. It is the policy of my Administration to protect the health and safety of workers from COVID–19.

The Federal Government must take swift action to reduce the risk that workers may contract COVID–19 in the workplace. That will require issuing science-based guidance to help keep workers safe from COVID–19 exposure, including with respect to mask-wearing; partnering with State and local governments to better protect public employees; enforcing worker health and safety requirements; and pushing for additional resources to help employers protect employees.

SEC. 2. *Protecting Workers from COVID–19 Under the Occupational Safety and Health Act*. The Secretary of Labor, acting through the Assistant Secretary of Labor for Occupational Safety and Health, in furtherance of the policy described in section 1 of this order and consistent with applicable law, shall:

(a) issue, within 2 weeks of the date of this order [Jan. 21, 2021] and in conjunction or consultation with the heads of any other appropriate executive departments and agencies (agencies), revised guidance to employers on workplace safety during the COVID–19 pandemic;

(b) consider whether any emergency temporary standards on COVID–19, including with respect to masks in the workplace, are necessary, and if such standards are determined to be necessary, issue them by March 15, 2021;

(c) review the enforcement efforts of the Occupational Safety and Health Administration (OSHA) related to COVID–19 and identify any short-, medium-, and long-term changes that could be made to better protect workers and ensure equity in enforcement;

(d) launch a national program to focus OSHA enforcement efforts related to COVID–19 on violations that put the largest number of workers at serious risk or are contrary to anti-retaliation principles; and

(e) coordinate with the Department of Labor's Office of Public Affairs and Office of Public Engagement and all regional OSHA offices to conduct, consistent with applicable law, a multilingual outreach campaign to inform workers and their representatives of their rights under applicable law. This campaign shall include engagement with labor unions, community organizations, and industries, and place a special emphasis on communities hit hardest by the pandemic.

SEC. 3. *Protecting Other Categories of Workers from COVID–19*. (a) The Secretary of Labor, acting through the Assistant Secretary of Labor for Occupational Safety and Health and consistent with applicable law, shall:

(i) coordinate with States that have occupational safety and health plans approved under section 18 of the Occupational Safety and Health Act (Act) (29 U.S.C. 667) to seek to ensure that workers covered by such plans are adequately protected from COVID–19, consistent with any revised guidance or emergency temporary standards issued by OSHA; and

(ii) in States that do not have such plans, consult with State and local government entities with responsibility for public employee safety and health and with public employee unions to bolster protection from COVID–19 for public sector workers.

(b) The Secretary of Agriculture, the Secretary of Labor, the Secretary of Health and Human Services, the Secretary of Transportation, and the Secretary of Energy, in consultation with the heads of any other appropriate agencies, shall, consistent with applicable law, explore mechanisms to protect workers not protected under the Act [29 U.S.C. 651 et seq.] so that they remain healthy and safe on the job during the COVID–19 pandemic.

(c) The Secretary of Labor, acting through the Assistant Secretary of Labor for Mine Safety and Health, shall consider whether any emergency temporary standards on COVID–19 applicable to coal and metal or non-metal mines are necessary, and if such standards are determined to be necessary and consistent with applicable law, issue them as soon as practicable.

SEC. 4. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

J.R. BIDEN, JR.

EX. ORD. NO. 14000. SUPPORTING THE REOPENING AND CONTINUING OPERATION OF SCHOOLS AND EARLY CHILDHOOD EDUCATION PROVIDERS

Ex. Ord. No. 14000, Jan. 21, 2021, 86 F.R. 7215, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, to ensure that students receive a high-quality education during the coronavirus disease 2019 (COVID–19) pandemic, and to support the safe reopening and continued operation of schools, child care providers, Head Start programs, and institutions of higher education, it is hereby ordered as follows:

SECTION 1. *Policy*. Every student in America deserves a high-quality education in a safe environment. This promise, which was already out of reach for too many, has been further threatened by the COVID–19 pandemic. School and higher education administrators, educators, faculty, child care providers, custodians and other staff, and families have gone above and beyond to support children's and students' learning and meet their needs during this crisis. Students and teachers alike have found new ways to teach and learn. Many child care providers continue to provide care and learning opportunities to children in homes and centers across the country. However, leadership and support from the Federal Government is needed. Two principles should guide the Federal Government's response to the COVID–19 crisis with respect to schools, child care providers, Head Start programs, and higher education institutions. First, the health and safety of children, students, educators, families, and communities is paramount. Second, every student in the United States should have the opportunity to receive a high-quality education, during and beyond the pandemic.

Accordingly, it is the policy of my Administration to provide support to help create the conditions for safe, in-person learning as quickly as possible; ensure high-quality instruction and the delivery of essential services often received by students and young children at school, institutions of higher education, child care providers, and Head Start programs; mitigate learning loss caused by the pandemic; and address educational disparities and inequities that the pandemic has created and exacerbated.

SEC. 2. *Agency Roles and Responsibilities*. The following assignments of responsibility shall be exercised in furtherance of the policy described in section 1 of this order:

(a) The Secretary of Education shall, consistent with applicable law:

(i) provide, in consultation with the Secretary of Health and Human Services, evidence-based guidance to assist States and elementary and secondary schools in deciding whether and how to reopen, and how to remain open, for in-person learning; and in safely conducting in-person learning, including by implementing mitigation measures such as cleaning, masking, proper ventilation, and testing;

(ii) provide, in consultation with the Secretary of Health and Human Services, evidence-based guidance to institutions of higher education on safely reopening for in-person learning, which shall take into account considerations such as the institution's setting, resources, and the population it serves;

(iii) provide advice to State, local, Tribal, and territorial educational authorities, institutions of higher education, local education agencies, and elementary and secondary schools regarding distance and online learning, blended learning, and in-person learning; and the promotion of mental health, social-emotional well-being, and communication with parents and families;

(iv) develop a Safer Schools and Campuses Best Practices Clearinghouse to enable schools and institutions of higher education to share lessons learned and best practices for operating safely during the pandemic;

(v) provide technical assistance to schools and institutions of higher education so that they can ensure high-quality learning during the pandemic;

(vi) direct the Department of Education's Assistant Secretary for Civil Rights to deliver a report as soon as practicable on the disparate impacts of COVID–19 on students in elementary, secondary, and higher education, including those attending historically black colleges and universities, Tribal colleges and universities, Hispanic-serving institutions, and other minority-serving institutions;

(vii) coordinate with the Director of the Institute of Education Sciences to facilitate, consistent with applicable law, the collection of data necessary to fully understand the impact of the COVID–19 pandemic on students and educators, including data on the status of in-person learning. These data shall be disaggregated by student demographics, including race, ethnicity, disability, English-language-learner status, and free or reduced lunch status or other appropriate indicators of family income; and

(viii) consult with those who have been struggling for months with the enormous challenges the COVID–19 pandemic poses for education, including students; educators; unions; families; State, local, Tribal, and territorial officials; and members of civil rights and disability rights organizations, in carrying out the directives in this order.

(b) The Secretary of Health and Human Services shall, consistent with applicable law:

(i) facilitate the collection of data needed to inform the safe reopening and continued operation of elementary and secondary schools, child care providers, and Head Start programs,

and ensure that such data are readily available to State, local, Tribal, and territorial leaders and the public, consistent with privacy interests, and that such data are disaggregated by race, ethnicity, and other factors as appropriate;

(ii) ensure, in coordination with the Coordinator of the COVID–19 Response and Counselor to the President (COVID–19 Response Coordinator) and other relevant agencies, that COVID–19-related supplies the Secretary administers, including testing materials, are equitably allocated to elementary and secondary schools, child care providers, and Head Start programs to support in-person care and learning;

(iii) to the maximum extent possible, support the development and operation of contact tracing programs at the State, local, Tribal, and territorial level, by providing guidance and technical support to ensure that contact tracing is available to facilitate the reopening and safe operation of elementary and secondary schools, child care providers, Head Start programs, and institutions of higher education;

(iv) provide guidance needed for child care providers and Head Start programs for safely reopening and operating, including procedures for mitigation measures such as cleaning, masking, proper ventilation, and testing, as well as guidance related to meeting the needs of children, families, and staff who have been affected by the COVID–19 pandemic, including trauma-informed care, behavioral and mental health support, and family support, as appropriate; and

(v) provide technical assistance to States, localities, Tribes, and territories to support the accelerated distribution of Federal COVID–19 relief funds to child care providers, and identify strategies to help child care providers safely remain open during the pandemic and beyond while the sector experiences widespread financial disruption due to increased costs and less revenue.

(c) The Secretary of Education and the Secretary of Health and Human Services shall submit a report to the Assistant to the President for Domestic Policy and the COVID–19 Response Coordinator identifying strategies to address the impact of COVID–19 on educational outcomes, especially along racial and socioeconomic lines, and shall share those strategies with State, local, Tribal, and territorial officials. In developing these strategies, the Secretaries shall, as appropriate and consistent with applicable law, consult with such officials, as well as with education experts; educators; unions; civil rights advocates; Tribal education experts; public health experts; child development experts; early educators, including child care providers; Head Start staff; school technology practitioners; foundations; families; students; community advocates; and others.

(d) The Federal Communications Commission is encouraged, consistent with applicable law, to increase connectivity options for students lacking reliable home broadband, so that they can continue to learn if their schools are operating remotely.

SEC. 3. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

J.R. BIDEN, JR.

ADDRESSING THE LONG-TERM EFFECTS OF COVID–19

Memorandum of President of the United States, Apr. 5, 2022, 87 F.R. 20995, provided:

Memorandum for the Heads of Executive Departments and Agencies

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Policy*. My Administration has made combating the coronavirus disease 2019 (COVID–19) pandemic, and guiding the Nation through the worst public health crisis in more than a century, our top priority. When I came into office, COVID–19 was wreaking havoc on our country-closing our businesses, keeping our kids out of school, and forcing us into isolation. Today, America has the tools to protect against COVID–19 and to dramatically decrease its risks. We move towards a future in which COVID–19 does not disrupt our daily lives and is something we prevent, protect against, and treat.

As we chart the path forward, we remember the more than 950,000 people in the United States lost to COVID–19. They were beloved parents, grandparents, children, siblings, spouses, neighbors, and friends. More than 200,000 children in the United States have lost a parent or caregiver to the disease. Each soul is irreplaceable, and the families and communities left behind are still reeling from profound loss. Many families and communities have already received support from Federal programs that help with the loss they have experienced. As we move forward, we commit to ensuring that families and communities can access these support programs and connect to resources they may need to help with their healing, health, and well-being.

At the same time, many of our family members, neighbors, and friends continue to experience negative long-term effects of COVID–19. Many individuals report debilitating, long-lasting effects of having been infected with COVID–19, often called "long COVID." These symptoms can happen to anyone who has had COVID–19-including individuals across ages, races, genders, and ethnicities; individuals with or without disabilities; individuals with or without underlying health conditions; and individuals whether or not they had initial symptoms. Individuals experiencing long COVID report experiencing new or recurrent symptoms, which can include anxiety and depression, fatigue, shortness of breath, difficulty concentrating, heart palpitations, disordered sleep, chest and joint pain, headaches, and other symptoms. These symptoms can persist long after the acute COVID–19 infection has resolved. Even young people and otherwise healthy people have reported long COVID symptoms that last for many months. These symptoms may be affecting individuals' ability to work, conduct daily activities, engage in educational activities, and participate in their communities. Our world-class research and public health organizations have begun the difficult work of understanding these new conditions, their causes, and potential prevention and treatment options. Our health care and support programs are working to help meet the needs of individuals experiencing the lasting effects of COVID–19. To organize the Federal Government's response, executive departments and agencies (agencies) must work together to use the expertise, resources, and benefit programs of the Federal Government to ensure that we are accelerating scientific progress and providing individuals with the support and services they need.

In addition, the American public is grappling with a mental health crisis exacerbated by the pandemic. Too many have felt the effects of social isolation, sickness, economic insecurity, increased caregiver burdens, and grief. My Administration has made significant investments in mental health as well as substance use disorder prevention, treatment, and recovery support for the American public, including by expanding access to community-based behavioral health services. We are committed to advancing these behavioral health efforts in order to better identify the effects of the pandemic on mental health, substance use, and well-being, and to take steps to address these effects for the people we serve.

Our Nation can continue to protect the public-and spare countless families from the deepest pain imaginable-if everybody does their part. Today, we have numerous tools to protect ourselves and our loved ones from COVID–19-from vaccines to tests, treatments, masks, and more. My Administration recognizes the toll of this pandemic on the American public and commits to redoubling our efforts to support the American people in addressing the long-term effects of COVID–19 on their lives and on society.

SEC. 2. *Organizing the Government-Wide Response to the Long-Term Effects of COVID–19*. (a) The Secretary of Health and Human Services (Secretary) shall coordinate the Government-wide response to the long-term effects of COVID–19. My Administration will harness the full potential of the Federal Government, in coordination with public- and private-sector partners, to mount a full and effective response. The Secretary shall report on the coordination efforts to the Coordinator of the COVID–19 Response and Counselor to the President and to the Assistant to the President for Domestic Policy.

(b) The heads of agencies shall assist and provide information to the Secretary, consistent with applicable law, as may be necessary to carry out the Secretary's duties described in subsection (a) of this section.

(c) In performing the duties described in subsection (a) of this section, the Secretary shall seek information from relevant nongovernmental experts, organizations, and stakeholders, including individuals affected directly by the long-term effects of COVID–19. The Secretary shall consider using all available legal authorities, as appropriate and consistent with applicable law, to assist in gathering relevant information, including a waiver under 42 U.S.C. 247d(f).

SEC. 3. *Report on the Long-Term Effects of COVID–19*. The Secretary, supported within the Department of Health and Human Services by the Assistant Secretary for Health and the Assistant Secretary for Mental Health and Substance Use, shall publish a public report within 120 days of the date of this memorandum [Apr. 5, 2022] outlining services and mechanisms of support across agencies to assist the American public in the face of the far-reaching and long-term effects of COVID–19. The report shall outline Federal Government services to support individuals experiencing long COVID, individuals and families experiencing a loss due to COVID–19, and all those grappling with mental health and substance use issues in the wake of this pandemic. The report shall also specifically address the long-term effects of COVID–19 on underserved communities and efforts to address disparities in availability and adoption of services and support for such communities.

SEC. 4. *National Research Action Plan on Long COVID*. (a) Coordinated efforts across the public and private sectors are needed to advance progress in prevention, diagnosis, treatment, and provision of services for individuals experiencing long COVID. The Secretary, supported by the Assistant Secretary for Health and in collaboration with the Secretary of Defense, the Secretary of Labor, the Secretary of Energy, and the Secretary of Veterans Affairs, shall coordinate a Government-wide effort to develop the first-ever interagency national research agenda on long COVID, to be reflected in a National Research Action Plan. The National Research Action Plan will build on ongoing efforts across the Federal Government, including the landmark RECOVER Initiative implemented by the National Institutes of Health. The Secretary shall release the jointly developed National Research Action Plan within 120 days of the date of this memorandum.

(b) The National Research Action Plan shall build upon existing research efforts and include strategies to:

(i) help measure and characterize long COVID in both children and adults, including with respect to its frequency, severity, duration, risk factors, and trends over time;

(ii) support the development of estimates on prevalence and incidence of long COVID disaggregated by demographic groups and symptoms;

(iii) better understand the epidemiology, course of illness, risk factors, and vaccine effectiveness in prevention of long COVID;

(iv) advance our understanding of the health and socioeconomic burdens on individuals affected by long COVID, including among different race and ethnicity groups, pregnant people, and those with underlying disabilities;

(v) foster development of new treatments and care models for long COVID based on a better understanding of the pathophysiological mechanisms of the SARS–CoV–2 virus;

(vi) inform decisions related to high-quality support, services, and interventions for long COVID;

(vii) improve data-sharing between agencies and academic and industry researchers about long COVID, to the extent permitted by law; and

(viii) specifically account for the pandemic's effect on underserved communities and rural populations.

SEC. 5. *General Provisions*. (a) Nothing in this memorandum shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This memorandum shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(d) The Secretary is authorized and directed to publish this memorandum in the Federal Register.

J.R. BIDEN, JR.

42 USC 247d-6d: Targeted liability protections for pandemic and epidemic products and security countermeasures
Text contains those laws in effect on April 14, 2025

From Title 42-THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A-PUBLIC HEALTH SERVICE
SUBCHAPTER II-GENERAL POWERS AND DUTIES
Part B-Federal-State Cooperation

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1944 PHSA Sec. 319F-3 = 42 USC 247d-6d = PREP Act, added 2005

§247d–6d. Targeted liability protections for pandemic and epidemic products and security countermeasures

(a) Liability protections

(1) In general

Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.

(2) Scope of claims for loss

(A) Loss

For purposes of this section, the term "loss" means any type of loss, including-
(i) death;
(ii) physical, mental, or emotional injury, illness, disability, or condition;
(iii) fear of physical, mental, or emotional injury, illness, disability, or condition, including any need for medical monitoring; and
(iv) loss of or damage to property, including business interruption loss.

Each of clauses (i) through (iv) applies without regard to the date of the occurrence, presentation, or discovery of the loss described in the clause.

(B) Scope

The immunity under paragraph (1) applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

(3) Certain conditions

Subject to the other provisions of this section, immunity under paragraph (1) with respect to a covered countermeasure applies only if-
(A) the countermeasure was administered or used during the effective period of the declaration that was issued under subsection (b) with respect to the countermeasure;
(B) the countermeasure was administered or used for the category or categories of diseases, health conditions, or threats to health specified in the declaration; and
(C) in addition, in the case of a covered person who is a program planner or qualified person with respect to the administration or use of the countermeasure, the countermeasure was administered to or used by an individual who-
(i) was in a population specified by the declaration; and
(ii) was at the time of administration physically present in a geographic area specified by the declaration or had a connection to such area specified in the declaration.

(4) Applicability of certain conditions

With respect to immunity under paragraph (1) and subject to the other provisions of this section:
(A) In the case of a covered person who is a manufacturer or distributor of the covered countermeasure involved, the immunity applies without regard to whether such countermeasure was administered to or used by an individual in accordance with the conditions described in paragraph (3)(C).
(B) In the case of a covered person who is a program planner or qualified person with respect to the administration or use of the covered countermeasure, the scope of immunity includes circumstances in which the countermeasure was administered to or used by an individual in circumstances in which the covered person reasonably could have believed that the countermeasure was administered or used in accordance with the conditions described in paragraph (3)(C).

(5) Effect of distribution method

The provisions of this section apply to a covered countermeasure regardless of whether such countermeasure is obtained by donation, commercial sale, or any other means of distribution, except to the extent that, under paragraph (2)(E) of subsection (b), the declaration under such subsection provides that subsection (a) applies only to covered countermeasures obtained through a particular means of distribution.

(6) Rebuttable presumption

For purposes of paragraph (1), there shall be a rebuttable presumption that any administration or use, during the effective period of the emergency declaration by the Secretary under subsection (b), of a covered countermeasure shall have been for the category or categories of diseases, health conditions, or threats to health with respect to which such declaration was issued.

(b) Declaration by Secretary

(1) Authority to issue declaration

Subject to paragraph (2), if the Secretary makes a determination that a disease or other health condition or other threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency, the Secretary may make a declaration, through publication in the Federal Register, recommending, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more covered countermeasures, and stating that subsection (a) is in effect with respect to the activities so recommended.

(2) Contents

In issuing a declaration under paragraph (1), the Secretary shall identify, for each covered countermeasure specified in the declaration-
(A) the category or categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure;
(B) the period or periods during which, including as modified by paragraph (3), subsection (a) is in effect, which period or periods may be designated by dates, or by milestones or other description of events, including factors specified in paragraph (6);
(C) the population or populations of individuals for which subsection (a) is in effect with respect to the administration or use of the countermeasure (which may be a specification that such subsection applies without geographic limitation to all individuals);
(D) the geographic area or areas for which subsection (a) is in effect with respect to the administration or use of the countermeasure (which may be a specification that such subsection applies without geographic limitation), including, with respect to individuals in the populations identified under subparagraph (C), a specification, as determined appropriate by the Secretary, of whether the declaration applies only to individuals physically present in such areas or whether in addition the declaration applies to individuals who have a connection to such areas, which connection is described in the declaration; and
(E) whether subsection (a) is effective only to a particular means of distribution as provided in subsection (a)(5) for obtaining the countermeasure, and if so, the particular means to which such subsection is effective.

(3) Effective period of declaration

(A) Flexibility of period

The Secretary may, in describing periods under paragraph (2)(B), have different periods for different covered persons to address different logistical, practical or other differences in responsibilities.

(B) Additional time to be specified

In each declaration under paragraph (1), the Secretary, after consulting, to the extent the Secretary deems appropriate, with the manufacturer of the covered countermeasure, shall also specify a date that is after the ending date specified under paragraph (2)(B) and that allows what the Secretary determines is-
(i) a reasonable period for the manufacturer to arrange for disposition of the covered countermeasure, including the return of such product to the manufacturer; and
(ii) a reasonable period for covered persons to take such other actions as may be appropriate to limit administration or use of the covered countermeasure.

(C) Additional period for certain strategic national stockpile countermeasures

With respect to a covered countermeasure that is in the stockpile under section 247d–6b of this title, if such countermeasure was the subject of a declaration under paragraph (1) at the time that it was obtained for the stockpile, the effective period of such declaration shall include a period when the countermeasure is administered or used pursuant to a distribution or release from the stockpile.

(4) Amendments to declaration

The Secretary may through publication in the Federal Register amend any portion of a declaration under paragraph (1). Such an amendment shall not retroactively limit the applicability of subsection (a) with respect to the administration or use of the covered countermeasure involved.

(5) Certain disclosures

In publishing a declaration under paragraph (1) in the Federal Register, the Secretary is not required to disclose any matter described in section 552(b) of title 5.

(6) Factors to be considered

In deciding whether and under what circumstances or conditions to issue a declaration under paragraph (1) with respect to a covered countermeasure, the Secretary shall consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of such countermeasure.

(7) Judicial review

No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection.

(8) Preemption of State law

During the effective period of a declaration under subsection (b), or at any time with respect to conduct undertaken in accordance with such declaration, no State or political subdivision of a State may establish, enforce, or continue in effect with respect to a covered countermeasure any provision of law or legal requirement that-

(A) is different from, or is in conflict with, any requirement applicable under this section; and

(B) relates to the design, development, clinical testing or investigation, formulation, manufacture, distribution, sale, donation, purchase, marketing, promotion, packaging, labeling, licensing, use, any other aspect of safety or efficacy, or the prescribing, dispensing, or administration by qualified persons of the covered countermeasure, or to any matter included in a requirement applicable to the covered countermeasure under this section or any other provision of this chapter, or under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(9) Report to Congress

Within 30 days after making a declaration under paragraph (1), the Secretary shall submit to the appropriate committees of the Congress a report that provides an explanation of the reasons for issuing the declaration and the reasons underlying the determinations of the Secretary with respect to paragraph (2). Within 30 days after making an amendment under paragraph (4), the Secretary shall submit to such committees a report that provides the reasons underlying the determination of the Secretary to make the amendment.

(c) Definition of willful misconduct

(1) Definition

(A) In general

Except as the meaning of such term is further restricted pursuant to paragraph (2), the term "willful misconduct" shall, for purposes of subsection (d), denote an act or omission that is taken-

(i) intentionally to achieve a wrongful purpose;

(ii) knowingly without legal or factual justification; and

(iii) in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit.

(B) Rule of construction

The criterion stated in subparagraph (A) shall be construed as establishing a standard for liability that is more stringent than a standard of negligence in any form or recklessness.

(2) Authority to promulgate regulatory definition

(A) In general

The Secretary, in consultation with the Attorney General, shall promulgate regulations, which may be promulgated through interim final rules, that further restrict the scope of actions or omissions by a covered person that may qualify as "willful misconduct" for purposes of subsection (d).

(B) Factors to be considered

In promulgating the regulations under this paragraph, the Secretary, in consultation with the Attorney General, shall consider the need to define the scope of permissible civil actions under subsection (d) in a way that will not adversely affect the public health.

(C) Temporal scope of regulations

The regulations under this paragraph may specify the temporal effect that they shall be given for purposes of subsection (d).

(D) Initial rulemaking

Within 180 days after December 30, 2005, the Secretary, in consultation with the Attorney General, shall commence and complete an initial rulemaking process under this paragraph.

(3) Proof of willful misconduct

In an action under subsection (d), the plaintiff shall have the burden of proving by clear and convincing evidence willful misconduct by each covered person sued and that such willful misconduct caused death or serious physical injury.

(4) Defense for acts or omissions taken pursuant to Secretary's declaration

Notwithstanding any other provision of law, a program planner or qualified person shall not have engaged in "willful misconduct" as a matter of law where such program planner or qualified person acted consistent with applicable directions, guidelines, or recommendations by the Secretary regarding the administration or use of a covered countermeasure that is specified in the declaration under subsection (b), provided either the Secretary, or a State or local health authority, was provided with notice of information regarding serious physical injury or death from the administration or use of a covered countermeasure that is material to the plaintiff's alleged loss within 7 days of the actual discovery of such information by such program planner or qualified person.

(5) Exclusion for regulated activity of manufacturer or distributor

(A) In general

If an act or omission by a manufacturer or distributor with respect to a covered countermeasure, which act or omission is alleged under subsection (e)(3)(A) to constitute willful misconduct, is subject to regulation by this chapter or by the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], such act or omission shall not constitute "willful misconduct" for purposes of subsection (d) if-

(i) neither the Secretary nor the Attorney General has initiated an enforcement action with respect to such act or omission; or

(ii) such an enforcement action has been initiated and the action has been terminated or finally resolved without a covered remedy.

Any action or proceeding under subsection (d) shall be stayed during the pendency of such an enforcement action.

(B) Definitions

For purposes of this paragraph, the following terms have the following meanings:

(i) Enforcement action

The term "enforcement action" means a criminal prosecution, an action seeking an injunction, a seizure action, a civil monetary proceeding based on willful misconduct, a mandatory recall of a product because voluntary recall was refused, a proceeding to compel repair or replacement of a product, a termination of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(i), 360j(g)], a debarment proceeding, an investigator disqualification proceeding where an investigator is an employee or agent of the manufacturer, a revocation, based on willful misconduct, of an authorization under section 564 of such Act [21 U.S.C. 360bbb–3], or a suspension or withdrawal, based on willful misconduct, of an approval or clearance under chapter V of such Act [21 U.S.C. 351 et seq.] or of a licensure under section 262 of this title.

(ii) Covered remedy

The term "covered remedy" means an outcome-

(I) that is a criminal conviction, an injunction, or a condemnation, a civil monetary payment, a product recall, a repair or replacement of a product, a termination of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(i), 360j(g)], a debarment, an investigator disqualification, a revocation of an authorization under section 564 of such Act [21 U.S.C. 360bbb–3], or a suspension or withdrawal of an approval or clearance under chapter 5 [1] of such Act or of a licensure under section 262 of this title; and

(II) that results from a final determination by a court or from a final agency action.

(iii) Final

The terms "final" and "finally"-

(I) with respect to a court determination, or to a final resolution of an enforcement action that is a court determination, mean a judgment from which an appeal of right cannot be taken or a voluntary or stipulated dismissal; and

(II) with respect to an agency action, or to a final resolution of an enforcement action that is an agency action, mean an order that is not subject to further review within the agency and that has not been reversed, vacated, enjoined, or otherwise nullified by a final court determination or a voluntary or stipulated dismissal.

(C) Rules of construction

(i) In general

Nothing in this paragraph shall be construed-

(I) to affect the interpretation of any provision of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], of this chapter, or of any other applicable statute or regulation; or

(II) to impair, delay, alter, or affect the authority, including the enforcement discretion, of the United States, of the Secretary, of the Attorney General, or of any other official with respect to any administrative or court proceeding under this chapter, under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], under title 18, or under any other applicable statute or regulation.

(ii) Mandatory recalls

A mandatory recall called for in the declaration is not a Food and Drug Administration enforcement action.

(d) Exception to immunity of covered persons

(1) In general

Subject to subsection (f), the sole exception to the immunity from suit and liability of covered persons set forth in subsection (a) shall be for an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct, as defined pursuant to subsection (c), by such covered person. For purposes of section 2679(b)(2)(B) of title 28, such a cause of action is not an action brought for violation of a statute of the United States under which an action against an individual is otherwise authorized.

(2) Persons who can sue

An action under this subsection may be brought for wrongful death or serious physical injury by any person who suffers such injury or by any representative of such a person.

(e) Procedures for suit

(1) Exclusive Federal jurisdiction

Any action under subsection (d) shall be filed and maintained only in the United States District Court for the District of Columbia.

(2) Governing law

The substantive law for decision in an action under subsection (d) shall be derived from the law, including choice of law principles, of the State in which the alleged willful misconduct occurred, unless such

law is inconsistent with or preempted by Federal law, including provisions of this section.

(3) Pleading with particularity

In an action under subsection (d), the complaint shall plead with particularity each element of the plaintiff's claim, including-

(A) each act or omission, by each covered person sued, that is alleged to constitute willful misconduct relating to the covered countermeasure administered to or used by the person on whose behalf the complaint was filed;

(B) facts supporting the allegation that such alleged willful misconduct proximately caused the injury claimed; and

(C) facts supporting the allegation that the person on whose behalf the complaint was filed suffered death or serious physical injury.

(4) Verification, certification, and medical records

(A) In general

In an action under subsection (d), the plaintiff shall verify the complaint in the manner stated in subparagraph (B) and shall file with the complaint the materials described in subparagraph (C). A complaint that does not substantially comply with subparagraphs (B) and (C) shall not be accepted for filing and shall not stop the running of the statute of limitations.

(B) Verification requirement

(i) In general

The complaint shall include a verification, made by affidavit of the plaintiff under oath, stating that the pleading is true to the knowledge of the deponent, except as to matters specifically identified as being alleged on information and belief, and that as to those matters the plaintiff believes it to be true.

(ii) Identification of matters alleged upon information and belief

Any matter that is not specifically identified as being alleged upon the information and belief of the plaintiff, shall be regarded for all purposes, including a criminal prosecution, as having been made upon the knowledge of the plaintiff.

(C) Materials required

In an action under subsection (d), the plaintiff shall file with the complaint-

(i) an affidavit, by a physician who did not treat the person on whose behalf the complaint was filed, certifying, and explaining the basis for such physician's belief, that such person suffered the serious physical injury or death alleged in the complaint and that such injury or death was proximately caused by the administration or use of a covered countermeasure; and

(ii) certified medical records documenting such injury or death and such proximate causal connection.

(5) Three-judge court

Any action under subsection (d) shall be assigned initially to a panel of three judges. Such panel shall have jurisdiction over such action for purposes of considering motions to dismiss, motions for summary judgment, and matters related thereto. If such panel has denied such motions, or if the time for filing such motions has expired, such panel shall refer the action to the chief judge for assignment for further proceedings, including any trial. Section 1253 of title 28 and paragraph (3) of subsection (b) of section 2284 of title 28 shall not apply to actions under subsection (d).

(6) Civil discovery

(A) Timing

In an action under subsection (d), no discovery shall be allowed-

(i) before each covered person sued has had a reasonable opportunity to file a motion to dismiss;

(ii) in the event such a motion is filed, before the court has ruled on such motion; and

(iii) in the event a covered person files an interlocutory appeal from the denial of such a motion, before the court of appeals has ruled on such appeal.

(B) Standard

Notwithstanding any other provision of law, the court in an action under subsection (d) shall permit discovery only with respect to matters directly related to material issues contested in such action, and the court shall compel a response to a discovery request (including a request for admission, an interrogatory, a request for production of documents, or any other form of discovery request) under Rule 37, Federal Rules of Civil Procedure, only if the court finds that the requesting party needs the information sought to prove or defend as to a material issue contested in such action and that the likely benefits of a response to such request equal or exceed the burden or cost for the responding party of providing such response.

(7) Reduction in award of damages for collateral source benefits

(A) In general

In an action under subsection (d), the amount of an award of damages that would otherwise be made to a plaintiff shall be reduced by the amount of collateral source benefits to such plaintiff.

(B) Provider of collateral source benefits not to have lien or subrogation

No provider of collateral source benefits shall recover any amount against the plaintiff or receive any lien or credit against the plaintiff's recovery or be equitably or legally subrogated to the right of the plaintiff in an action under subsection (d).

(C) Collateral source benefit defined

For purposes of this paragraph, the term "collateral source benefit" means any amount paid or to be paid in the future to or on behalf of the plaintiff, or any service, product, or other benefit provided or to be provided in the future to or on behalf of the plaintiff, as a result of the injury or wrongful death, pursuant to-

(i) any State or Federal health, sickness, income-disability, accident, or workers' compensation law;

(ii) any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;

(iii) any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income disability benefits; or

(iv) any other publicly or privately funded program.

(8) Noneconomic damages

In an action under subsection (d), any noneconomic damages may be awarded only in an amount directly proportional to the percentage of responsibility of a defendant for the harm to the plaintiff. For purposes of this paragraph, the term "noneconomic damages" means damages for losses for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium, hedonic damages, injury to reputation, and any other nonpecuniary losses.

(9) Rule 11 sanctions

Whenever a district court of the United States determines that there has been a violation of Rule 11 of the Federal Rules of Civil Procedure in an action under subsection (d), the court shall impose upon the attorney, law firm, or parties that have violated Rule 11 or are responsible for the violation, an appropriate sanction, which may include an order to pay the other party or parties for the reasonable expenses incurred as a direct result of the filing of the pleading, motion, or other paper that is the subject of the violation, including a reasonable attorney's fee. Such sanction shall be sufficient to deter repetition of such conduct or comparable conduct by others similarly situated, and to compensate the party or parties injured by such conduct.

(10) Interlocutory appeal

The United States Court of Appeals for the District of Columbia Circuit shall have jurisdiction of an interlocutory appeal by a covered person taken within 30 days of an order denying a motion to dismiss or a motion for summary judgment based on an assertion of the immunity from suit conferred by subsection (a) or based on an assertion of the exclusion under subsection (c)(5).

(f) Actions by and against the United States

Nothing in this section shall be construed to abrogate or limit any right, remedy, or authority that the United States or any agency thereof may possess under any other provision of law or to waive sovereign immunity or to abrogate or limit any defense or protection available to the United States or its agencies, instrumentalities, officers, or employees under any other law, including any provision of chapter 171 of title 28 (relating to tort claims procedure).

(g) Severability

If any provision of this section, or the application of such provision to any person or circumstance, is held to be unconstitutional, the remainder of this section and the application of such remainder to any person or circumstance shall not be affected thereby.

(h) Rule of construction concerning National Vaccine Injury Compensation Program

Nothing in this section, or any amendment made by the Public Readiness and Emergency Preparedness Act, shall be construed to affect the National Vaccine Injury Compensation Program under subchapter XIX of this chapter.

(i) Definitions

In this section:

(1) Covered countermeasure

The term "covered countermeasure" means-

(A) a qualified pandemic or epidemic product (as defined in paragraph (7));

(B) a security countermeasure (as defined in section 247d–6b(c)(1)(B) of this title);

(C) a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)), biological product (as such term is defined by section 262(i) of this title), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) that is authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–3, 360bbb–3a, 360bbb–3b]; or

(D) a respiratory protective device that is approved by the National Institute for Occupational Safety and Health under part 84 of title 42, Code of Federal Regulations (or any successor regulations), and that the Secretary determines to be a priority for use during a public health emergency declared under section 247d of this title.

(2) Covered person

The term "covered person", when used with respect to the administration or use of a covered countermeasure, means-

(A) the United States; or

(B) a person or entity that is-

(i) a manufacturer of such countermeasure;

(ii) a distributor of such countermeasure;

(iii) a program planner of such countermeasure;

(iv) a qualified person who prescribed, administered, or dispensed such countermeasure; or

(v) an official, agent, or employee of a person or entity described in clause (i), (ii), (iii), or (iv).

(3) Distributor

The term "distributor" means a person or entity engaged in the distribution of drugs, biologics, or devices, including but not limited to manufacturers; repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies.

(4) Manufacturer

The term "manufacturer" includes-

(A) a contractor or subcontractor of a manufacturer;

(B) a supplier or licenser of any product, intellectual property, service, research tool, or component or other article used in the design, development, clinical testing, investigation, or manufacturing of a covered countermeasure; and

(C) any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

(5) Person

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

(6) Program planner

The term "program planner" means a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration under subsection (b).

(7) Qualified pandemic or epidemic product

The term "qualified pandemic or epidemic product" means a drug (as such term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)(1)),[2] biological product (as such term is defined by section 262(i) of this title), or device (as such term is defined by section 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(h)) [2] that is-

(A)(i) a product manufactured, used, designed, developed, modified, licensed, or procured-

(I) to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic; or

(II) to limit the harm such pandemic or epidemic might otherwise cause;

(ii) a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in clause (i); or

(iii) a product or technology intended to enhance the use or effect of a drug, biological product, or device described in clause (i) or (ii); and

(B)(i) approved or cleared under chapter V of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 351 et seq.] or licensed under section 262 of this title;

(ii) the object of research for possible use as described by subparagraph (A) and is the subject of an exemption under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(i), 360j(g)]; or

(iii) authorized for emergency use in accordance with section 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–3, 360bbb–3a, 360bbb–3b].

(8) Qualified person

The term "qualified person", when used with respect to the administration or use of a covered countermeasure, means-

(A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or

(B) a person within a category of persons so identified in a declaration by the Secretary under subsection (b).

(9) Security countermeasure

The term "security countermeasure" has the meaning given such term in section 247d–6b(c)(1)(B) of this title.

(10) Serious physical injury

The term "serious physical injury" means an injury that-

(A) is life threatening;

(B) results in permanent impairment of a body function or permanent damage to a body structure; or

(C) necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(July 1, 1944, ch. 373, title III, §319F–3, as added Pub. L. 109–148, div. C, §2, Dec. 30, 2005, 119 Stat. 2818 ; amended Pub. L. 113–5, title IV, §402(g)(2), (3), Mar. 13, 2013, 127 Stat. 196 ; Pub. L. 116–127, div. F, §6005, Mar. 18, 2020, 134 Stat. 207 ; Pub. L. 116–136, div. A, title III, §3103, Mar. 27, 2020, 134 Stat. 361 .)

Editorial Notes

References in Text

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (b)(8)(B), (c)(5)(A), (B)(i), (ii)(I), (C)(i), and (i)(7)(B)(i), is act June 25, 1938, ch. 675, 52 Stat. 1040 , which is classified generally to chapter 9 (§301 et seq.) of Title 21, Food and Drugs. Chapter V of the Act is classified generally to subchapter V (§351 et seq.) of chapter 9 of Title 21. For complete classification of this Act to the Code, see section 301 of Title 21 and Tables.

The Federal Rules of Civil Procedure, referred to in subsec. (e)(6)(B), (9), are set out in the Appendix to Title 28, Judiciary and Judicial Procedure.

The Public Readiness and Emergency Preparedness Act, referred to in subsec. (h), is div. C of Pub. L. 109–148, Dec. 30, 2005, 119 Stat. 2818 , which enacted this section, section 247d–6e of this title, and provisions set out as a note under section 201 of this title. For complete classification of this Act to the Code, see Short Title of 2005 Amendment note set out under section 201 of this title and Tables.

Amendments

2020-Subsec. (i)(1)(D). Pub. L. 116–136 amended subpar. (D) generally. Prior to amendment, subpar. (D) read as follows: "a personal respiratory protective device that is-

"(i) approved by the National Institute for Occupational Safety and Health under part 84 of title 42, Code of Federal Regulations (or successor regulations);

"(ii) subject to the emergency use authorization issued by the Secretary on March 2, 2020, or subsequent emergency use authorizations, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–3] (authorizing emergency use of personal respiratory protective devices during the COVID–19 outbreak); and

"(iii) used during the period beginning on January 27, 2020, and ending on October 1, 2024, in response to the public health emergency declared on January 31, 2020, pursuant to section 247d of this title as a result of confirmed cases of 2019 Novel Coronavirus (2019-nCoV)."

Pub. L. 116–127 added subpar. (D).

2013-Subsec. (i)(1)(C). Pub. L. 113–5, §402(g)(3)(A), inserted ", 564A, or 564B" after "564".

Subsec. (i)(7)(A)(iii). Pub. L. 113–5, §402(g)(2), added cl. (iii).

Subsec. (i)(7)(B)(iii). Pub. L. 113–5, §402(g)(3)(B), inserted ", 564A, or 564B" after "564".

[1] *So in original. Probably should be chapter "V".*

[2] *So in original. A third closing parenthesis probably should appear.*

42 USC 247d-6e: Covered countermeasure process
Text contains those laws in effect on April 14, 2025

From Title 42-THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A-PUBLIC HEALTH SERVICE
SUBCHAPTER II-GENERAL POWERS AND DUTIES
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PREP Act, Covered countermeasure process
Added 2005

§247d–6e. Covered countermeasure process

(a) Establishment of Fund

Upon the issuance by the Secretary of a declaration under section 247d–6d(b) of this title, there is hereby established in the Treasury an emergency fund designated as the "Covered Countermeasure Process Fund" for purposes of providing timely, uniform, and adequate compensation to eligible individuals for covered injuries directly caused by the administration or use of a covered countermeasure pursuant to such declaration, which Fund shall consist of such amounts designated as emergency appropriations under section 402 of H. Con. Res. 95 of the 109th Congress, this emergency designation shall remain in effect through October 1, 2006.

(b) Payment of compensation

(1) In general

If the Secretary issues a declaration under 247d–6d(b) of this title, the Secretary shall, after amounts have by law been provided for the Fund under subsection (a), provide compensation to an eligible individual for a covered injury directly caused by the administration or use of a covered countermeasure pursuant to such declaration.

(2) Elements of compensation

The compensation that shall be provided pursuant to paragraph (1) shall have the same elements, and be in the same amount, as is prescribed by sections 239c, 239d, and 239e of this title in the case of certain individuals injured as a result of administration of certain countermeasures against smallpox, except that section 239e(a)(2)(B) of this title shall not apply.

(3) Rule of construction

Neither reasonable and necessary medical benefits nor lifetime total benefits for lost employment income due to permanent and total disability shall be limited by section 239e of this title.

(4) Determination of eligibility and compensation

Except as provided in this section, the procedures for determining, and for reviewing a determination of, whether an individual is an eligible individual, whether such individual has sustained a covered injury, whether compensation may be available under this section, and the amount of such compensation shall be those stated in section 239a of this title (other than in subsection (d)(2) of such section), in regulations issued pursuant to that section, and in such additional or alternate regulations as the Secretary may promulgate for purposes of this section. In making determinations under this section, other than those described in paragraph (5)(A) as to the direct causation of a covered injury, the Secretary may only make such determination based on compelling, reliable, valid, medical and scientific evidence.

(5) Covered countermeasure injury table

(A) In general

The Secretary shall by regulation establish a table identifying covered injuries that shall be presumed to be directly caused by the administration or use of a covered countermeasure and the time period in which the first symptom or manifestation of onset of each such adverse effect must manifest in order for such presumption to apply. The Secretary may only identify such covered injuries, for purpose of inclusion on the table, where the Secretary determines, based on compelling, reliable, valid, medical and scientific evidence that administration or use of the covered countermeasure directly caused such covered injury.

(B) Amendments

The provisions of section 239b of this title (other than a provision of subsection (a)(2) of such section that relates to accidental vaccinia inoculation) shall apply to the table established under this section.

(C) Judicial review

No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this paragraph.

(6) Meanings of terms

In applying sections 239a, 239b, 239c, 239d, and 239e of this title for purposes of this section-
(A) the terms "vaccine" and "smallpox vaccine" shall be deemed to mean a covered countermeasure;
(B) the terms "smallpox vaccine injury table" and "table established under section 239b of this title" shall be deemed to refer to the table established under paragraph (4); and
(C) other terms used in those sections shall have the meanings given to such terms by this section.

(c) Voluntary program

The Secretary shall ensure that a State, local, or Department of Health and Human Services plan to administer or use a covered countermeasure is consistent with any declaration under 247d–6d of this title and any applicable guidelines of the Centers for Disease Control and Prevention and that potential participants are educated with respect to contraindications, the voluntary nature of the program, and the availability of potential benefits and compensation under this part.

(d) Exhaustion; exclusivity; election

(1) Exhaustion

Subject to paragraph (5), a covered individual may not bring a civil action under section 247d–6d(d) of this title against a covered person (as such term is defined in section 247d–6d(i)(2) of this title) unless such individual has exhausted such remedies as are available under subsection (a), except that if amounts have not by law been provided for the Fund under subsection (a), or if the Secretary fails to make a final determination on a request for benefits or compensation filed in accordance with the requirements of this section within 240 days after such request was filed, the individual may seek any remedy that may be available under section 247d–6d(d) of this title.

(2) Tolling of statute of limitations

The time limit for filing a civil action under section 247d–6d(d) of this title for an injury or death shall be tolled during the pendency of a claim for compensation under subsection (a).

(3) Rule of construction

This section shall not be construed as superseding or otherwise affecting the application of a requirement, under chapter 171 of title 28, to exhaust administrative remedies.

(4) Exclusivity

The remedy provided by subsection (a) shall be exclusive of any other civil action or proceeding for any claim or suit this section encompasses, except for a proceeding under section 247d–6d of this title.

(5) Election

If under subsection (a) the Secretary determines that a covered individual qualifies for compensation, the individual has an election to accept the compensation or to bring an action under section 247d–6d(d) of this title. If such individual elects to accept the compensation, the individual may not bring such an action.

(e) Definitions

For purposes of this section, the following terms shall have the following meanings:

(1) Covered countermeasure

The term "covered countermeasure" has the meaning given such term in section 247d–6d of this title.

(2) Covered individual

The term "covered individual", with respect to administration or use of a covered countermeasure pursuant to a declaration, means an individual-
(A) who is in a population specified in such declaration, and with respect to whom the administration or use of the covered countermeasure satisfies the other specifications of such declaration; or
(B) who uses the covered countermeasure, or to whom the covered countermeasure is administered, in a good faith belief that the individual is in the category described by subparagraph (A).

(3) Covered injury

The term "covered injury" means serious physical injury or death.

(4) Declaration

The term "declaration" means a declaration under section 247d–6d(b) of this title.

(5) Eligible individual

The term "eligible individual" means an individual who is determined, in accordance with subsection (b), to be a covered individual who sustains a covered injury.

(July 1, 1944, ch. 373, title III, §319F–4, as added Pub. L. 109–148, div. C, §3, Dec. 30, 2005, 119 Stat. 2829 .)

Editorial Notes

References In Text

H. Con. Res. 95 of the 109th Congress, referred to in subsec. (a), is H. Con. Res. 95, Apr. 28, 2005, 119 Stat. 3633, which is not classified to the Code.

42 USC 247d-7e: Biomedical Advanced Research and Development Authority
Text contains those laws in effect on April 14, 2025

From Title 42-THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A-PUBLIC HEALTH SERVICE
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1944 PHSA Sec. 319-L = 42 USC 247d-7e, BARDA. Added 2006

§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.

(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 support, maintain, and improve domestic manufacturing surge capacity and capabilities, as appropriate, including through the utilization of advanced manufacturing and platform technologies, to increase the availability of products that are or may become qualified countermeasures or qualified pandemic or epidemic products;

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

(vi) such other activities as are part of the advanced stages of testing, refinement, improvement, manufacturing, 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.

(b) Strategic plan for countermeasure research, development, and procurement

(1) In general

Not later than 6 months after December 19, 2006, the Secretary shall develop and make public a strategic plan to integrate biodefense and emerging infectious disease requirements with the advanced research and development, strategic initiatives for innovation, support for domestic manufacturing surge capacity and capabilities, and the procurement of qualified countermeasures and qualified pandemic or epidemic products. The Secretary shall carry out such activities as may be practicable to disseminate the information contained in such plan to persons who may have the capacity to substantially contribute to the activities described in such strategic plan. The Secretary shall update and incorporate such plan as part of the National Health Security Strategy described in section 300hh–1 of this title.

(2) Content

The strategic plan under paragraph (1) shall guide-

(A) research and development, conducted or supported by the Department of Health and Human Services, of qualified countermeasures and qualified pandemic or epidemic products against possible biological, chemical, radiological, and nuclear agents and to emerging infectious diseases;

(B) innovation in technologies that may assist advanced research and development of qualified countermeasures and qualified pandemic or epidemic products (such research and development referred to in this section as "countermeasure and product advanced research and development");

(C) activities to support, maintain, and improve domestic manufacturing surge capacity and capabilities, as appropriate, including through the utilization of advanced manufacturing and platform technologies, to increase the availability of products that are or may become qualified countermeasures or qualified pandemic or epidemic products; and

(D) procurement of such qualified countermeasures and qualified pandemic or epidemic products by such Department.

(c) Biomedical Advanced Research and Development Authority

(1) Establishment

There is established within the Department of Health and Human Services the Biomedical Advanced Research and Development Authority.

(2) In general

Based upon the strategic plan described in subsection (b), the Secretary shall coordinate the acceleration of countermeasure and product advanced research and development by-

(A) facilitating collaboration between the Department of Health and Human Services and other Federal agencies, relevant industries, academia, and other persons, with respect to such advanced research and development;

(B) promoting countermeasure and product advanced research and development, including through the establishment and maintenance of domestic manufacturing surge capacity and capabilities, consistent with subsection (a)(6)(B)(iv);

(C) facilitating contacts between interested persons and the offices or employees authorized by the Secretary to advise such persons regarding requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and under section 262 of this title; and

(D) promoting innovation to reduce the time and cost of countermeasure and product advanced research and development.

(3) Director

The BARDA shall be headed by a Director (referred to in this section as the "Director") who shall be appointed by the Secretary and to whom the Secretary shall delegate such functions and authorities as necessary to implement this section, including the execution of procurement contracts, grants, and cooperative agreements pursuant to this section.

(4) Duties

(A) Collaboration

To carry out the purpose described in paragraph (2)(A), the Secretary shall-

(i) facilitate and increase the expeditious and direct communication between the Department of Health and Human Services and relevant persons with respect to countermeasure and product advanced research and development, including by-

(I) facilitating such communication regarding the processes for procuring such advanced research and development with respect to qualified countermeasures and qualified pandemic or epidemic products of interest;

(II) soliciting information about and data from research on potential qualified countermeasures and qualified pandemic or epidemic products and related technologies;

(III) facilitating such communication, as appropriate, regarding manufacturing surge capacity and capabilities with respect to qualified countermeasures and qualified pandemic or epidemic products to prepare for, or respond to, a public health emergency or potential public health emergency; and

(IV) facilitating such communication, as appropriate and in a manner that does not compromise national security, with respect to potential eligibility for the material threat medical countermeasure priority review voucher program under section 565A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–4a];

(ii) at least annually-

(I) convene meetings with representatives from relevant industries, academia, other Federal agencies, international agencies as appropriate, and other interested persons;

(II) sponsor opportunities to demonstrate the operation and effectiveness of relevant biodefense countermeasure technologies; and

(III) convene such working groups on countermeasure and product advanced research and development as the Secretary may determine are necessary to carry out this section;

(iii) communicate regularly with entities in receipt of an award pursuant to subparagraph (B)(v), and facilitate communication between such entities and other entities in receipt of an award pursuant to subparagraph (B)(iv), as appropriate, for purposes of planning and response regarding the availability of countermeasures and the maintenance of domestic manufacturing surge capacity and capabilities, including any planned uses of such capacity and capabilities in the near- and mid-term, and identification of any significant challenges related to the long-term maintenance of such capacity and capabilities; and

(iv) carry out the activities described in section 247d–7f of this title.

(B) Support advanced research and development

To carry out the purpose described in paragraph (2)(B), the Secretary shall-

(i) conduct ongoing searches for, and support calls for, potential qualified countermeasures and qualified pandemic or epidemic products;

(ii) direct and coordinate the countermeasure and product advanced research and development activities of the Department of Health and Human Services;

(iii) establish strategic initiatives to accelerate countermeasure and product advanced research and development (which may include advanced research and development for purposes of fulfilling requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] or section 262 of this title) and innovation in such areas as the Secretary may identify as priority unmet need areas;

(iv) award contracts, grants, cooperative agreements, and enter into other transactions, for countermeasure and product advanced research and development; and

(v) award contracts, grants, and cooperative agreements and enter into other transactions to support, maintain, and improve domestic manufacturing surge capacity and capabilities, including through supporting flexible or advanced manufacturing, to ensure that additional capacity is available to rapidly manufacture products that are or may become qualified countermeasures or qualified pandemic or epidemic products in the event of a public health emergency declaration or significant potential for a public health emergency.

(C) Facilitating advice

To carry out the purpose described in paragraph (2)(C) the Secretary shall-

(i) connect interested persons with the offices or employees authorized by the Secretary to advise such persons regarding the regulatory requirements under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] and under section 262 of this title related to the approval, clearance, or licensure of qualified countermeasures or qualified pandemic or epidemic products;

(ii) with respect to persons performing countermeasure and product advanced research and development funded under this section, enable such offices or employees to provide to the extent practicable such advice in a manner that is ongoing and that is otherwise designed to facilitate expeditious development of qualified countermeasures and qualified pandemic or epidemic products that may achieve such approval, clearance, or licensure; and

(iii) consult with the Commissioner of Food and Drugs, pursuant to section 565(b)(2) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–4(b)(2)], to ensure that facilities performing manufacturing, pursuant to an award under subparagraph (B)(v), are in compliance with applicable requirements under such Act and this chapter, as appropriate, including current good manufacturing practice pursuant to section 501(a)(2)(B) of the Food, Drug, and Cosmetic Act [21 U.S.C. 351(a)(2)(B)]; and

(D) Supporting innovation

To carry out the purpose described in paragraph (2)(D), the Secretary may award contracts, grants, and cooperative agreements, or enter into other transactions, such as prize payments, to promote-

(i) innovation in technologies that may assist countermeasure and product advanced research and development, including to improve manufacturing capacities and capabilities for medical countermeasures;

(ii) research on and development of research tools and other devices and technologies; and

(iii) research to promote strategic initiatives, such as rapid diagnostics, broad spectrum antimicrobials, vaccine-manufacturing technologies, dose-sparing technologies, efficacy-increasing technologies, platform technologies, technologies to administer countermeasures, and technologies to improve storage and transportation of countermeasures.

(E) Medical countermeasures innovation partner

(i) In general

To support the purposes described in paragraph (2), the Secretary, acting through the Director of BARDA, may enter into an agreement (including through the use of grants, contracts, cooperative agreements, or other transactions as described in paragraph (5)) with an independent, nonprofit entity to-

(I) foster and accelerate the development and innovation of medical countermeasures and technologies that may assist advanced research and the development of qualified countermeasures and qualified pandemic or epidemic products, including through the use of strategic venture capital practices and methods;

(II) promote the development of new and promising technologies that address urgent medical countermeasure needs, as identified by the Secretary;

(III) address unmet public health needs that are directly related to medical countermeasure requirements, such as novel antimicrobials for multidrug resistant organisms and multiuse platform technologies for diagnostics, prophylaxis, vaccines, and therapeutics; and

(IV) provide expert consultation and advice to foster viable medical countermeasure innovators, including helping qualified countermeasure innovators navigate unique industry challenges with respect to developing chemical, biological, radiological, and nuclear countermeasure products.

(ii) Eligibility

(I) In general

To be eligible to enter into an agreement under clause (i) an entity shall-

(aa) be an independent, nonprofit entity;

(bb) have a demonstrated record of being able to create linkages between innovators and investors and leverage such partnerships and resources for the purpose of addressing identified strategic needs of the Federal Government;

(cc) have experience in promoting novel technology innovation;

(dd) be problem-driven and solution-focused based on the needs, requirements, and problems identified by the Secretary under clause (iv);

(ee) demonstrate the ability, or the potential ability, to promote the development of medical countermeasure products;

(ff) demonstrate expertise, or the capacity to develop or acquire expertise, related to technical and regulatory considerations with respect to medical countermeasures; and

(gg) not be within the Department of Health and Human Services.

(II) Partnering experience

In selecting an entity with which to enter into an agreement under clause (i), the Secretary shall place a high value on the demonstrated experience of the entity in partnering with the Federal Government to meet identified strategic needs.

(iii) Not agency

An entity that enters into an agreement under clause (i) shall not be deemed to be a Federal agency for any purpose, including for any purpose under title 5.

(iv) Direction

Pursuant to an agreement entered into under this subparagraph, the Secretary, acting through the Director of BARDA, shall provide direction to the entity that enters into an agreement under clause (i). As part of this agreement the Director of BARDA shall-

(I) communicate the medical countermeasure needs, requirements, and problems to be addressed by the entity under the agreement;

(II) develop a description of work to be performed by the entity under the agreement;

(III) provide technical feedback and appropriate oversight over work carried out by the entity under the agreement, including subsequent development and partnerships consistent with the needs and requirements set forth in this subparagraph;

(IV) ensure fair consideration of products developed under the agreement in order to maintain competition to the maximum practical extent, as applicable and appropriate under applicable provisions of this section; and

(V) ensure, as a condition of the agreement that the entity-

(aa) has in place a comprehensive set of policies that demonstrate a commitment to transparency and accountability;

(bb) protects against conflicts of interest through a comprehensive set of policies that address potential conflicts of interest, ethics, disclosure, and reporting requirements;

(cc) provides monthly accounting on the use of funds provided under such agreement; and

(dd) provides on a quarterly basis, reports regarding the progress made toward meeting the identified needs set forth in the agreement.

(v) Supplement not supplant

Activities carried out under this subparagraph shall supplement, and not supplant, other activities carried out under this section.

(vi) No establishment of entity

To prevent unnecessary duplication and target resources effectively, nothing in this subparagraph shall be construed to authorize the Secretary to establish within the Department of Health and Human Services an entity for the purposes of carrying out this subparagraph.

(vii) Transparency and oversight

Upon request, the Secretary shall provide to Congress the information provided to the Secretary under clause (iv)(V)(dd).

(viii) Independent evaluation

Not later than 4 years after December 13, 2016, the Comptroller General of the United States shall conduct an independent evaluation, and submit to the Secretary and the appropriate committees of Congress a report, concerning the activities conducted under this subparagraph. Such report shall include recommendations with respect to any agreement or activities carried out pursuant to this subparagraph.

(ix) Sunset

This subparagraph shall have no force or effect after September 30, 2028.

(F) Strategic initiatives

The Secretary, acting through the Director of BARDA, may implement strategic initiatives, including by building on existing programs and by awarding contracts, grants, and cooperative agreements, or entering into other transactions, to support innovative candidate products in preclinical and clinical development that address priority, naturally occurring and man-made threats that, as determined by the Secretary, pose a significant level of risk to national security based on the characteristics of a chemical, biological, radiological or nuclear threat, or existing capabilities to respond to such a threat (including medical response and treatment capabilities and manufacturing infrastructure). Such initiatives shall accelerate and support the advanced research, development, and procurement of countermeasures and products, as applicable, to address areas including-

(i) chemical, biological, radiological, or nuclear threats, including emerging infectious diseases, for which insufficient approved, licensed, or authorized countermeasures exist, or for which such threat, or the result of an exposure to such threat, may become resistant to countermeasures or existing countermeasures may be rendered ineffective;

(ii) threats that consistently exist or continually circulate and have a significant potential to become a pandemic, such as pandemic influenza, which may include the advanced research and development, manufacturing, and appropriate stockpiling of qualified pandemic or epidemic products, and products, technologies, or processes to support the advanced research and development of such countermeasures (including multiuse platform technologies for diagnostics, vaccines, and therapeutics; virus seeds; clinical trial lots; novel virus strains; and antigen and adjuvant material); and

(iii) threats that may result primarily or secondarily from a chemical, biological, radiological, or nuclear agent, or emerging infectious diseases, and which may present increased treatment complications such as the occurrence of resistance to available countermeasures or potential countermeasures, including antimicrobial resistant pathogens.

(G) Annual reports by award recipients

As a condition of receiving an award under subparagraph (B)(v), a recipient shall develop and submit to the Secretary annual reports related to the maintenance of such capacity and capabilities, including ensuring that such capacity and capabilities are able to support the rapid manufacture of countermeasures as required by the Secretary.

(5) Transaction authorities

(A) Other transactions

(i) In general

The Secretary shall have the authority to enter into other transactions (as defined in subsection (a)(3)) under this subsection.

(ii) Limitations on authority

(I) In general

To the maximum extent practicable, competitive procedures shall be used when entering into transactions to carry out projects under this subsection.

(II) Written determinations required

The authority of this subparagraph may be exercised for a project that is expected to cost the Department of Health and Human Services in excess of $100,000,000 only upon a written determination by the Assistant Secretary for Financial Resources, that the use of such authority is essential to promoting the success of the project. The authority of the Assistant Secretary for Financial Resources under this subclause may not be delegated.

(iii) Authority during a public health emergency

(I) In general

Notwithstanding clause (ii), the Secretary, shall, to the maximum extent practicable, use competitive procedures when entering into transactions to carry out projects under this subsection for purposes of a public health emergency declared by the Secretary under section 247d of this title. Any such transactions entered into during such public health emergency shall not be terminated solely due to the expiration of such public health emergency, if such public health emergency ends before the completion of the terms of such agreement.

(II) Report

After the expiration of the public health emergency declared by the Secretary under section 247d of this title, the Secretary shall provide a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding the use of any funds pursuant to the authority under subclause (I), including any outcomes, benefits, and risks associated with the use of such funds, and a description of the reasons for the use of such authority for the project or projects.

(iv) Guidelines

The Secretary shall establish guidelines regarding the use of the authority under clause (i). Such guidelines shall include auditing requirements.

(B) Expedited authorities

(i) In general

In awarding contracts, grants, and cooperative agreements, and in entering into other transactions under subparagraph (B) or (D) of paragraph (4), the Secretary shall have the expedited procurement authorities, the authority to expedite peer review, and the authority for personal services contracts, supplied by subsections (b), (c), and (d) of section 247d–6a of this title.

(ii) Application of provisions

Provisions in such section 247d–6a of this title that apply to such authorities and that require institution of internal controls, limit review, provide for Federal Tort Claims Act coverage of personal services contractors, and commit decisions to the discretion of the Secretary shall apply to the authorities as exercised pursuant to this paragraph.

(iii) Authority to limit competition

For purposes of applying section 247d–6a(b)(1)(D) of this title to this paragraph, the phrase "BioShield Program under the Project BioShield Act of 2004" shall be deemed to mean the countermeasure and product advanced research and development program under this section.

(iv) Availability of data

The Secretary shall require that, as a condition of being awarded a contract, grant, cooperative agreement, or other transaction under subparagraph (B) or (D) of paragraph (4), a person make available to the Secretary on an ongoing basis, and submit upon request to the Secretary, all data related to or resulting from countermeasure and product advanced research and development carried out pursuant to this section.

(C) Advance payments; advertising

The Secretary may waive the requirements of section 3324(a) of title 31 or section 6101 of title 41 upon the determination by the Secretary that such waiver is necessary to obtain countermeasures or products under this section.

(D) Milestone-based payments allowed

In awarding contracts, grants, and cooperative agreements, and in entering into other transactions, under this section, the Secretary may use milestone-based awards and payments.

(E) Foreign nationals eligible

The Secretary may under this section award contracts, grants, and cooperative agreements to, and may enter into other transactions with, highly qualified foreign national persons outside the United States, alone or in collaboration with American participants, when such transactions may inure to the benefit of the American people.

(F) Establishment of research centers

The Secretary may assess the feasibility and appropriateness of establishing, through contract, grant, cooperative agreement, or other transaction, an arrangement with an existing research center in order to achieve the goals of this section. If such an agreement is not feasible and appropriate, the Secretary may establish one or more federally-funded research and development centers, or university-affiliated research centers, in accordance with section 3304(a)(3) of title 41.

(G) Government purpose

In awarding contracts, grants, and cooperative agreements under this section, the Secretary shall provide a clear statement of defined Government purpose related to activities included in subsection (a)(6)(B) for a qualified countermeasure or qualified pandemic or epidemic product.

(H) Supporting warm-base and surge capacity and capabilities

Pursuant to an award under subparagraph (B)(v),[1] the Secretary may make payments for activities necessary to maintain domestic manufacturing surge capacity and capabilities supported under such award to ensure that such capacity and capabilities are able to support the rapid manufacture of countermeasures as required by the Secretary to prepare for, or respond to, an existing or potential public health emergency or otherwise address threats that pose a significant level of risk to national security. The Secretary may support the utilization of such capacity and capabilities under awards for countermeasure and product advanced research and development, as appropriate, to provide for the maintenance of such capacity and capabilities.

(6) At-risk individuals

In carrying out the functions under this section, the Secretary may give priority to the advanced research and development of qualified countermeasures and qualified pandemic or epidemic products that are likely to be safe and effective with respect to children, pregnant women, older adults, and other at-risk individuals with relevant characteristics that warrant consideration during the process of researching and developing such countermeasures and products.

(7) Personnel authorities

(A) Specially qualified scientific and professional personnel

(i) In general

In addition to any other personnel authorities, the Secretary may-

(I) without regard to those provisions of title 5 governing appointments in the competitive service, appoint highly qualified individuals to scientific or professional positions in BARDA, such as program managers, to carry out this section; and

(II) compensate them in the same manner and subject to the same terms and conditions in which individuals appointed under section 9903 of such title are compensated, without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates.

(ii) Manner of exercise of authority

The authority provided for in this subparagraph shall be exercised subject to the same limitations described in section 247d–6a(e)(2) of this title.

(iii) Term of appointment

The term limitations described in section 9903(c) of title 5 shall apply to appointments under this subparagraph, except that the references to the "Secretary" and to the "Department of Defense's national security missions" shall be deemed to be to the Secretary of Health and Human Services and to the mission of the Department of Health and Human Services under this section.

(B) Special consultants

In carrying out this section, the Secretary may appoint special consultants pursuant to section 209(f) of this title.

(C) Limitation

(i) In general

The Secretary may hire up to 100 highly qualified individuals, or up to 50 percent of the total number of employees, whichever is less, under the authorities provided for in subparagraphs (A) and (B).

(ii) Report

The Secretary shall report to Congress on a biennial basis on the implementation of this subparagraph.

(d) Fund

(1) Establishment

There is established the Biodefense Medical Countermeasure Development Fund, which shall be available to carry out this section in addition to such amounts as are otherwise available for this purpose.

(2) Funding

To carry out the purposes of this section, there is authorized to be appropriated to the Fund $611,700,000 for each of fiscal years 2019 through 2023, such amounts to remain available until expended.

(e) Inapplicability of certain provisions

(1) Disclosure

(A) Nondisclosure of information

(i) In general

Information described in clause (ii) shall be deemed to be information described in section 552(b)(3) of title 5.

(ii) Information described

The information described in this clause is information relevant to programs of the Department of Health and Human Services that could compromise national security and reveal significant and not otherwise publicly known vulnerabilities of existing medical or public health defenses against chemical, biological, radiological, or nuclear threats, and is comprised of-

(I) specific technical data or scientific information that is created or obtained during the countermeasure and product advanced research and development carried out under subsection (c);

(II) information pertaining to the location security, personnel, and research materials and methods of high-containment laboratories conducting research with select agents, toxins, or other agents with a material threat determination under section 247d–6b(c)(2) of this title; or

(III) security and vulnerability assessments.

(B) Review

Information subject to nondisclosure under subparagraph (A) shall be reviewed by the Secretary every 5 years, or more frequently as determined necessary by the Secretary, to determine the relevance or necessity of continued nondisclosure.

(C) Reporting

One year after June 24, 2019, and annually thereafter, the Secretary shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the number of instances in which the Secretary has used the authority under this subsection to withhold information from disclosure, as well as the nature of any request under section 552 of title 5 that was denied using such authority.

(D) Sunset

This paragraph shall cease to have force or effect after September 30, 2025.

(2) Review

Notwithstanding section 1013 of title 5, a working group of BARDA under this section and the National Biodefense Science Board under section 247d–7g of this title shall each terminate on the date that is 5 years after the date on which each such group or Board, as applicable, was established. Such 5-year period may be extended by the Secretary for one or more additional 5-year periods if the Secretary determines that any such extension is appropriate.

(f) Independent evaluation

(1) In general

Not later than 180 days after December 29, 2022, the Comptroller General of the United States shall conduct an independent evaluation of the activities carried out to facilitate flexible manufacturing capacity pursuant to this section.

(2) Report

Not later than 1 year after December 29, 2022, the Comptroller General of the United States shall submit to the appropriate committees of Congress a report concerning the results of the evaluation conducted under paragraph (1). Such report shall review and assess-

(A) the extent to which flexible manufacturing capacity under this section is dedicated to chemical, biological, radiological, and nuclear threats;

(B) the activities supported by flexible manufacturing initiatives;

(C) the ability of flexible manufacturing activities carried out under this section to-

(i) secure and leverage leading technical expertise with respect to countermeasure advanced research, development, and manufacturing processes; and

(ii) meet the surge manufacturing capacity needs presented by novel and emerging threats, including chemical, biological, radiological, and nuclear agents; and

(D) plans for the near-, mid-, and long-term sustainment of manufacturing activities carried out under this section, including such activities pursuant to subsection (c)(5)(H), specific actions to regularly assess the ability of recipients of an award under subsection (c)(4)(B)(v) to rapidly manufacture countermeasures as required by the Secretary, and recommendations to address challenges, if any, related to such activities.

(July 1, 1944, ch. 373, title III, §319L, as added Pub. L. 109–417, title IV, §401, Dec. 19, 2006, 120 Stat. 2865 ; amended Pub. L. 113–5, title IV, §402(a)–(d), (f), Mar. 13, 2013, 127 Stat. 194 , 195; Pub. L. 114–255, div. A, title III, §§3082(b), 3084, Dec. 13, 2016, 130 Stat. 1141 ; Pub. L. 116–22, title III, §303(b), title IV, §404(a), title V, §504(b), title VI, §§601, 602, title VII, §701(d), (e)(2)(B), (f), June 24, 2019, 133 Stat. 935 , 948, 951-953, 961; Pub. L. 116–136, div. A, title III, §3301, Mar. 27, 2020, 134 Stat. 383 ; Pub. L. 117–286, §4(a)(228), Dec. 27, 2022, 136 Stat. 4331 ; Pub. L. 117–328, div. FF, title II, §2401(a), Dec. 29, 2022, 136 Stat. 5782 ; Pub. L. 118–22, div. B, title II, §203(b), Nov. 17, 2023, 137 Stat. 120 ; Pub. L. 118–35, div. B, title I, §103(b), Jan. 19, 2024, 138 Stat. 5 ; Pub. L. 118–42, div. G, title I, §103(b), Mar. 9, 2024, 138 Stat. 398 ; Pub. L. 118–158, div. C, title I, §3103(b), Dec. 21, 2024, 138 Stat. 1763 ; Pub. L. 119–4, div. B, title I, §2103(b), Mar. 15, 2025, 139 Stat. 41 .)

Editorial Notes

References in Text

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (a)(6)(A)(ii), (B)(i) and (c)(2)(C), (4)(B)(iii), (C)(i), (iii), is act June 25, 1938, ch. 675, 52 Stat. 1040 , 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 Federal Tort Claims Act, referred to in subsec. (c)(5)(B)(ii), is title IV of act Aug. 2, 1946, ch. 753, 60 Stat. 842 , which was classified principally to chapter 20 (§§921, 922, 931–934, 941–946) of former Title 28, Judicial Code and Judiciary. Title IV of act Aug. 2, 1946, was substantially repealed and reenacted as sections 1346(b) and 2671 et seq. of Title 28, Judiciary and Judicial Procedure, by act June 25, 1948, ch. 646, 62 Stat. 992 , the first section of which enacted Title 28. The Federal Tort Claims Act is also commonly used to refer to chapter 171 of Title 28, Judiciary and Judicial Procedure. For complete classification of title IV to the Code, see Tables. For distribution of former sections of Title 28 into the revised Title 28, see Table at the beginning of Title 28.

Codification

In subsec. (c)(5)(C), "section 6101 of title 41" substituted for "section 3709 of the Revised Statutes of the United States (41 U.S.C. 5)" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854 , which Act enacted Title 41, Public Contracts.

In subsec. (c)(5)(F), "section 3304(a)(3) of title 41" substituted for "section 303(c)(3) of the Federal Property and Administrative Services Act of 1949 (41 U.S.C. 253(c)(3))" on authority of Pub. L. 111–350, §6(c), Jan. 4, 2011, 124 Stat. 3854 , which Act enacted Title 41, Public Contracts.

Amendments

2025-Subsec. (e)(1)(D). Pub. L. 119–4 substituted "September 30, 2025" for "March 31, 2025".

2024-Subsec. (e)(1)(D). Pub. L. 118–158 substituted "March 31, 2025" for "December 31, 2024".

Pub. L. 118–42 substituted "December 31, 2024" for "March 8, 2024".

Pub. L. 118–35 substituted "March 8, 2024" for "January 19, 2024".

2023-Subsec. (e)(1)(D). Pub. L. 118–22 substituted "after January 19, 2024" for "on the date that is 17 years after December 19, 2006".

2022-Subsec. (a)(6)(B)(iv), (v). Pub. L. 117–328, §2401(a)(1)(A), (B), added cl. (iv) and redesignated former cl. (iv) as (v). Former cl. (v) redesignated (vi).

Subsec. (a)(6)(B)(vi). Pub. L. 117–328, §2401(a)(1)(A), (C), redesignated cl. (v) as (vi) and inserted "manufacturing," after "improvement,".

Subsec. (b)(1). Pub. L. 117–328, §2401(a)(2)(A), inserted "support for domestic manufacturing surge capacity and capabilities," after "initiatives for innovation,".

Subsec. (b)(2)(C), (D). Pub. L. 117–328, §2401(a)(2)(B), added subpar. (C) and redesignated former subpar. (C) as (D).

Subsec. (c)(2)(B). Pub. L. 117–328, §2401(a)(3)(A), inserted ", including through the establishment and maintenance of domestic manufacturing surge capacity and capabilities, consistent with subsection (a)(6)(B)(iv)" after "development".

Subsec. (c)(4)(A)(i)(III), (IV). Pub. L. 117–328, §2401(a)(3)(B)(i)(I), added subcls. (III) and (IV).

Subsec. (c)(4)(A)(iii), (iv). Pub. L. 117–328, §2401(a)(3)(B)(i)(II)–(IV), added cl. (iii) and redesignated former cl. (iii) as (iv).

Subsec. (c)(4)(B)(v). Pub. L. 117–328, §2401(a)(3)(B)(ii), added cl. (v).
Subsec. (c)(4)(C)(iii). Pub. L. 117–328, §2401(a)(3)(B)(iii), added cl. (iii).
Subsec. (c)(4)(D)(i). Pub. L. 117–328, §2401(a)(3)(B)(iv), inserted ", including to improve manufacturing capacities and capabilities for medical countermeasures" after "development".
Subsec. (c)(4)(E)(ix). Pub. L. 117–328, §2401(a)(3)(B)(v), substituted "2028" for "2023".
Subsec. (c)(4)(G). Pub. L. 117–328, §2401(a)(3)(B)(vi), added subpar. (G).
Subsec. (c)(5)(H). Pub. L. 117–328, §2401(a)(3)(C), added subpar. (H).
Subsec. (e)(2). Pub. L. 117–286 substituted "section 1013 of title 5," for "section 14 of the Federal Advisory Committee Act,".
Subsec. (f)(1). Pub. L. 117–328, §2401(a)(4)(A), substituted "Not later than 180 days after December 29, 2022" for "Not later than 180 days after March 13, 2013".
Subsec. (f)(2). Pub. L. 117–328, §2401(a)(4)(B)(i), substituted "December 29, 2022" for "March 13, 2013" in introductory provisions.
Subsec. (f)(2)(D). Pub. L. 117–328, §2401(a)(4)(B)(ii)–(C), added subpar. (D).
2020-Subsec. (c)(5)(A)(iii), (iv). Pub. L. 116–136 added cl. (iii) and redesignated former cl. (iii) as (iv).
2019-Subsec. (a)(3). Pub. L. 116–22, §602(1), struck out ", such as the Secretary of Defense may enter into under section 2371 of title 10" before period at end.
Subsec. (c)(4)(A)(iii). Pub. L. 116–22, §701(e)(2)(B), substituted "section 247d–7f of this title" for "section 405 of the Pandemic and All-Hazards Preparedness Act".
Subsec. (c)(4)(D)(iii). Pub. L. 116–22, §601, substituted "platform technologies, technologies to administer countermeasures, and technologies to improve storage and transportation of countermeasures" for "and platform technologies".
Subsec. (c)(4)(E)(ix). Pub. L. 116–22, §701(d), substituted "2023" for "2022".
Subsec. (c)(4)(F). Pub. L. 116–22, §404(a), added subpar. (F).
Subsec. (c)(5)(A)(i). Pub. L. 116–22, §602(2)(A), substituted "(as defined in subsection (a)(3)) under this subsection" for "under this subsection in the same manner as the Secretary of Defense enters into such transactions under section 2371 of title 10".
Subsec. (c)(5)(A)(ii)(I). Pub. L. 116–22, §602(2)(B)(i), amended subcl. (I) generally. Prior to amendment, text read as follows: "Subsections (b), (c), and (h) of section 845 of the National Defense Authorization Act for Fiscal Year 1994 (10 U.S.C. 2371 note) shall apply to other transactions under this subparagraph as if such transactions were for prototype projects described by subsection (a) of such section 845."
Subsec. (c)(5)(A)(ii)(II). Pub. L. 116–22, §602(2)(B)(ii), substituted "$100,000,000" for "$20,000,000", "Assistant Secretary for Financial Resources" for "senior procurement executive for the Department (as designated for purpose of section 16(c) of the Office of Federal Procurement Policy Act (41 U.S.C. 414(c)))", and "Assistant Secretary for Financial Resources under" for "senior procurement executive under".
Subsec. (c)(6). Pub. L. 116–22, §303(b), substituted "older adults" for "elderly" and inserted "with relevant characteristics that warrant consideration during the process of researching and developing such countermeasures and products" before period at end.
Subsec. (d)(2). Pub. L. 116–22, §504(b), substituted "$611,700,000 for each of fiscal years 2019 through 2023" for "$415,000,000 for each of fiscal years 2014 through 2018".
Subsec. (e)(1)(A). Pub. L. 116–22, §701(f)(1), amended subpar. (A) generally. Prior to amendment, text read as follows: "The Secretary shall withhold from disclosure under section 552 of title 5 specific technical data or scientific information that is created or obtained during the countermeasure and product advanced research and development carried out under subsection (c) that reveals significant and not otherwise publicly known vulnerabilities of existing medical or public health defenses against biological, chemical, nuclear, or radiological threats. Such information shall be deemed to be information described in section 552(b)(3) of title 5."
Subsec. (e)(1)(C). Pub. L. 116–22, §701(f)(3), added subpar. (C). Former subpar. (C) redesignated (D).
Subsec. (e)(1)(D). Pub. L. 116–22, §701(f)(2), (4), redesignated subpar. (C) as (D) and substituted "17" for "12".
2016-Subsec. (c)(3). Pub. L. 114–255, §3082(b), inserted ", including the execution of procurement contracts, grants, and cooperative agreements pursuant to this section" before period at end.
Subsec. (c)(4)(E). Pub. L. 114–255, §3084, added subpar. (E).
2013-Subsec. (c)(4)(B)(iii). Pub. L. 113–5, §402(a)(1), inserted "(which may include advanced research and development for purposes of fulfilling requirements under the Federal Food, Drug, and Cosmetic Act or section 262 of this title)" after "research and development".
Subsec. (c)(4)(D)(iii). Pub. L. 113–5, §402(a)(2), substituted "vaccine-manufacturing technologies, dose-sparing technologies, efficacy-increasing technologies, and platform technologies" for "and vaccine manufacturing technologies".
Subsec. (c)(5)(G). Pub. L. 113–5, §402(b), added subpar. (G).
Subsec. (d)(2). Pub. L. 113–5, §402(c), amended par. (2) generally. Prior to amendment, text read as follows: "To carry out the purposes of this section, there are authorized to be appropriated to the Fund-
"(A) $1,070,000,000 for fiscal years 2006 through 2008, the amounts to remain available until expended; and
"(B) such sums as may be necessary for subsequent fiscal years, the amounts to remain available until expended."
Subsec. (e)(1)(C). Pub. L. 113–5, §402(d), substituted "12 years" for "7 years".
Subsec. (f). Pub. L. 113–5, §402(f), added subsec. (f).

EXECUTIVE DOCUMENTS

EX. ORD. NO. 13887. MODERNIZING INFLUENZA VACCINES IN THE UNITED STATES TO PROMOTE NATIONAL SECURITY AND PUBLIC HEALTH

Ex. Ord. No. 13887, Sept. 19, 2019, 84 F.R. 49935, provided:
By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, it is hereby ordered as follows:
SECTION 1. *Findings*. (a) Influenza viruses are constantly changing as they circulate globally in humans and animals. Relatively minor changes in these viruses cause annual seasonal influenza outbreaks, which result in millions of illnesses, hundreds of thousands of hospitalizations, and tens of thousands of deaths each year in the United States. Periodically, new influenza A viruses emerge from animals, including birds and pigs, that can spread efficiently and have sustained transmission among humans. This situation is called an influenza pandemic (pandemic). Unlike seasonal influenza, a pandemic has the potential to spread rapidly around the globe, infect higher numbers of people, and cause high rates of illness and death in populations that lack prior immunity. While it is not possible to predict when or how frequently a pandemic may occur, there have been 4 pandemics in the last 100 years. The most devastating pandemic occurred in 1918–1919 and is estimated to have killed more than 50 million people worldwide, including 675,000 Americans.
(b) Vaccination is the most effective defense against influenza. Despite recommendations by the Centers for Disease Control and Prevention (CDC) that nearly every American should receive the influenza vaccine annually, however, seasonal influenza vaccination levels in the United States have currently reached only about 45 percent of CDC goals.
(c) All influenza vaccines presently in use have been developed for circulating or anticipated influenza viruses. These vaccines must be reformulated for each influenza season as well as in the event of a pandemic. Additional research is needed to develop influenza vaccines that provide more effective and longer-lasting protection against many or all influenza viruses.
(d) The current domestic enterprise for manufacturing influenza vaccines has critical shortcomings. Most influenza vaccines are made in chicken eggs, using a 70-year-old process that requires months-long production timelines, limiting their utility for pandemic control; rely on a potentially vulnerable supply chain of eggs; require the use of vaccine viruses adapted for growth in eggs, which could introduce mutations of the influenza vaccine virus that may render the final product less effective; and are unsuitable for efficient and scalable continuous manufacturing platforms.
(e) The seasonal influenza vaccine market rewards manufacturers that deliver vaccines in time for the influenza season, without consideration of the speed or scale of these manufacturers' production processes. This approach is insufficient to meet the response needs in the event of a pandemic, which can emerge rapidly and with little warning. Because the market does not sufficiently reward speed, and because a pandemic has the potential to overwhelm or compromise essential government functions, including defense and homeland security, the Government must take action to promote faster and more scalable manufacturing platforms.
SEC. 2. *Policy*. It is the policy of the United States to modernize the domestic influenza vaccine enterprise to be highly responsive, flexible, scalable, and more effective at preventing the spread of influenza viruses. This is a public health and national security priority, as influenza has the potential to significantly harm the United States and our interests, including through large-scale illness and death, disruption to military operations, and damage to the economy. This order directs actions to reduce the United States' reliance on egg-based influenza vaccine production; to expand domestic capacity of alternative methods that allow more agile and rapid responses to emerging influenza viruses; to advance the development of new, broadly protective vaccine candidates that provide more effective and longer lasting immunities; and to support the promotion of increased influenza vaccine immunization across recommended populations.
SEC. 3. *National Influenza Vaccine Task Force*. (a) There is hereby established a National Influenza Vaccine Task Force (Task Force). The Task Force shall identify actions to achieve the objectives identified in section 2 of this order and monitor and report on the implementation and results of those actions. The Task Force shall be co-chaired by the Secretary of Defense and the Secretary of Health and Human Services, or their designees.
(b) In addition to the Co-Chairs, the Task Force shall consist of a senior official from the following executive branch departments, agencies, and offices:
(i) the Department of Defense (DOD);
(ii) the Department of Justice;
(iii) the Department of Agriculture;
(iv) the Department of Veterans Affairs (VA);
(v) the Department of Homeland Security;
(vi) the United States Food and Drug Administration;
(vii) the Centers for Disease Control and Prevention;
(viii) the National Institutes of Health (NIH);
(ix) the Centers for Medicare and Medicaid Services (CMS); and
(x) the Biomedical Advanced Research and Development Authority (BARDA).
(c) The Co-Chairs may jointly invite additional Federal Government representatives, with the consent of the applicable executive department, agency, or office head, to attend meetings of the Task Force or to become members of the Task Force, as appropriate.
(d) The staffs of the Department of State, the Office of Management and Budget (OMB), the National Security Council, the Council of Economic Advisers, the Domestic Policy Council, the National Economic Council, and the Office of Science and Technology Policy (OSTP) may attend and participate in any Task Force meetings or discussions.

(e) The Task Force may consult with State, local, tribal, and territorial government officials and private sector representatives, as appropriate and consistent with applicable law.

(f) Within 120 days of the date of this order [Sept. 19, 2019], the Task Force shall submit a report to the President, through the Assistant to the President for National Security Affairs, the Assistant to the President for Domestic Policy, the Director of the Office of Management and Budget, and the Director of the Office of Science and Technology Policy. The report shall include:

(i) a 5-year national plan (Plan) to promote the use of more agile and scalable vaccine manufacturing technologies and to accelerate development of vaccines that protect against many or all influenza viruses;

(ii) recommendations for encouraging non-profit, academic, and private-sector influenza vaccine innovation; and

(iii) recommendations for increasing influenza vaccination among the populations recommended by the CDC and for improving public understanding of influenza risk and informed influenza vaccine decision-making.

(g) Not later than June 1 of each of the 5 years following submission of the report described in subsection (f) of this section, the Task Force shall submit an update on implementation of the Plan and, as appropriate, new recommendations for achieving the policy objectives set forth in section 2 of this order.

SEC. 4. *Agency Implementation*. The heads of executive departments and agencies shall also implement the policy objectives defined in section 2 of this order, consistent with existing authorities and appropriations, as follows:

(a) The Secretary of HHS shall:

(i) through the Assistant Secretary for Preparedness and Response and BARDA:

(A) estimate the cost of expanding and diversifying domestic vaccine-manufacturing capacity to use innovative, faster, and more scalable technologies, including cell-based and recombinant vaccine manufacturing, through cost-sharing agreements with the private sector, which shall include an agreed-upon pricing strategy during a pandemic;

(B) estimate the cost of expanding domestic production capacity of adjuvants in order to combine such adjuvants with both seasonal and pandemic influenza vaccines;

(C) estimate the cost of expanding domestic fill-and-finish capacity to rapidly fulfill antigen and adjuvant needs for pandemic response;

(D) estimate the cost of developing, evaluating, and implementing delivery systems to augment limited supplies of needles and syringes and to enable the rapid and large-scale administration of pandemic influenza vaccines;

(E) evaluate incentives for the development and production of vaccines by private manufacturers and public-private partnerships, including, in emergency situations, the transfer of technology to public-private partnerships-such as the HHS Centers for Innovation and Advanced Development and Manufacturing or other domestic manufacturing facilities-in advance of a pandemic, in order to be able to ensure adequate domestic pandemic manufacturing capacity and capability;

(F) support, in coordination with the DOD, NIH, and VA, a suite of clinical studies featuring different adjuvants to support development of improved vaccines and further expand vaccine supply by reducing the dose of antigen required; and

(G) update, in coordination with other relevant public health agencies, the research agenda to dramatically improve the effectiveness, efficiency, and reliability of influenza vaccine production;

(ii) through the Director of NIH, provide to the Task Force estimated timelines for implementing NIH's strategic plan and research agenda for developing influenza vaccines that can protect individuals over many years against multiple types of influenza viruses;

(iii) through the Commissioner of Food and Drugs:

(A) further implement vaccine production process improvements to reduce the time required for vaccine production (e.g., through the use of novel technologies for vaccine seed virus development and through implementation of improved potency and sterility assays);

(B) develop, in conjunction with the CDC, proposed alternatives for the timing of vaccine virus selection to account for potentially shorter timeframes associated with non-egg based manufacturing and to facilitate vaccines optimally matched to the circulating strains;

(C) further support the conduct, in collaboration with the DOD, BARDA, and CDC, of applied scientific research regarding developing cell lines and expression systems that markedly increase the yield of cell-based and recombinant influenza vaccine manufacturing processes; and

(D) assess, in coordination with BARDA and relevant vaccine manufacturers, the use and potential effects of using advanced manufacturing platforms for influenza vaccines;

(iv) through the Director of the CDC:

(A) expand vaccine effectiveness studies to more rapidly evaluate the effectiveness of cell-based and recombinant influenza vaccines relative to egg-based vaccines;

(B) explore options to expand the production capacity of cell-based vaccine candidates used by industry;

(C) develop a plan to expand domestic capacity for whole genome characterization of influenza viruses;

(D) increase influenza vaccine use through enhanced communication and by removing barriers to vaccination; and

(E) enhance communication to healthcare providers about the performance of influenza vaccines, in order to assist them in promoting the most effective vaccines for their patient populations; and

(v) through the Administrator of CMS, examine the current legal, regulatory, and policy framework surrounding payment for influenza vaccines and assess adoption of domestically manufactured vaccines that have positive attributes for pandemic response (such as scalability and speed of manufacturing).

(b) The Secretary of Defense shall:

(i) provide OMB with a cost estimate for transitioning DOD's annual procurement of influenza vaccines to vaccines manufactured both domestically and through faster, more scalable, and innovative technologies;

(ii) direct, in coordination with the VA, CDC, and other components of HHS, the conduct of epidemiological studies of vaccine effectiveness to improve knowledge of the clinical effect of the currently licensed influenza vaccines;

(iii) use DOD's network of clinical research sites to evaluate the effectiveness of licensed influenza vaccines, including methods of boosting their effectiveness;

(iv) identify opportunities to use DOD's vaccine research and development enterprise, in collaboration with HHS, to include both early discovery and design of influenza vaccines as well as later-stage evaluation of candidate influenza vaccines;

(v) investigate, in collaboration with HHS, alternative correlates of immune protection that could facilitate development of next-generation influenza vaccines;

(vi) direct the conduct of a study to assess the feasibility of using DOD's advanced manufacturing facility for manufacturing cell-based or recombinant influenza vaccines during a pandemic; and

(vii) accelerate, in collaboration with HHS, research regarding rapidly scalable prophylactic influenza antibody approaches to complement a universal vaccine initiative and address gaps in current vaccine coverage.

(c) The Secretary of VA shall provide OMB with a cost estimate for transitioning its annual procurement of influenza vaccines to vaccines manufactured both domestically and with faster, more scalable, and innovative technologies.

SEC. 5. *Termination*. The Task Force shall terminate upon direction from the President or, with the approval of the President, upon direction from the Task Force Co-Chairs.

SEC. 6. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

DONALD J. TRUMP.

[1] *So in original. Probably should be "paragraph (4)(B)(v).".*

Title 42, PUBLIC HEALTH SERVICE ACT -
Chapter 6A - Public Health Service
PART F - Licensing of Biological Products and Clinical Laboratories
Sections 262 through 263a-7 as of April 15, 2025

1944 PHSA as of April 2025, highlighting, under Part F, Regulation of biological products, 42 USC 262 (1944); Enhanced control of dangerous biological agents and toxins, 42 USC 262a (added 2002), Preparation of (1944); Education on (added 2021)

Highlighting:
42 USC 262. Regulation of biological products
42 USC 262a. Enhanced control of dangerous biological agents and toxins
42 USC 263. Preparation of biological products by Service
42 USC 263-1. Education on biological products.

subpart 2—clinical laboratories (sections 263a to 263a-7)
[View]

subpart 3—mammography facilities (section 263b)
[View]

42 USC 262: Regulation of biological products
Text contains those laws in effect on April 14, 2025

From Title 42-THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A-PUBLIC HEALTH SERVICE
SUBCHAPTER II-GENERAL POWERS AND DUTIES
Part F-Licensing of Biological Products and Clinical Laboratories
subpart 1-biological products

Jump To:

1944 PHSA Sec. 351 = 42 USC 262.

§262. Regulation of biological products

(a) Biologics license

(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless-
(A) a biologics license under this subsection or subsection (k) is in effect for the biological product; and
(B) each package of the biological product is plainly marked with-
(i) the proper name of the biological product contained in the package;
(ii) the name, address, and applicable license number of the manufacturer of the biological product; and
(iii) the expiration date of the biological product.

(2)(A) The Secretary shall establish, by regulation, requirements for the approval, suspension, and revocation of biologics licenses.
(B) PEDIATRIC STUDIES.-A person that submits an application for a license under this paragraph shall submit to the Secretary as part of the application any assessments required under section 505B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355c].
(C) The Secretary shall approve a biologics license application-
(i) on the basis of a demonstration that-
(I) the biological product that is the subject of the application is safe, pure, and potent; and
(II) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent; and

(ii) if the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

(D) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING; RISK EVALUATION AND MITIGATION STRATEGY.-A person that submits an application for a license under this paragraph is subject to sections 505(o), 505(p), and 505–1 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(o), (p), 355–1].
(E)(i) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under this subsection, if such supplemental application complies with the requirements of subparagraph (B) of section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(c)(5)].
(ii) In this subparagraph, the terms "qualified indication" and "qualified data summary" have the meanings given such terms in section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act.
(3) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).

(b) Falsely labeling or marking package or container; altering label or mark

No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark.

(c) Inspection of establishment for propagation and preparation

Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any biological product.

(d) Recall of product presenting imminent hazard; violations

(1) Upon a determination that a batch, lot, or other quantity of a product licensed under this section presents an imminent or substantial hazard to the public health, the Secretary shall issue an order immediately ordering the recall of such batch, lot, or other quantity of such product. An order under this paragraph shall be issued in accordance with section 554 of title 5.
(2) Any violation of paragraph (1) shall subject the violator to a civil penalty of up to $100,000 per day of violation. The amount of a civil penalty under this paragraph shall, effective December 1 of each year beginning 1 year after the effective date of this paragraph, be increased by the percent change in the Consumer Price Index for the base quarter of such year over the Consumer Price Index for the base quarter of the preceding year, adjusted to the nearest 1/10 of 1 percent. For purposes of this paragraph, the term "base quarter", as used with respect to a year, means the calendar quarter ending on September 30 of such year and the price index for a base quarter is the arithmetical mean of such index for the 3 months comprising such quarter.

(e) Interference with officers

No person shall interfere with any officer, agent, or employee of the Service in the performance of any duty imposed upon him by this section or by regulations made by authority thereof.

(f) Penalties for offenses

Any person who shall violate, or aid or abet in violating, any of the provisions of this section shall be punished upon conviction by a fine not exceeding $500 or by imprisonment not exceeding one year, or by both such fine and imprisonment, in the discretion of the court.

(g) Construction with other laws

Nothing contained in this chapter shall be construed as in any way affecting, modifying, repealing, or superseding the provisions of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].

(h) Exportation of partially processed biological products

A partially processed biological product which-
(1) is not in a form applicable to the prevention, treatment, or cure of diseases or injuries of man;
(2) is not intended for sale in the United States; and
(3) is intended for further manufacture into final dosage form outside the United States,

shall be subject to no restriction on the export of the product under this chapter or the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] if the product is manufactured, processed, packaged, and held in conformity with current good manufacturing practice requirements or meets international manufacturing standards as certified by an international standards organization recognized by the Secretary and meets the requirements of section 801(e)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381(e)).

(i) "Biological product" defined

In this section:
(1) The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.
(2) The term "biosimilar" or "biosimilarity", in reference to a biological product that is the subject of an application under subsection (k), means-
(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and
(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

(3) The term "interchangeable" or "interchangeability", in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.
(4) The term "reference product" means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).

(j) Application of Federal Food, Drug, and Cosmetic Act

The Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], including the requirements under sections 505(o), 505(p), and 505–1 of such Act [21 U.S.C. 355(o), (p), 355–1], applies to a biological product subject to regulation under this section, except that a product for which a license has been approved under subsection (a) shall not be required to have an approved application under section 505 of such Act.

(k) Licensure of biological products as biosimilar or interchangeable

(1) In general

Any person may submit an application for licensure of a biological product under this subsection.

(2) Content

(A) In general

(i) Required information

An application submitted under this subsection shall include information demonstrating that-
(I) the biological product is biosimilar to a reference product based upon data derived from-
(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;
(bb) an assessment of toxicity (which may rely on, or consist of, a study or studies described in item (aa) or (cc)); and

(cc) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product;

(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;
(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;
(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and
(V) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

(ii) Determination by Secretary

The Secretary may determine, in the Secretary's discretion, that an element described in clause (i)(I) is unnecessary in an application submitted under this subsection.

(iii) Additional information

An application submitted under this subsection-
(I) shall include publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent;
(II) may include any additional information in support of the application, including publicly-available information with respect to the reference product or another biological product; and
(III) may include information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product.

(B) Interchangeability

An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological product meets the standards described in paragraph (4).

(3) Evaluation by Secretary

Upon review of an application (or a supplement to an application) submitted under this subsection, the Secretary shall license the biological product under this subsection if-
(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product-
(i) is biosimilar to the reference product; or
(ii) meets the standards described in paragraph (4), and therefore is interchangeable with the reference product; and

(B) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

(4) Safety standards for determining interchangeability

Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that-
(A) the biological product-
(i) is biosimilar to the reference product; and
(ii) can be expected to produce the same clinical result as the reference product in any given patient; and

(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

(5) General rules

(A) One reference product per application

A biological product, in an application submitted under this subsection, may not be evaluated against more than 1 reference product.

(B) Review

An application submitted under this subsection shall be reviewed by the division within the Food and Drug Administration that is responsible for the review and approval of the application under which the reference product is licensed.

(C) Risk evaluation and mitigation strategies

The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.] shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

(6) Exclusivity for first interchangeable biological product

The Secretary shall not make approval as an interchangeable biological product effective with respect to an application submitted under this subsection that relies on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, until the earlier of-
(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;
(B) 18 months after-
(i) a final court decision on all patents in suit in an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or
(ii) the dismissal with or without prejudice of an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (l)(6) and such litigation is still ongoing within such 42-month period; or
(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (l)(6).

For purposes of this paragraph, the term "final court decision" means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken, and the term "first interchangeable biosimilar biological product" means any interchangeable biosimilar biological product that is approved on the first day on which such a product is approved as interchangeable with the reference product.

(7) Exclusivity for reference product

(A) Effective date of biosimilar application approval

Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

(B) Filing period

An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

(C) First licensure

Subparagraphs (A) and (B) shall not apply to a license for or approval of-
(i) a supplement for the biological product that is the reference product; or
(ii) a subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for-
(I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or
(II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

(D) Deemed licenses

(i) No additional exclusivity through deeming

An approved application that is deemed to be a license for a biological product under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009 shall not be treated as having been first licensed under subsection (a) for purposes of subparagraphs (A) and (B).

(ii) Application of limitations on exclusivity

Subparagraph (C) shall apply with respect to a reference product referred to in such subparagraph that was the subject of an approved application that was deemed to be a license pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.

(iii) Applicability

The exclusivity periods described in section 527, section 505A(b)(1)(A)(ii), and section 505A(c)(1)(A)(ii) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360cc and 355a(b)(1)(A)(ii), (c)(1)(A)(ii)] shall continue to apply to a biological product after an approved application for the biological product is deemed to be a license for the biological product under subsection (a) pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.

(8) Guidance documents

(A) In general

The Secretary may, after opportunity for public comment, issue guidance in accordance, except as provided in subparagraph (B)(i), with section 701(h) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 371(h)] with respect to the licensure of a biological product under this subsection. Any such guidance may be general or specific.

(B) Public comment

(i) In general

The Secretary shall provide the public an opportunity to comment on any proposed guidance issued under subparagraph (A) before issuing final guidance.

(ii) Input regarding most valuable guidance

The Secretary shall establish a process through which the public may provide the Secretary with input regarding priorities for issuing guidance.

(C) No requirement for application consideration

The issuance (or non-issuance) of guidance under subparagraph (A) shall not preclude the review of, or action on, an application submitted under this subsection.

(D) Requirement for product class-specific guidance

If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of-

(i) the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and

(ii) the criteria, if available, that the Secretary will use to determine whether a biological product meets the standards described in paragraph (4).

(E) Certain product classes

(i) Guidance

The Secretary may indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class (not including any recombinant protein) does not allow approval of an application for a license as provided under this subsection for such product or product class.

(ii) Modification or reversal

The Secretary may issue a subsequent guidance document under subparagraph (A) to modify or reverse a guidance document under clause (i).

(iii) No effect on ability to deny license

Clause (i) shall not be construed to require the Secretary to approve a product with respect to which the Secretary has not indicated in a guidance document that the science and experience, as described in clause (i), does not allow approval of such an application.

(9) Public listing

(A) In general

(i) Initial publication

Not later than 180 days after December 27, 2020, the Secretary shall publish and make available to the public in a searchable, electronic format-

(I) a list of each biological product, by nonproprietary name (proper name), for which, as of December 27, 2020, a biologics license under subsection (a) or this subsection is in effect, or that, as of such date of enactment, is deemed to be licensed under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009;

(II) the date of licensure of the marketing application and the application number; and

(III) with respect to each biological product described in subclause (I), the licensure status, and, as available, the marketing status.

(ii) Revisions

Every 30 days after the publication of the first list under clause (i), the Secretary shall revise the list to include each biological product which has been licensed under subsection (a) or this subsection during the 30-day period or deemed licensed under this section pursuant to section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009.

(iii) Patent information

Not later than 30 days after a list of patents under subsection (l)(3)(A), or a supplement to such list under subsection (l)(7), has been provided by the reference product sponsor to the subsection (k) applicant respecting a biological product included on the list published under this subparagraph, the reference product sponsor shall provide such list of patents (or supplement thereto) and their corresponding expiry dates to the Secretary, and the Secretary shall, in revisions made under clause (ii), include such information for such biological product. Within 30 days of providing any subsequent or supplemental list of patents to any subsequent subsection (k) applicant under subsection (l)(3)(A) or (l)(7), the reference product sponsor shall update the information provided to the Secretary under this clause with any additional patents from such subsequent or supplemental list and their corresponding expiry dates.

(iv) Listing of exclusivities

For each biological product included on the list published under this subparagraph, the Secretary shall specify each exclusivity period under paragraph (6) or paragraph (7) for which the Secretary has determined such biological product to be eligible and that has not concluded.

(B) Revocation or suspension of license

If the license of a biological product is determined by the Secretary to have been revoked or suspended for safety, purity, or potency reasons, it may not be published in the list under subparagraph (A). If such revocation or suspension occurred after inclusion of such biological product in the list published under subparagraph (A), the reference product sponsor shall notify the Secretary that-

(i) the biological product shall be immediately removed from such list for the same period as the revocation or suspension; and

(ii) a notice of the removal shall be published in the Federal Register.

(l) Patents

(1) Confidential access to subsection (k) application

(A) Application of paragraph

Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the "subsection (k) applicant") and the sponsor of the application for the reference product (referred to in this subsection as the "reference product sponsor"), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

(B) In general

(i) Provision of confidential information

When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the "confidential information").

(ii) Recipients of information

The persons described in this clause are the following:

(I) Outside counsel

One or more attorneys designated by the reference product sponsor who are employees of an entity other than the reference product sponsor (referred to in this paragraph as the "outside counsel"), provided that such attorneys do not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(II) In-house counsel

One attorney that represents the reference product sponsor who is an employee of the reference product sponsor, provided that such attorney does not engage, formally or informally, in patent prosecution relevant or related to the reference product.

(iii) Patent owner access

A representative of the owner of a patent exclusively licensed to a reference product sponsor with respect to the reference product and who has retained a right to assert the patent or participate in litigation concerning the patent may be provided the confidential information, provided that the representative informs the reference product sponsor and the subsection (k) applicant of his or her agreement to be subject to the confidentiality provisions set forth in this paragraph, including those under clause (ii).

(C) Limitation on disclosure

No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including the reference product sponsor employees, outside scientific consultants, or other outside counsel retained by the reference product sponsor, without the prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.

(D) Use of confidential information

Confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

(E) Ownership of confidential information

The confidential information disclosed under this paragraph is, and shall remain, the property of the subsection (k) applicant. By providing the confidential information pursuant to this paragraph, the subsection (k) applicant does not provide the reference product sponsor or the outside counsel any interest in or license to use the confidential information, for purposes other than those specified in subparagraph (D).

(F) Effect of infringement action

In the event that the reference product sponsor files a patent infringement suit, the use of confidential information shall continue to be governed by the terms of this paragraph until such time as a court enters a protective order regarding the information. Upon entry of such order, the subsection (k) applicant may redesignate confidential information in accordance with the terms of that order. No confidential information shall be included in any publicly-available complaint or other pleading. In the event that the reference product sponsor does not file an infringement action by the date specified in paragraph (6), the reference product sponsor shall return or destroy all confidential information received under this paragraph, provided that if the reference product sponsor opts to destroy such information, it will confirm destruction in writing to the subsection (k) applicant.

(G) Rule of construction

Nothing in this paragraph shall be construed-

(i) as an admission by the subsection (k) applicant regarding the validity, enforceability, or infringement of any patent; or

(ii) as an agreement or admission by the subsection (k) applicant with respect to the competency, relevance, or materiality of any confidential information.

(H) Effect of violation

The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

(2) Subsection (k) application information

Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant-

(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and

(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

(3) List and description of patents

(A) List by reference product sponsor

Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant-

(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and

(ii) an identification of the patents on such list that the reference product sponsor would be prepared to license to the subsection (k) applicant.

(B) List and description by subsection (k) applicant

Not later than 60 days after receipt of the list under subparagraph (A), the subsection (k) applicant-

(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application;

(ii) shall provide to the reference product sponsor, with respect to each patent listed by the reference product sponsor under subparagraph (A) or listed by the subsection (k) applicant under clause (i)-

(I) a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or

(II) a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires; and

(iii) shall provide to the reference product sponsor a response regarding each patent identified by the reference product sponsor under subparagraph (A)(ii).

(C) Description by reference product sponsor

Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

(4) Patent resolution negotiations

(A) In general

After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6).

(B) Failure to reach agreement

If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

(5) Patent resolution if no agreement

(A) Number of patents

The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I).

(B) Exchange of patent lists

(i) In general

On a date agreed to by the subsection (k) applicant and the reference product sponsor, but in no case later than 5 days after the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k) applicant and the reference product sponsor shall simultaneously exchange-

(I) the list of patents that the subsection (k) applicant believes should be the subject of an action for patent infringement under paragraph (6); and

(II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6).

(ii) Number of patents listed by reference product sponsor

(I) In general

Subject to subclause (II), the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).

(II) Exception

If a subsection (k) applicant does not list any patent under clause (i)(I), the reference product sponsor may list 1 patent under clause (i)(II).

(6) Immediate patent infringement action

(A) Action if agreement on patent list

If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent.

(B) Action if no agreement on patent list

If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

(C) Notification and publication of complaint

(i) Notification to Secretary

Not later than 30 days after a complaint is served to a subsection (k) applicant in an action for patent infringement described under this paragraph, the subsection (k) applicant shall provide the Secretary with notice and a copy of such complaint.

(ii) Publication by Secretary

The Secretary shall publish in the Federal Register notice of a complaint received under clause (i).

(7) Newly issued or licensed patents

In the case of a patent that-

(A) is issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product sponsor provided the list to the subsection (k) applicant under paragraph (3)(A); and

(B) the reference product sponsor reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application,

not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference product sponsor under paragraph (3)(A) that includes such patent, not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a statement to the reference product sponsor in accordance with paragraph (3)(B), and such patent shall be subject to paragraph (8).

(8) Notice of commercial marketing and preliminary injunction

(A) Notice of commercial marketing

The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

(B) Preliminary injunction

After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is-

(i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and

(ii) not included, as applicable, on-

(I) the list of patents described in paragraph (4); or

(II) the lists of patents described in paragraph (5)(B).

(C) Reasonable cooperation

If the reference product sponsor has sought a preliminary injunction under subparagraph (B), the reference product sponsor and the subsection (k) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion.

(9) Limitation on declaratory judgment action

(A) Subsection (k) application provided

If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

(B) Subsequent failure to act by subsection (k) applicant

If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

(C) Subsection (k) application not provided

If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28 for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.

(m) Pediatric studies

(1) Application of certain provisions

The provisions of subsections (a), (d), (e), (f), (h), (i), (j), (k), (l), (n), and (p) of section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(a), (d), (e), (f), (h), (i), (j), (k), (l), (n), (p)] shall apply with respect to the extension of a period under paragraphs (2) and (3) to the same extent and in the same manner as such provisions apply with respect to the extension of a period under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(b), (c)].

(2) Market exclusivity for new biological products

If, prior to approval of an application that is submitted under subsection (a), the Secretary determines that information relating to the use of a new biological product in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(4)]-

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526 [1] [21 U.S.C. 360bb] for a rare disease or condition, the period for such biological product referred to in section 527(a) [1] [21 U.S.C. 360cc(a)] is deemed to be 7 years and 6 months rather than 7 years.

(3) Market exclusivity for already-marketed biological products

If the Secretary determines that information relating to the use of a licensed biological product in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under subsection (a) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(4)]-

(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

(B) if the biological product is designated under section 526 [1] [21 U.S.C. 360bb] for a rare disease or condition, the period for such biological product referred to in section 527(a) [1] [21 U.S.C. 360cc(a)] is deemed to be 7 years and 6 months rather than 7 years.

(4) Exception

The Secretary shall not extend a period referred to in paragraph (2)(A), (2)(B), (3)(A), or (3)(B) if the determination under section 505A(d)(4) [1] [21 U.S.C. 355a(d)(4)] is made later than 9 months prior to the expiration of such period.

(n) Date of approval in the case of recommended controls under the CSA

(1) In general

In the case of an application under subsection (a) with respect to a biological product for which the Secretary provides notice to the sponsor that the Secretary intends to issue a scientific and medical evaluation and recommend controls under the Controlled Substances Act [21 U.S.C. 801 et seq.], approval of such application shall not take effect until the interim final rule controlling the biological product is issued in accordance with section 201(j) of the Controlled Substances Act [21 U.S.C. 811(j)].

(2) Date of approval

For purposes of this section, with respect to an application described in paragraph (1), references to the date of approval of such application, or licensure of the product subject to such application, shall mean the later of-

(A) the date an application is approved under subsection (a); or

(B) the date of issuance of the interim final rule controlling the biological product.

(July 1, 1944, ch. 373, title III, §351, 58 Stat. 702 ; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 85–881, §2, Sept. 2, 1958, 72 Stat. 1704 ; Pub. L. 91–515, title II, §291, Oct. 30, 1970, 84 Stat. 1308 ; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695 ; Pub. L. 99–660, title I, §105(a), title III, §315, Nov. 14, 1986, 100 Stat. 3751 , 3783; Pub. L. 102–300, §6(b)(1), June 16, 1992, 106 Stat. 240 ; Pub. L. 104–134, title II, §§2102(d)(2), 2104, Apr. 26, 1996, 110 Stat. 1321–319 , 1321-320; Pub. L. 105–115, title I, §123(a)–(d), (g), Nov. 21, 1997, 111 Stat. 2323 , 2324; Pub. L. 108–155, §2(b)(3), Dec. 3, 2003, 117 Stat. 1941 ; Pub. L. 110–85, title IX, §901(c), Sept. 27, 2007, 121 Stat. 939 ; Pub. L. 111–148, title VII, §7002(a), (b), (g)(1), Mar. 23, 2010, 124 Stat. 804 , 814, 819; Pub. L. 112–144, title V, §502(a)(2), July 9, 2012, 126 Stat. 1040 ; Pub. L. 114–89, §2(a)(2), Nov. 25, 2015, 129 Stat. 698 ; Pub. L. 114–255, div. A, title III, §3031(b), Dec. 13, 2016, 130 Stat. 1100 ; Pub. L. 115–52, title V, §505(b)(2)(B), Aug. 18, 2017, 131 Stat. 1046 ; Pub. L. 116–94, div. N, title I, §§605, 606, Dec. 20, 2019, 133 Stat. 3127 ; Pub. L. 116–260, div. BB, title III, §§322, 325(a), Dec. 27, 2020, 134 Stat. 2933 , 2936; Pub. L. 117–328, div. FF, title III, §§3206, 3209(b), Dec. 29, 2022, 136 Stat. 5820 , 5822.)

Editorial Notes

References in Text

The effective date of this paragraph, referred to in subsec. (d)(2), is the effective date of section 315 of Pub. L. 99–660 which added subsec. (d)(2). See Effective Date of 1986 Amendment note set out below.

The Federal Food, Drug, and Cosmetic Act, referred to in subsecs. (g), (h), (j), and (k)(5)(C), is act June 25, 1938, ch. 675, 52 Stat. 1040 , 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.

Section 7002(e)(4) of the Biologics Price Competition and Innovation Act of 2009, referred to in subsec. (k)(7)(D), (9)(A)(i)(I), (ii), is section 7002(e)(4) of Pub. L. 111–148, which is set out in a note under this section.

Sections 526, 527(a), and 505A(d)(4), referred to in subsec. (m)(2)(B), (3)(B), (4), probably mean sections 526, 527(a), and 505A(d)(4) of the Federal Food, Drug, and Cosmetic Act, act June 25, 1938, ch. 675, which are classified to sections 360bb, 360cc(a), and 355a(d)(4), respectively, of Title 21, Food and Drugs.

The Controlled Substances Act, referred to in subsec. (n)(1), is title II of Pub. L. 91–513, Oct. 27, 1970, 84 Stat. 1242 , which is classified principally to subchapter I (§801 et seq.) of chapter 13 of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Short Title note set out under section 801 of Title 21 and Tables.

Amendments

2022-Subsec. (k)(2)(A)(i)(I)(bb). Pub. L. 117–328, §3209(b), amended item (bb) generally. Prior to amendment, item (bb) read as follows: "animal studies (including the assessment of toxicity); and".

Subsec. (k)(6). Pub. L. 117–328, §3206(2), substituted "taken, and the term 'first interchangeable biosimilar biological product' means any interchangeable biosimilar biological product that is approved on the first day on which such a product is approved as interchangeable with the reference product." for "taken." in concluding provisions.

Pub. L. 117–328, §3206(1), substituted "The Secretary shall not make approval as an interchangeable biological product effective with respect to" for "Upon review of" and "that relies on" for "relying on" and struck out "the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use" before "until the earlier of" in introductory provisions.

2020-Subsec. (k)(2)(A)(iii)(III). Pub. L. 116–260, §322, added subcl. (III).

Subsec. (k)(9). Pub. L. 116–260, §325(a), added par. (9).

2019-Subsec. (i)(1). Pub. L. 116–94, §605, struck out "(except any chemically synthesized polypeptide)" after "protein".

Subsec. (k)(7)(D). Pub. L. 116–94, §606, added subpar. (D).

2017-Subsec. (m)(2) to (4). Pub. L. 115–52 substituted "section 505A(d)(4)" for "section 505A(d)(3)".

2016-Subsec. (a)(2)(E). Pub. L. 114–255 added subpar. (E).

2015-Subsec. (n). Pub. L. 114–89 added subsec. (n).

2012-Subsec. (m)(1). Pub. L. 112–144 substituted "(f), (h), (i), (j), (k), (l), (n), and (p)" for "(f), (i), (j), (k), (l), (p), and (q)".

2010-Subsec. (a)(1)(A). Pub. L. 111–148, §7002(a)(1), inserted "under this subsection or subsection (k)" after "biologics license".

Subsec. (i). Pub. L. 111–148, §7002(b), substituted "In this section:" for "In this section,", designated remainder of existing provisions as par. (1), substituted "The term" for "the term", inserted "protein (except any chemically synthesized polypeptide)," after "allergenic product,", and added pars. (2) to (4).

Subsecs. (k), (l). Pub. L. 111–148, §7002(a)(2), added subsecs. (k) and (l).

Subsec. (m). Pub. L. 111–148, §7002(g)(1), added subsec. (m).

2007-Subsec. (a)(2)(D). Pub. L. 110–85, §901(c)(1), added subpar. (D).

Subsec. (j). Pub. L. 110–85, §901(c)(2), inserted ", including the requirements under sections 505(o), 505(p), and 505–1 of such Act," after "and Cosmetic Act".

2003-Subsec. (a)(2)(B), (C). Pub. L. 108–155 added subpar. (B) and redesignated former subpar. (B) as (C).

1997-Subsec. (a). Pub. L. 105–115, §123(a)(1), amended subsec. (a) generally. Prior to amendment, subsec. (a) related to intrastate and interstate traffic in biological products and suspension or revocation of licenses as affecting prior sales.

Subsec. (b). Pub. L. 105–115, §123(b), amended subsec. (b) generally. Prior to amendment, subsec. (b) read as follows: "No person shall falsely label or mark any package or container of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid; nor alter any label or mark on any package or container of any virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid so as to falsify such label or mark."

Subsec. (c). Pub. L. 105–115, §123(c), substituted "biological product." for "virus, serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or other product aforesaid for sale, barter, or exchange in the District of Columbia, or to be sent, carried, or brought from any State or possession into any other State or possession or into any foreign country, or from any foreign country into any State or possession."

Subsec. (d). Pub. L. 105–115, §123(a)(2), designated par. (2) as subsec. (d), redesignated subpars. (A) and (B) of par. (2) as pars. (1) and (2), respectively, in par. (2), substituted "Any violation of paragraph (1)" for "Any violation of subparagraph (A)" and substituted "this paragraph" for "this subparagraph" wherever appearing, and struck out former par. (1) which read as follows: "Licenses for the maintenance of establishments for the propagation or manufacture and preparation of products described in subsection (a) of this section may be issued only upon a showing that the establishment and the products for which a license is desired meet standards, designed to insure the continued safety, purity, and potency of such products, prescribed in regulations, and licenses for new products may be issued only upon a showing that they meet such standards. All such licenses shall be issued, suspended, and revoked as prescribed by regulations and all licenses issued for the maintenance of establishments for the propagation or manufacture and preparation, in any foreign country, of any such products for sale, barter, or exchange in any State or possession shall be issued upon condition that the licensees will permit the inspection of their establishments in accordance with subsection (c) of this section."

Subsec. (i). Pub. L. 105–115, §123(d), added subsec. (i).

Subsec. (j). Pub. L. 105–115, §123(g), added subsec. (j).

1996-Subsec. (h). Pub. L. 104–134, §2104, amended subsec. (h) generally, revising and restating former provisions, which also related to exportation of partially processed biological products.

Subsec. (h)(1)(A). Pub. L. 104–134, §2102(d)(2), substituted "in a country listed under section 802(b)(1)" for "in a country listed under section 802(b)(A)" and "to a country listed under section 802(b)(1)" for "to a country listed under section 802(b)(4)".

1992-Subsec. (c). Pub. L. 102–300, which directed substitution of "Health and Human Services" for "Health, Education, and Welfare", could not be executed because the words "Health, Education, and Welfare" did not appear in original statutory text. Previously, references to Department and Secretary of Health and Human Services were substituted for references to Federal Security Agency and its Administrator pursuant to provisions cited in Transfer of Functions note below.

1986-Subsec. (d). Pub. L. 99–660, §315, designated existing provisions as par. (1) and added par. (2).

Subsec. (h). Pub. L. 99–660, §105(a), added subsec. (h).

1970-Subsecs. (a) to (c). Pub. L. 91–515 inserted "vaccine, blood, blood component or derivative, allergenic product," after "antitoxin" wherever appearing.

1958-Subsec. (d). Pub. L. 85–881 struck out "made jointly by the Surgeon General, the Surgeon General of the Army, and the Surgeon General of the Navy, and approved by the Secretary" after "regulations" in first sentence.

Statutory Notes and Related Subsidiaries

Change of Name

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsecs. (a), (c), (d), (h), and (k) to (n), and "Department of Health and Human Services" substituted for "Department of Health, Education, and Welfare" in subsec. (c), pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

Effective Date of 2007 Amendment

Amendment by Pub. L. 110–85 effective 180 days after Sept. 27, 2007, see section 909 of Pub. L. 110–85, set out as a note under section 331 of Title 21, Food and Drugs.

Effective Date of 2003 Amendment

Amendment by Pub. L. 108–155 effective Dec. 3, 2003, except as otherwise provided, see section 4 of Pub. L. 108–155, set out as an Effective Date note under section 355c of Title 21, Food and Drugs.

Effective Date of 1997 Amendment

Amendment by Pub. L. 105–115 effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as a note under section 321 of Title 21, Food and Drugs.

Effective Date of 1986 Amendment

Pub. L. 99–660, title I, §105(b), Nov. 14, 1986, 100 Stat. 3752 , provided that: "Paragraph (1) of section 351(h) of the Public Health Service Act [former 42 U.S.C. 262(h)(1)] as added by subsection (a) shall take effect upon the expiration of 90 days after the date of the enactment of this Act [Nov. 14, 1986]."

Amendment by section 315 of Pub. L. 99–660 effective Dec. 22, 1987, see section 323 of Pub. L. 99–660, as amended, set out as an Effective Date note under section 300aa–1 of this title.

Products Previously Approved Under the Federal Food, Drug, and Cosmetic Act

Pub. L. 111–148, title VII, §7002(e), Mar. 23, 2010, 124 Stat. 817 , as amended by Pub. L. 116–94, div. N, title I, §607, Dec. 20, 2019, 133 Stat. 3127 , provided that:

"(1) Requirement to follow section 351.-Except as provided in paragraph (2), an application for a biological product shall be submitted under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).

"(2) Exception.-An application for a biological product may be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if-

"(A) such biological product is in a product class for which a biological product in such product class is the subject of an application approved under such section 505 not later than the date of enactment of this Act [Mar. 23, 2010]; and

"(B) such application-

"(i) has been submitted to the Secretary of Health and Human Services (referred to in this subtitle [subtitle A (§§7001–7003) of title VII of Pub. L. 111–148, see Short Title of 2010 Amendment note under section 201 of this title] as the 'Secretary') before the date of enactment of this Act; or

"(ii) is submitted to the Secretary not later than the date that is 10 years after the date of enactment of this Act.

"(3) Limitation.-Notwithstanding paragraph (2), an application for a biological product may not be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if there is another biological product approved under subsection (a) of section 351 of the Public Health Service Act [42 U.S.C. 262] that could be a reference product with respect to such application (within the meaning of such section 351) if such application were submitted under subsection (k) of such section 351.

"(4) Deemed approved under section 351.-

"(A) In general.-An approved application for a biological product under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) shall be deemed to be a license for the biological product under such section 351 on the date that is 10 years after the date of enactment of this Act.

"(B) Treatment of certain applications.-

"(i) In general.-With respect to an application for a biological product submitted under subsection (b) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) that is filed not later than March 23, 2019, and is not approved as of March 23, 2020, the Secretary shall continue to review such application under such section 505 after March 23, 2020.

"(ii) Effect on listed drugs.-Only for purposes of carrying out clause (i), with respect to any applicable listed drug with respect to such application, the following shall apply:

"(I) Any drug that is a biological product that has been deemed licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) pursuant to subparagraph (A) and that is referenced in an application described in clause (i), shall continue to be identified as a listed drug on the list published pursuant to section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, and the information for such drug on such list shall not be revised after March 20, 2020, until-

"(aa) such drug is removed from such list in accordance with subclause (III) or subparagraph (C) of such section 505(j)(7); or

"(bb) this subparagraph no longer has force or effect.

"(II) Any drug that is a biological product that has been deemed licensed under section 351 of the Public Health Service Act (42 U.S.C. 262) pursuant to subparagraph (A) and that is referenced in an application described in clause (i) shall be subject only to requirements applicable to biological products licensed under such section.

"(III) Upon approval under subsection (c) or (j) of section 505 of the Federal Food, Drug, and Cosmetic Act of an application described in clause (i), the Secretary shall remove from the list published pursuant to section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act any listed drug that is a biological product that has been deemed licensed under section 351 of the Public Health Service Act pursuant to subparagraph (A) and that is referenced in such approved application, unless such listed drug is referenced in one or more additional applications described in clause (i).

"(iii) Deemed licensure.-Upon approval of an application described in clause (i), such approved application shall be deemed to be a license for the biological product under section 351 of the Public Health Service Act.

"(iv) Rule of construction.-

"(I) Application of certain provisions.-

"(aa) Patent certification or statement.-An application described in clause (i) shall contain a patent certification or statement described in, as applicable, section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act or clauses (vii) and (viii) of section 505(j)(2)(A) of such Act and, with respect to any listed drug referenced in such application, comply with related requirements concerning any timely filed patent information listed pursuant to section 505(j)(7) of such Act.

"(bb) Date of approval.-The earliest possible date on which any pending application described in clause (i) may be approved shall be determined based on-

"(AA) the last expiration date of any applicable period of exclusivity that would prevent such approval and that is described in section 505(c)(3)(E), 505(j)(5)(B)(iv), 505(j)(5)(F), 505A [21 U.S.C. 355a], 505E [21 U.S.C. 355f], or 527 [21 U.S.C. 360cc] of the Federal Food, Drug, and Cosmetic Act; and

"(BB) if the application was submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act and references any listed drug, the last applicable date determined under subparagraph (A), (B), or (C) of section 505(c)(3) of such Act, or, if the application was submitted under section 505(j) of such Act, the last applicable date determined under clause (i), (ii), or (iii) of section 505(j)(5)(B) of such Act.

"(II) Exclusivity.-Nothing in this subparagraph shall be construed to affect section 351(k)(7)(D) of the Public Health Service Act.

"(v) Listing.-The Secretary may continue to review an application after March 23, 2020, pursuant to clause (i), and continue to identify any applicable listed drug pursuant to clause (ii) on the list published pursuant to section 505(j)(7) of the Federal Food, Drug, and Cosmetic Act, even if such review or listing may reveal the existence of such application and the identity of any listed drug for which the investigations described in section 505(b)(1)(A) of the Federal Food, Drug, and Cosmetic Act are relied upon by the applicant for approval of the pending application. Nothing in this subparagraph shall be construed as authorizing the Secretary to disclose any other information that is a trade secret or confidential information described in section 552(b)(4) of title 5, United States Code.

"(vi) SUNSET.-Beginning on October 1, 2022, this subparagraph shall have no force or effect and any applications described in clause (i) that have not been approved shall be deemed withdrawn.

"(5) DEFINITIONS.-For purposes of this subsection, the term 'biological product' has the meaning given such term under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act)."

COSTS OF REVIEWING BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS

Pub. L. 111–148, title VII, §7002(f)(3)(B), (C), Mar. 23, 2010, 124 Stat. 818 , 819, provided that:

"(B) EVALUATION OF COSTS OF REVIEWING BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS.-During the period beginning on the date of enactment of this Act [Mar. 23, 2010] and ending on October 1, 2010, the Secretary [of Health and Human Services] shall collect and evaluate data regarding the costs of reviewing applications for biological products submitted under section 351(k) of the Public Health Service Act [42 U.S.C. 262(k)] (as added by this Act) during such period.

"(C) AUDIT.-

"(i) IN GENERAL.-On the date that is 2 years after first receiving a user fee applicable to an application for a biological product under section 351(k) of the Public Health Service Act [42 U.S.C. 262(k)] (as added by this Act), and on a biennial basis thereafter until October 1, 2013, the Secretary shall perform an audit of the costs of reviewing such applications under such section 351(k). Such an audit shall compare-

"(I) the costs of reviewing such applications under such section 351(k) to the amount of the user fee applicable to such applications; and

"(II)(aa) such ratio determined under subclause (I); to

"(bb) the ratio of the costs of reviewing applications for biological products under section 351(a) of such Act [42 U.S.C. 262(a)] (as amended by this Act) to the amount of the user fee applicable to such applications under such section 351(a).

"(ii) ALTERATION OF USER FEE.-If the audit performed under clause (i) indicates that the ratios compared under subclause (II) of such clause differ by more than 5 percent, then the Secretary shall alter the user fee applicable to applications submitted under such section 351(k) [42 U.S.C. 262(k)] to more appropriately account for the costs of reviewing such applications.

"(iii) ACCOUNTING STANDARDS.-The Secretary shall perform an audit under clause (i) in conformance with the accounting principles, standards, and requirements prescribed by the Comptroller General of the United States under section 3511 of title 31, United State Code, to ensure the validity of any potential variability."

LICENSING OF ORPHAN PRODUCTS

Pub. L. 111–148, title VII, §7002(h), Mar. 23, 2010, 124 Stat. 821 , provided that: "If a reference product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act) has been designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) for a rare disease or condition, a biological product seeking approval for such disease or condition under subsection (k) of such section 351 as biosimilar to, or interchangeable with, such reference product may be licensed by the Secretary [of Health and Human Services] only after the expiration for such reference product of the later of-

"(1) the 7-year period described in section 527(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)); and

"(2) the 12-year period described in subsection (k)(7) of such section 351."

SAVINGS GENERATED BY 2010 AMENDMENT

Pub. L. 111–148, title VII, §7003, Mar. 23, 2010, 124 Stat. 821 , provided that:

"(a) DETERMINATION.-The Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, shall for each fiscal year determine the amount of savings to the Federal Government as a result of the enactment of this subtitle [subtitle A (§§7001–7003) of title VII of Pub. L. 111–148, see Short Title of 2010 Amendment note under section 201 of this title].

"(b) USE.-Notwithstanding any other provision of this subtitle (or an amendment made by this subtitle), the savings to the Federal Government generated as a result of the enactment of this subtitle shall be used for deficit reduction."

ENHANCED PENALTIES AND CONTROL OF BIOLOGICAL AGENTS

Pub. L. 104–132, title V, §511, Apr. 24, 1996, 110 Stat. 1284 , as amended by Pub. L. 107–188, title II, §204, June 12, 2002, 116 Stat. 647 , provided that:

"(a) FINDINGS.-The Congress finds that-

"(1) certain biological agents have the potential to pose a severe threat to public health and safety;

"(2) such biological agents can be used as weapons by individuals or organizations for the purpose of domestic or international terrorism or for other criminal purposes;

"(3) the transfer and possession of potentially hazardous biological agents should be regulated to protect public health and safety; and

"(4) efforts to protect the public from exposure to such agents should ensure that individuals and groups with legitimate objectives continue to have access to such agents for clinical and research purposes.

"(b) CRIMINAL ENFORCEMENT.-[Amended sections 175, 177, and 178 of Title 18, Crimes and Criminal Procedure.]

"(c) TERRORISM.-[Amended section 2332a of Title 18.]"

EXECUTIVE DOCUMENTS

TRANSFER OF FUNCTIONS

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

References to Secretary and Department of Health, Education, and Welfare substituted for references to Federal Security Administrator and Federal Security Agency, respectively, pursuant to Reorg. Plan No. 1 of 1953, §5, set out as a note under section 3501 of this title, which transferred all functions of Federal Security Administrator to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency to Department of Health, Education, and Welfare. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

[1] *See References in Text note below.*

42 USC 262a: Enhanced control of dangerous biological agents and toxins
Text contains those laws in effect on April 14, 2025

From Title 42-THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A-PUBLIC HEALTH SERVICE
SUBCHAPTER II-GENERAL POWERS AND DUTIES
Part F-Licensing of Biological Products and Clinical Laboratories
subpart 1-biological products

Jump To:

1944 PHSA Sec. 351A = 42 USC 262a
Added 2002

§262a. Enhanced control of dangerous biological agents and toxins

(a) Regulatory control of certain biological agents and toxins

(1) List of biological agents and toxins

(A) In general

The Secretary shall by regulation establish and maintain a list of each biological agent and each toxin that has the potential to pose a severe threat to public health and safety.

(B) Criteria

In determining whether to include an agent or toxin on the list under subparagraph (A), the Secretary shall-

(i) consider-

(I) the effect on human health of exposure to the agent or toxin;

(II) the degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans;

(III) the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or toxin; and

(IV) any other criteria, including the needs of children and other vulnerable populations, that the Secretary considers appropriate; and

(ii) consult with appropriate Federal departments and agencies and with scientific experts representing appropriate professional groups, including groups with pediatric expertise.

(2) Biennial review

The Secretary shall review and republish the list under paragraph (1) biennially, or more often as needed, and shall by regulation revise the list as necessary in accordance with such paragraph.

(b) Regulation of transfers of listed agents and toxins

The Secretary shall by regulation provide for-

(1) the establishment and enforcement of safety procedures for the transfer of listed agents and toxins, including measures to ensure-

(A) proper training, including with respect to notification requirements under this section, of-

(i) individuals who are involved in the handling and use of such agents and toxins, including appropriate skills to handle such agents and toxins;

(ii) individuals whose responsibilities routinely place them in close proximity to laboratory facilities in which such agents and toxins are being transferred, possessed, or used; and

(iii) individuals who perform administrative or oversight functions of the facility related to the transfer, possession, or use of such agents and toxins on behalf of registered persons;

(B) proper laboratory facilities to contain and dispose of such agents and toxins;

(2) the establishment and enforcement of safeguard and security measures to prevent access to such agents and toxins for use in domestic or international terrorism or for any other criminal purpose;

(3) the establishment of procedures to protect the public safety in the event of a transfer or potential transfer of such an agent or toxin in violation of the safety procedures established under paragraph (1) or the safeguard and security measures established under paragraph (2); and

(4) appropriate availability of biological agents and toxins for research, education, and other legitimate purposes.

(c) Possession and use of listed agents and toxins

The Secretary shall by regulation provide for the establishment and enforcement of standards and procedures governing the possession and use of listed agents and toxins, including the provisions described in paragraphs (1) through (4) of subsection (b), in order to protect the public health and safety.

(d) Registration; identification; database

(1) Registration

Regulations under subsections (b) and (c) shall require registration with the Secretary of the possession, use, and transfer of listed agents and toxins, and shall include provisions to ensure that persons seeking to register under such regulations have a lawful purpose to possess, use, or transfer such agents and toxins, including provisions in accordance with subsection (e)(6).

(2) Identification; database

Regulations under subsections (b) and (c) shall require that registration include (if available to the person registering) information regarding the characterization of listed agents and toxins to facilitate their identification, including their source. The Secretary shall maintain a national database that includes the names and locations of registered persons, the listed agents and toxins such persons are possessing, using, or transferring, and information regarding the characterization of such agents and toxins.

(e) Safeguard and security requirements for registered persons

(1) In general

Regulations under subsections (b) and (c) shall include appropriate safeguard and security requirements for persons possessing, using, or transferring a listed agent or toxin commensurate with the risk such agent or toxin poses to public health and safety (including risks posed by the release, theft, or loss of such agent or toxin, or use in domestic or international terrorism). The Secretary shall establish such requirements in collaboration with the Secretary of Homeland Security and the Attorney General, and shall ensure compliance with such requirements as part of the registration system under such regulations.

(2) Limiting access to listed agents and toxins

Requirements under paragraph (1) shall include provisions to ensure that registered persons-

(A) provide access to listed agents and toxins to only those individuals whom the registered person involved determines have a legitimate need to handle or use such agents and toxins;

(B) submit the names and other identifying information for such individuals to the Secretary and the Attorney General, promptly after first determining that the individuals need access under subparagraph (A), and periodically thereafter while the individuals have such access, not less frequently than once every five years;

(C) deny access to such agents and toxins by individuals whom the Attorney General has identified as restricted persons; and

(D) limit or deny access to such agents and toxins by individuals whom the Attorney General has identified as within any category under paragraph (3)(B)(ii), if limiting or denying such access by the individuals involved is determined appropriate by the Secretary, in consultation with the Attorney General.

(3) Submitted names; use of databases by attorney general

(A) In general

Upon the receipt of names and other identifying information under paragraph (2)(B), the Attorney General shall, for the sole purpose of identifying whether the individuals involved are within any of the categories specified in subparagraph (B), promptly use criminal, immigration, national security, and other electronic databases that are available to the Federal Government and are appropriate for such purpose.

(B) Certain individuals

For purposes of subparagraph (A), the categories specified in this subparagraph regarding an individual are that-

(i) the individual is a restricted person; or

(ii) the individual is reasonably suspected by any Federal law enforcement or intelligence agency of-

(I) committing a crime set forth in section 2332b(g)(5) of title 18;

(II) knowing involvement with an organization that engages in domestic or international terrorism (as defined in section 2331 of such title 18) or with any other organization that engages in intentional crimes of violence; or

(III) being an agent of a foreign power (as defined in section 1801 of title 50).

(C) Notification by Attorney General regarding submitted names

After the receipt of a name and other identifying information under paragraph (2)(B), the Attorney General shall promptly notify the Secretary whether the individual is within any of the categories specified in subparagraph (B).

(4) Notifications by Secretary

The Secretary, after receiving notice under paragraph (3) regarding an individual, shall promptly notify the registered person involved of whether the individual is granted or denied access under paragraph (2). If the individual is denied such access, the Secretary shall promptly notify the individual of the denial.

(5) Expedited review

Regulations under subsections (b) and (c) shall provide for a procedure through which, upon request to the Secretary by a registered person who submits names and other identifying information under

paragraph (2)(B) and who demonstrates good cause, the Secretary may, as determined appropriate by the Secretary-
(A) request the Attorney General to expedite the process of identification under paragraph (3)(A) and notification of the Secretary under paragraph (3)(C); and
(B) expedite the notification of the registered person by the Secretary under paragraph (4).

(6) Process regarding persons seeking to register

(A) Individuals

Regulations under subsections (b) and (c) shall provide that an individual who seeks to register under either of such subsections is subject to the same processes described in paragraphs (2) through (4) as apply to names and other identifying information submitted to the Attorney General under paragraph (2)(B). Paragraph (5) does not apply for purposes of this subparagraph.

(B) Other persons

Regulations under subsections (b) and (c) shall provide that, in determining whether to deny or revoke registration by a person other than an individual, the Secretary shall submit the name of such person to the Attorney General, who shall use criminal, immigration, national security, and other electronic databases available to the Federal Government, as appropriate for the purpose of promptly notifying the Secretary whether the person, or, where relevant, the individual who owns or controls such person, is a restricted person or is reasonably suspected by any Federal law enforcement or intelligence agency of being within any category specified in paragraph (3)(B)(ii) (as applied to persons, including individuals). Such regulations shall provide that a person who seeks to register under either of such subsections is subject to the same processes described in paragraphs (2) and (4) as apply to names and other identifying information submitted to the Attorney General under paragraph (2)(B). Paragraph (5) does not apply for purposes of this subparagraph. The Secretary may exempt Federal, State, or local governmental agencies from the requirements of this subparagraph.

(7) Review

(A) Administrative review

(i) In general

Regulations under subsections (b) and (c) shall provide for an opportunity for a review by the Secretary-
(I) when requested by the individual involved, of a determination under paragraph (2) to deny the individual access to listed agents and toxins; and
(II) when requested by the person involved, of a determination under paragraph (6) to deny or revoke registration for such person.

(ii) Ex parte review

During a review under clause (i), the Secretary may consider information relevant to the review ex parte to the extent that disclosure of the information could compromise national security or an investigation by any law enforcement agency.

(iii) Final agency action

The decision of the Secretary in a review under clause (i) constitutes final agency action for purposes of section 702 of title 5.

(B) Certain procedures

(i) Submission of ex parte materials in judicial proceedings

When reviewing a decision of the Secretary under subparagraph (A), and upon request made ex parte and in writing by the United States, a court, upon a sufficient showing, may review and consider ex parte documents containing information the disclosure of which could compromise national security or an investigation by any law enforcement agency. If the court determines that portions of the documents considered ex parte should be disclosed to the person involved to allow a response, the court shall authorize the United States to delete from such documents specified items of information the disclosure of which could compromise national security or an investigation by any law enforcement agency, or to substitute a summary of the information to which the person may respond. Any order by the court authorizing the disclosure of information that the United States believes could compromise national security or an investigation by any law enforcement agency shall be subject to the processes set forth in subparagraphs (A) and (B)(i) of section 2339B(f)(5) of title 18 (relating to interlocutory appeal and expedited consideration).

(ii) Disclosure of information

In a review under subparagraph (A), and in any judical [1] proceeding conducted pursuant to such review, neither the Secretary nor the Attorney General may be required to disclose to the public any information that under subsection (h) shall not be disclosed under section 552 of title 5.

(8) Notifications regarding theft or loss of agents

Requirements under paragraph (1) shall include the prompt notification of the Secretary, and appropriate Federal, State, and local law enforcement agencies, of the theft or loss of listed agents and toxins.

(9) Technical assistance for registered persons

The Secretary, in consultation with the Attorney General, may provide technical assistance to registered persons to improve security of the facilities of such persons.

(f) Inspections

The Secretary shall have the authority to inspect persons subject to regulations under subsection (b) or (c) to ensure their compliance with such regulations, including prohibitions on restricted persons and other provisions of subsection (e).

(g) Exemptions

(1) Clinical or diagnostic laboratories

Regulations under subsections (b) and (c) shall exempt clinical or diagnostic laboratories and other persons who possess, use, or transfer listed agents or toxins that are contained in specimens presented for diagnosis, verification, or proficiency testing, provided that-
(A) the identification of such agents or toxins is reported to the Secretary, and when required under Federal, State, or local law, to other appropriate authorities; and
(B) such agents or toxins are transferred or destroyed in a manner set forth by the Secretary by regulation.

(2) Products

(A) In general

Regulations under subsections (b) and (c) shall exempt products that are, bear, or contain listed agents or toxins and are cleared, approved, licensed, or registered under any of the Acts specified in subparagraph (B), unless the Secretary by order determines that applying additional regulation under subsection (b) or (c) to a specific product is necessary to protect public health and safety.

(B) Relevant laws

For purposes of subparagraph (A), the Acts specified in this subparagraph are the following:
(i) The Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.].
(ii) Section 262 of this title.
(iii) The Act commonly known as the Virus-Serum-Toxin Act (the eighth paragraph under the heading "Bureau of Animal Industry" in the Act of March 4, 1913; 21 U.S.C. 151–159).
(iv) The Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. 136 et seq.].

(C) Investigational use

(i) In general

The Secretary may exempt an investigational product that is, bears, or contains a listed agent or toxin from the applicability of provisions of regulations under subsection (b) or (c) when such product is being used in an investigation authorized under any Federal Act and the Secretary determines that applying additional regulation under subsection (b) or (c) to such product is not necessary to protect public health and safety.

(ii) Certain processes

Regulations under subsections (b) and (c) shall set forth the procedures for applying for an exemption under clause (i). In the case of investigational products authorized under any of the Acts specified in subparagraph (B), the Secretary shall make a determination regarding a request for an exemption not later than 14 days after the first date on which both of the following conditions have been met by the person requesting the exemption:
(I) The person has submitted to the Secretary an application for the exemption meeting the requirements established by the Secretary.
(II) The person has notified the Secretary that the investigation has been authorized under such an Act.

(3) Public health emergencies

The Secretary may temporarily exempt a person from the applicability of the requirements of this section, in whole or in part, if the Secretary determines that such exemption is necessary to provide for the timely participation of the person in a response to a domestic or foreign public health emergency (whether determined under section 247d(a) of this title or otherwise) that involves a listed agent or toxin. With respect to the emergency involved, such exemption for a person may not exceed 30 days, except that the Secretary, after review of whether such exemption remains necessary, may provide one extension of an additional 30 days.

(4) Agricultural emergencies

Upon request of the Secretary of Agriculture, after the granting by such Secretary of an exemption under section 8401(g)(1)(D) of title 7 pursuant to a finding that there is an agricultural emergency, the Secretary of Health and Human Services may temporarily exempt a person from the applicability of the requirements of this section, in whole or in part, to provide for the timely participation of the person in a response to the agricultural emergency. With respect to the emergency involved, the exemption under this paragraph for a person may not exceed 30 days, except that upon request of the Secretary of Agriculture, the Secretary of Health and Human Services may, after review of whether such exemption remains necessary, provide one extension of an additional 30 days.

(h) Disclosure of information

(1) Nondisclosure of certain information

No Federal agency specified in paragraph (2) shall disclose under section 552 of title 5 any of the following:
(A) Any registration or transfer documentation submitted under subsections (b) and (c) for the possession, use, or transfer of a listed agent or toxin; or information derived therefrom to the extent that it identifies the listed agent or toxin possessed, used, or transferred by a specific registered person or discloses the identity or location of a specific registered person.
(B) The national database developed pursuant to subsection (d), or any other compilation of the registration or transfer information submitted under subsections (b) and (c) to the extent that such compilation discloses site-specific registration or transfer information.
(C) Any portion of a record that discloses the site-specific or transfer-specific safeguard and security measures used by a registered person to prevent unauthorized access to listed agents and toxins.
(D) Any notification of a release of a listed agent or toxin submitted under subsections (b) and (c), or any notification of theft or loss submitted under such subsections.
(E) Any portion of an evaluation or report of an inspection of a specific registered person conducted under subsection (f) that identifies the listed agent or toxin possessed by a specific registered person or that discloses the identity or location of a specific registered person if the agency determines that public disclosure of the information would endanger public health or safety.

(2) Covered agencies

For purposes of paragraph (1) only, the Federal agencies specified in this paragraph are the following:

(A) The Department of Health and Human Services, the Department of Justice, the Department of Agriculture, and the Department of Transportation.

(B) Any Federal agency to which information specified in paragraph (1) is transferred by any agency specified in subparagraph (A) of this paragraph.

(C) Any Federal agency that is a registered person, or has a sub-agency component that is a registered person.

(D) Any Federal agency that awards grants or enters into contracts or cooperative agreements involving listed agents and toxins to or with a registered person, and to which information specified in paragraph (1) is transferred by any such registered person.

(3) Other exemptions

This subsection may not be construed as altering the application of any exemptions to public disclosure under section 552 of title 5, except as to subsection [2] 552(b)(3) of such title, to any of the information specified in paragraph (1).

(4) Rule of construction

Except as specifically provided in paragraph (1), this subsection may not be construed as altering the authority of any Federal agency to withhold under section 552 of title 5, or the obligation of any Federal agency to disclose under section 552 of title 5, any information, including information relating to-

(A) listed agents and toxins, or individuals seeking access to such agents and toxins;

(B) registered persons, or persons seeking to register their possession, use, or transfer of such agents and toxins;

(C) general safeguard and security policies and requirements under regulations under subsections (b) and (c); or

(D) summary or statistical information concerning registrations, registrants, denials or revocations of registrations, listed agents and toxins, inspection evaluations and reports, or individuals seeking access to such agents and toxins.

(5) Disclosures to Congress; other disclosures

This subsection may not be construed as providing any authority-

(A) to withhold information from the Congress or any committee or subcommittee thereof; or

(B) to withhold information from any person under any other Federal law or treaty.

(i) Civil money penalty

(1) In general

In addition to any other penalties that may apply under law, any person who violates any provision of regulations under subsection (b) or (c) shall be subject to the United States for a civil money penalty in an amount not exceeding $250,000 in the case of an individual and $500,000 in the case of any other person.

(2) Applicability of certain provisions

The provisions of section 1320a–7a of this title (other than subsections (a), (b), (h), and (i), the first sentence of subsection (c), and paragraphs (1) and (2) of subsection (f)) shall apply to a civil money penalty under paragraph (1) in the same manner as such provisions apply to a penalty or proceeding under section 1320a–7a(a) of this title. The Secretary may delegate authority under this subsection in the same manner as provided in section 1320a–7a(j)(2) of this title, and such authority shall include all powers as contained in section 406 of title 5.

(j) Notification in event of release

Regulations under subsections (b) and (c) shall require the prompt notification of the Secretary by a registered person whenever a release, meeting criteria established by the Secretary, of a listed agent or toxin has occurred outside of the biocontainment area of a facility of the registered person. Upon receipt of such notification and a finding by the Secretary that the release poses a threat to public health or safety, the Secretary shall take appropriate action to notify relevant State and local public health authorities, other relevant Federal authorities, and, if necessary, other appropriate persons (including the public). If the released listed agent or toxin is an overlap agent or toxin (as defined in subsection (l)), the Secretary shall promptly notify the Secretary of Agriculture upon notification by the registered person.

(k) Reports

(1) Notification with respect to Federal facilities

In the event of the release, loss, or theft of an agent or toxin listed by the Secretary pursuant to subsection (a)(1), or by the Secretary of Agriculture pursuant to section 8401(a)(1) of title 7, from or within a laboratory facility owned or operated by the Department of Health and Human Services, or other Federal laboratory facility subject to the requirements of this section, the Secretary, in a manner that does not compromise national security, shall-

(A) not later than 72 hours after such event is reported to the Secretary, notify the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives of such event, including-

(i) the Federal laboratory facility in which such release, loss, or theft occurred; and

(ii) the circumstances of such release, loss, or theft; and

(B) not later than 14 days after such notification, update such Committees on-

(i) any actions taken or planned by the Secretary to mitigate any potential threat such release, loss, or theft may pose to public health and safety; and

(ii) any actions taken or planned by the Secretary to review the circumstances of such release, loss, or theft, and prevent similar events.

(2) Annual report

The Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on an annual basis a report-

(A) summarizing the number and nature of notifications received under subsection (e)(8) (relating to theft or loss) and subsection (j) (relating to releases), during the preceding fiscal year;

(B) describing actions taken by the Secretary to address such incidents, such as any corrective action plans required and steps taken to promote adherence to, and compliance with, safety and security best practices, standards, and regulations; and

(C) describing any gaps, challenges, or limitations with respect to ensuring that such safety and security practices are consistently applied and adhered to, and actions taken to address such gaps, challenges, or limitations.

(3) Implementation of recommendations of the Federal Experts Security Advisory Panel and the fast track action committee on select agent regulations

(A) In general

Not later than 1 year after June 24, 2019, the Secretary shall report to the congressional committees of jurisdiction on the implementation of recommendations of the Federal Experts Security Advisory Panel concerning the select agent program.

(B) Continued updates

The Secretary shall report to the congressional committees of jurisdiction annually following the submission of the report under subparagraph (A) until the recommendations described in such subparagraph are fully implemented, or a justification is provided for the delay in, or lack of, implementation.

(l) Definitions

For purposes of this section:

(1) The terms "biological agent" and "toxin" have the meanings given such terms in section 178 of title 18.

(2) The term "listed agents and toxins" means biological agents and toxins listed pursuant to subsection (a)(1).

(3) The term "listed agents or toxins" means biological agents or toxins listed pursuant to subsection (a)(1).

(4) The term "overlap agents and toxins" means biological agents and toxins that-

(A) are listed pursuant to subsection (a)(1); and

(B) are listed pursuant to section 8401(a)(1) of title 7.

(5) The term "overlap agent or toxin" means a biological agent or toxin that-

(A) is listed pursuant to subsection (a)(1); and

(B) is listed pursuant to section 8401(a)(1) of title 7.

(6) The term "person" includes Federal, State, and local governmental entities.

(7) The term "registered person" means a person registered under regulations under subsection (b) or (c).

(8) The term "restricted person" has the meaning given such term in section 175b of title 18.

(m) 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 2023 through 2027.

(July 1, 1944, ch. 373, title III, §351A, as added Pub. L. 107–188, title II, §201(a), June 12, 2002, 116 Stat. 637 ; amended Pub. L. 107–296, title XVII, §1709(a), Nov. 25, 2002, 116 Stat. 2318 ; Pub. L. 116–22, title IV, §405, June 24, 2019, 133 Stat. 949 ; Pub. L. 117–286, §4(b)(75), Dec. 27, 2022, 136 Stat. 4351 ; Pub. L. 117–328, div. FF, title II, §2311, Dec. 29, 2022, 136 Stat. 5759 .)

EDITORIAL NOTES

REFERENCES IN TEXT

The Federal Food, Drug, and Cosmetic Act, referred to in subsec.(g)(2)(B)(i), is act June 25, 1938, ch. 675, 52 Stat. 1040 , 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 Act commonly known as the Virus-Serum-Toxin Act, referred to in subsec. (g)(2)(B)(iii), is the eighth paragraph under the heading "Bureau of Animal Industry" of act Mar. 4, 1913, ch. 145, 37 Stat. 832 , which is classified generally to chapter 5 (§151 et seq.) of Title 21, Food and Drugs. For complete classification of this Act to the Code, see Short Title note set out under section 151 of Title 21 and Tables.

The Federal Insecticide, Fungicide, and Rodenticide Act, referred to in subsec. (g)(2)(B)(iv), is act June 25, 1947, ch. 125, as amended generally by Pub. L. 92–516, Oct. 21, 1972, 86 Stat. 973 , which is classified generally to subchapter II (§136 et seq.) of chapter 6 of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 136 of Title 7 and Tables.

AMENDMENTS

2022-Subsec. (b)(1)(A). Pub. L. 117–328, §2311(1), amended subpar. (A) generally. Prior to amendment, text read as follows: "proper training and appropriate skills to handle such agents and toxins; and".

Subsec. (e)(1). Pub. L. 117–328, §2311(2), substituted "(including risks posed by the release, theft, or loss of such agent or toxin, or use in domestic or international terrorism)" for "(including the risk of use in domestic or international terrorism)".

Subsec. (i)(2). Pub. L. 117–286 substituted "section 406 of title 5." for "section 6 of the Inspector General Act of 1978 (5 U.S.C. App.)."

Subsec. (k)(1). Pub. L. 117–328, §2311(3)(B), added par. (1). Former par. (1) redesignated (2).

Subsec. (k)(2). Pub. L. 117–328, §2311(3)(A), (C), redesignated par. (1) as (2) and amended it generally. Prior to amendment, text read as follows: "The Secretary shall report to the Congress annually on the number and nature of notifications received under subsection (e)(8) (relating to theft or loss) and subsection (j) (relating to releases)." Former par. (2) redesignated (3).

Subsec. (k)(3). Pub. L. 117–328, §2311(3)(A), redesignated par. (2) as (3).

Subsec. (m). Pub. L. 117–328, §2311(4), substituted "fiscal years 2023 through 2027" for "fiscal years 2002 through 2007".

2019-Subsec. (k). Pub. L. 116–22 designated existing provisions as par. (1), inserted heading, and added par. (2).

2002-Subsec. (e)(1). Pub. L. 107–296 substituted "collaboration with the Secretary of Homeland Security and" for "consultation with".

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2002 AMENDMENT

Amendment by Pub. L. 107–296 effective 60 days after Nov. 25, 2002, see section 4 of Pub. L. 107–296, set out as an Effective Date note under section 101 of Title 6, Domestic Security.

EFFECTIVE DATE

Pub. L. 107–188, title II, §203(b), June 12, 2002, 116 Stat. 647 , provided that: "Subsection (h) of section 351A of the Public Health Service Act [42 U.S.C. 262a(h)], as added by section 201 of this Act, is deemed to have taken effect on the effective date of the Antiterrorism and Effective Death Penalty Act of 1996 [Pub. L. 104–132, Apr. 24, 1996, 110 Stat. 1214]."

REGULATIONS

Pub. L. 107–188, title II, §203(a), June 12, 2002, 116 Stat. 647 , provided that: "Regulations promulgated by the Secretary of Health and Human Services under section 511 of the Antiterrorism and Effective Death Penalty Act of 1996 [Pub. L. 104–132, 42 U.S.C. 262 note] are deemed to have been promulgated under section 351A of the Public Health Service Act [42 U.S.C. 262a], as added by section 201 of this Act. Such regulations, including the list under [former] subsection (d)(1) of such section 511, that were in effect on the day before the date of the enactment of this Act [June 12, 2002] remain in effect until modified by the Secretary in accordance with such section 351A and with section 202 of this Act [set out as a note below]."

IMPROVING RESEARCH AND DEVELOPMENT OF MEDICAL COUNTERMEASURES FOR NOVEL PATHOGENS

Pub. L. 117–328, div. FF, title II, §2303(a), Dec. 29, 2022, 136 Stat. 5758 , provided that:

"(1) SAMPLE ACCESS.-Not later than 1 year after the date of enactment of this Act [Dec. 29, 2022], the Secretary of Health and Human Services (referred to in this subsection as the 'Secretary') shall make publicly available policies and procedures related to public and private entities accessing specimens of, or specimens containing, pathogens or suitable surrogates for, or alternatives to, such pathogens as the Secretary determines appropriate to support public health preparedness and response activities or biomedical research for purposes of the development and validation, as applicable, of medical products to address emerging infectious diseases and for use to otherwise respond to emerging infectious diseases. Such policies and procedures shall take into account, as appropriate, any applicable existing Federal resources.

"(2) GUIDANCE.-The Secretary shall issue guidance regarding the procedures for carrying out paragraph (1), including-

"(A) the method for requesting such samples;

"(B) considerations for sample availability and use of suitable surrogates or alternatives to such pathogens, as appropriate, including applicable safeguard and security measures; and

"(C) information required to be provided in order to receive such samples or suitable surrogates or alternatives."

STRATEGY FOR FEDERAL HIGH-CONTAINMENT LABORATORIES

Pub. L. 117–328, div. FF, title II, §2312, Dec. 29, 2022, 136 Stat. 5761 , provided that:

"(a) STRATEGY FOR FEDERAL HIGH-CONTAINMENT LABORATORIES.-Not later than 1 year after the date of enactment of this Act [Dec. 29, 2022], the Director of the Office of Science and Technology Policy, in consultation with relevant Federal departments and agencies, shall establish a strategy for the management, maintenance, and oversight of federally-owned laboratory facilities operating at Biosafety Level 3 or 4, including equivalent classification levels and facilities with Biosafety Level 4 capabilities. Such strategy shall include-

"(1) a description of the roles and responsibilities of relevant Federal departments and agencies with respect to the management, maintenance, and oversight of Biosafety Level 3 or 4 laboratory facilities;

"(2) an assessment of the needs of the Federal Government with respect to Biosafety Level 3 or 4 laboratory facilities;

"(3) a summary of existing federally-owned Biosafety Level 3 or 4 laboratory facility capacity;

"(4) a summary of other Biosafety Level 3 or 4 laboratory facility capacity established through Federal funds;

"(5) a description of how the capacity described in paragraphs (3) and (4) addresses the needs of the Federal Government, including-

"(A) how relevant Federal departments and agencies coordinate to provide access to appropriate laboratory facilities to reduce unnecessary duplication; and

"(B) any gaps in such capacity related to such needs;

"(6) a summary of plans that are in place for the maintenance of such capacity within each relevant Federal department or agency, as applicable and appropriate, including processes for determining whether to maintain or expand such capacity, and a description of how the Federal Government will address rapid changes in the need for such capacity within each relevant Federal department or agency during a public health emergency; and

"(7) a description of how the heads of relevant Federal departments and agencies will coordinate to ensure appropriate oversight of federally-owned laboratory facility capacity and leverage such capacity within each relevant Federal department, as appropriate, to fulfill the needs of each Federal department and agency in order to reduce unnecessary duplication and improve collaboration within the Federal Government.

"(b) CLARIFICATION.-The strategy under subsection (a) shall not be construed to supersede the authorities of each relevant Federal department or agency with respect to the management, maintenance, and oversight of the Federally-owned laboratory facilities operated by any such Federal department or agency."

RESEARCH TO IMPROVE BIOSAFETY

Pub. L. 117–328, div. FF, title II, §2314, Dec. 29, 2022, 136 Stat. 5763 , provided that:

"(a) IN GENERAL.-The Secretary of Health and Human Services (referred to in this section as the 'Secretary') shall, as appropriate, conduct or support research to improve the safe conduct of biomedical research activities involving pathogens of pandemic potential or biological agents or toxins listed pursuant to section 351A(a)(1) of the Public Health Service Act (42 U.S.C. 262a(a)(1)).

"(b) REPORT.-Not later than 5 years after the date of enactment of this Act [Dec. 29, 2022], the Secretary shall prepare and submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives regarding an overview of any research conducted or supported under this section, any relevant findings, and steps the Secretary is taking to disseminate any such findings to support the reduction of risks associated with biomedical research involving pathogens of pandemic potential or biological agents or toxins listed pursuant to section 351A(a)(1) of the Public Health Service Act (42 U.S.C. 262a(a)(1))."

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

Pub. L. 109–417, title II, §205, Dec. 19, 2006, 120 Stat. 2851 , formerly set out as a note under this section, was transferred and is set out as a National Science Advisory Board for Biosecurity: Provision of Advice, Guidance, or Recommendations note under section 283r of this title.

REPORT TO CONGRESS

Pub. L. 107–188, title II, §201(b), June 12, 2002, 116 Stat. 646 , required the Secretary of Health and Human Services to report to Congress not later than one year after June 12, 2002, on the implementation, compliance, and future plans under this section.

IMPLEMENTATION BY DEPARTMENT OF HEALTH AND HUMAN SERVICES

Pub. L. 107–188, title II, §202, June 12, 2002, 116 Stat. 646 , provided that:

"(a) DATE CERTAIN FOR NOTICE OF POSSESSION.-Not later than 90 days after the date of the enactment of this Act [June 12, 2002], all persons (unless exempt under subsection (g) of section 351A of the Public Health Service Act [42 U.S.C. 262a(g)], as added by section 201 of this Act) in possession of biological agents or toxins listed under such section 351A of the Public Health Service Act [42 U.S.C. 262a] shall notify the Secretary of Health and Human Services of such possession. Not later than 30 days after such date of enactment, the Secretary shall provide written guidance on how such notice is to be provided to the Secretary.

"(b) DATE CERTAIN FOR PROMULGATION; EFFECTIVE DATE REGARDING CRIMINAL AND CIVIL PENALTIES.-Not later than 180 days after the date of the enactment of this Act [June 12, 2002], the Secretary of Health and Human Services shall promulgate an interim final rule for carrying out section 351A of the Public Health Service Act [42 U.S.C. 262a], subject to subsection (c). Such interim final rule shall take effect 60 days after the date on which such rule is promulgated, including for purposes of-

"(1) section 175b(c) of title 18, United States Code (relating to criminal penalties), as added by section 231(a)(5) of this Act; and

"(2) section 351A(i) of the Public Health Service Act [42 U.S.C. 262a(i)] (relating to civil penalties).

"(c) TRANSITIONAL PROVISION REGARDING CURRENT RESEARCH AND EDUCATION.-The interim final rule under subsection (b) shall include time frames for the applicability of the rule that minimize disruption of research or educational projects that involve biological agents and toxins listed pursuant to section 351A(a)(1) of the Public Health Service Act [42 U.S.C. 262a(a)(1)] and that were underway as of the effective date of such rule."

EXECUTIVE DOCUMENTS

EX. ORD. NO. 13546. OPTIMIZING THE SECURITY OF BIOLOGICAL SELECT AGENTS AND TOXINS IN THE UNITED STATES

Ex. Ord. No. 13546, July 2, 2010, 75 F.R. 39439, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

SECTION 1. *Policy*. It is the policy of the United States that:

(a) A robust and productive scientific enterprise that utilizes biological select agents and toxins (BSAT) is essential to national security;

(b) BSAT shall be secured in a manner appropriate to their risk of misuse, theft, loss, and accidental release; and

(c) Security measures shall be taken in a coordinated manner that balances their efficacy with the need to minimize the adverse impact on the legitimate use of BSAT.

SEC. 2. *Definitions*. (a) "Select Agent Program" (SAP) means the regulatory oversight and administrative activities conducted by the Secretaries of Health and Human Services and Agriculture and the Attorney General to implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and the Agricultural Bioterrorism Protection Act of 2002.

(b) "Select Agent Regulations" (SAR) means the Federal regulations found in Part 73 of Title 42 of the Code of Federal Regulations, Part 331 of Title 7 of the Code of Federal Regulations, and Part 121 of Title 9 of the Code of Federal Regulations.

(c) "Biological Select Agents and Toxins" means biological agents and toxins with the potential to pose a severe threat to public health and safety, animal and plant health, or animal and plant products and whose possession, use, and transfer are regulated by the Department of Health and Human Services and the Department of Agriculture under the SAR.

SEC. 3. *Findings*. (a) The use of BSAT presents the risk that BSAT might be lost, stolen, or diverted for malicious purpose. The SAP exists to provide effective regulatory oversight of the possession, use, and transfer of BSAT that reduces the risk of their misuse or mishandling. The absence of clearly defined, risk-based security measures in the SAR/SAP has raised concern about the need for optimized security and for risk management.

(b) In addition, variations in, and limited coordination of, individual executive departments' and agencies' oversight, security practices, and inspections have raised concerns that the cost and complexity of compliance for those who are registered to work with BSAT could discourage research or other legitimate activities.

(c) Understanding that research and laboratory work on BSAT is essential to both public health and national security, it is in the interest of the United States to address these issues.

SEC. 4. *Risk-based Tiering of the Select Agent List*. To help ensure that BSAT are secured according to level of risk, the Secretaries of Health and Human Services and Agriculture shall, through their ongoing review of the biological Select Agents and Toxins List ("Select Agent List") contained in regulations, and no later than 18 months from the date of this order:

(a) designate a subset of the Select Agent List (Tier 1) that presents the greatest risk of deliberate misuse with most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence;

(b) explore options for graded protection of Tier 1 agents and toxins as described in subsection (a) of this section to permit tailored risk management practices based upon relevant contextual factors; and

(c) consider reducing the overall number of agents and toxins on the Select Agent List.

SEC. 5. *Revision of Regulations, Rules, and Guidance to Accommodate a Tiered Select Agent List*. Consistent with section 4 of this order, I request that:

(a) The Secretaries of Health and Human Services and Agriculture, no later than 15 months from the date of this order, propose amendments to their respective parts of the SAR that would establish security standards specific to Tier 1 agents and toxins.

(b) The Secretaries of Health and Human Services and Agriculture each, no later than 27 months from the date of this order, promulgate final rules and guidance that clearly articulate security actions for registrants who possess, use, or transfer Tier 1 agents and toxins.

SEC. 6. *Coordination of Federal Oversight for BSAT Security*. To ensure that the policies and practices used to secure BSAT are harmonized and that the related oversight activities of the Federal Government are coordinated, the heads of executive departments and agencies identified in section 7(a)(ii) of this order shall:

(a) no later than 6 months from the date of this order, develop and implement a plan for the coordination of BSAT security oversight that:

(i) articulates a mechanism for coordinated and reciprocal inspection of and harmonized administrative practices for facilities registered with the SAP;

(ii) ensures consistent and timely identification and resolution of BSAT security and compliance issues;

(iii) facilitates information sharing among departments and agencies regarding ongoing oversight and inspection activities; and

(iv) provides for comprehensive and effective Federal oversight of BSAT security; and

(b) no later than 6 months from the issuance of final rules and guidance as described in section 5 of this order, and annually thereafter, review for inconsistent requirements and revise or rescind, as appropriate, any regulations, directives, guidance, or policies regarding BSAT security within their department or agency that exceed those in the updated SAR and guidance as described in section 5 of this order.

SEC. 7. *Implementation*. (a) Establishment, Operation, and Functions of the Federal Experts Security Advisory Panel.

(i) There is hereby established, within the Department of Health and Human Services for administrative purposes only, the Federal Experts Security Advisory Panel (Panel), which shall make technical and substantive recommendations on BSAT security concerning the SAP.

(ii) The Panel shall consist of representatives from the following, who may consult with additional experts from their department or agency as required:

1. the Department of State;
2. the Department of Defense;
3. the Department of Justice;
4. the Department of Agriculture (Co-Chair);
5. the Department of Commerce;
6. the Department of Health and Human Services (Co-Chair);
7. the Department of Transportation;
8. the Department of Labor;
9. the Department of Energy;
10. the Department of Veterans Affairs;
11. the Department of Homeland Security;
12. the Environmental Protection Agency;
13. the Office of the Director of National Intelligence;
14. the Office of Science and Technology Policy;
15. the Joint Chiefs of Staff; and
16. any other department or agency designated by the Co-Chairs.

(iii) To assist the Secretaries of Health and Human Services and Agriculture and the Attorney General in implementing the policies set forth in sections 1, 4, 5, and 6 of this order, the Panel shall, no later than 4 months from the date of this order, provide consensus recommendations concerning the SAP on:

1. the designation of Tier 1 agents and toxins;
2. reduction in the number of agents on the Select Agent List;
3. the establishment of appropriate practices to ensure reliability of personnel with access to Tier 1 agents and toxins at registered facilities;
4. the establishment of appropriate practices for physical security and cyber security for facilities that possess Tier 1 agents. The Department of Homeland Security shall Chair a Working Group of the Panel that develops recommended laboratory critical infrastructure security standards in these areas; and
5. other emerging policy issues relevant to the security of BSAT.

Thereafter, the Panel shall continue to provide technical advice concerning the SAP on request.

(iv) If the Panel is unable to reach consensus on recommendations for an issue within its charge, the matter shall be resolved through the interagency policy committee process led by the National Security Staff.

(v) The Secretaries of Health and Human Services and Agriculture and the Attorney General shall report to the Assistant to the President for Homeland Security and Counterterrorism on the consideration and implementation of Panel recommendations concerning the SAP, including a rationale for failure to implement any recommendations.

(vi) The Panel shall be chartered for a period of 4 years subject to renewal through the interagency policy committee process led by the National Security Staff.

(b) To further assist the Secretaries of Health and Human Services and Agriculture and the Attorney General in implementing the policy set forth in sections 1, 4, 5, and 6 of this order, the National Science Advisory Board for Biosecurity shall provide technical advice and serve as a conduit for public consultation, as needed, on topics of relevance to the SAP.

SEC. 8. *Sharing of Select Agent Program Information*. (a) Consistent with applicable laws and regulations, the Secretaries of Health and Human Services and Agriculture and the Attorney General shall, no later than 6 months from the date of this order, develop a process and the criteria for making SAP information available to executive departments and agencies when such information is necessary for furthering a public health, safety, security, law enforcement, or national security mission.

(b) SAP information shall continue to be safeguarded properly and handled securely to minimize the risk of disclosing sensitive, personal, and other information protected by the Privacy Act, 5 U.S.C. 552a.

SEC. 9. *General Provisions*. (a) The National Security Staff shall, on a biennial basis, review the implementation and effectiveness of this order and refer to the interagency policy committee process any issues that require further deliberation or adjudication.

(b) Nothing in this order shall be construed to impair or otherwise affect the authority granted by law to a department or agency, or the head thereof, or functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(c) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(d) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

BARACK OBAMA.

[Reference to the National Security Staff deemed to be a reference to the National Security Council Staff, see Ex. Ord. No. 13657, set out as a note under section 3021 of Title 50, War and National Defense.]

[1] So in original. Probably should be "judicial".

[2] So in original. Probably should be "section".

42 USC 263: Preparation of biological products by Service
Text contains those laws in effect on April 14, 2025

From Title 42-THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A-PUBLIC HEALTH SERVICE
SUBCHAPTER II-GENERAL POWERS AND DUTIES
Part F-Licensing of Biological Products and Clinical Laboratories
subpart 1-biological products

Jump To:

1944 PHSA Sec. 352 = 42 USC 263

§263. Preparation of biological products by Service

(a) The Service may prepare for its own use any product described in section 262 of this title and any product necessary to carrying out any of the purposes of section 241 of this title.
(b) The Service may prepare any product described in section 262 of this title for the use of other Federal departments or agencies, and public or private agencies and individuals engaged in work in the field of medicine when such product is not available from establishments licensed under such section.

(July 1, 1944, ch. 373, title III, §352, 58 Stat. 703 .)

Statutory Notes and Related Subsidiaries

Change of Name

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

Executive Documents

Transfer of Functions

Functions of Public Health Service, Surgeon General of Public Health Service, and all other officers and employees of Public Health Service, and functions of all agencies of or in Public Health Service transferred to Secretary of Health, Education, and Welfare by Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, set out as a note under section 202 of this title.

42 USC 263-1: Education on biological products
Text contains those laws in effect on April 14, 2025

From Title 42-THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A-PUBLIC HEALTH SERVICE
SUBCHAPTER II-GENERAL POWERS AND DUTIES
Part F-Licensing of Biological Products and Clinical Laboratories
subpart 1-biological products

Jump To:
Source Credit

1944 PHSA Sec 352A = 42 USC 263-1
Added 2021

§263–1. Education on biological products

(a) Internet website

(1) In general

The Secretary may maintain and operate an internet website to provide educational materials for health care providers, patients, and caregivers, regarding the meaning of the terms, and the standards for review and licensing of, biological products, including biosimilar biological products and interchangeable biosimilar biological products.

(2) Content

Educational materials provided under paragraph (1) may include-

(A) explanations of key statutory and regulatory terms, including "biosimilar" and "interchangeable", and clarification regarding the use of interchangeable biosimilar biological products;

(B) information related to development programs for biological products, including biosimilar biological products and interchangeable biosimilar biological products and relevant clinical considerations for prescribers, which may include, as appropriate and applicable, information related to the comparability of such biological products;

(C) an explanation of the process for reporting adverse events for biological products, including biosimilar biological products and interchangeable biosimilar biological products; and

(D) an explanation of the relationship between biosimilar biological products and interchangeable biosimilar biological products licensed under section 262(k) of this title and reference products (as defined in section 262(i) of this title), including the standards for review and licensing of each such type of biological product.

(3) Format

The educational materials provided under paragraph (1) may be-

(A) in formats such as webinars, continuing education modules, videos, fact sheets, infographics, stakeholder toolkits, or other formats as appropriate and applicable; and

(B) tailored for the unique needs of health care providers, patients, caregivers, and other audiences, as the Secretary determines appropriate.

(4) Other information

In addition to the information described in paragraph (2), the Secretary shall continue to publish-

(A) the action package of each biological product licensed under subsection (a) or (k) of section 262 of this title; or

(B) the summary review of each biological product licensed under subsection (a) or (k) of section 262 of this title.

(5) Confidential and trade secret information

This subsection does not authorize the disclosure of any trade secret, confidential commercial or financial information, or other matter described in section 552(b) of title 5.

(b) Continuing education

The Secretary shall advance education and awareness among health care providers regarding biological products, including biosimilar biological products and interchangeable biosimilar biological products, as appropriate, including by developing or improving continuing education programs that advance the education of such providers on the prescribing of, and relevant clinical considerations with respect to, biological products, including biosimilar biological products and interchangeable biosimilar biological products.

(July 1, 1944, ch. 373, title III, §352A, as added Pub. L. 117–8, §2, Apr. 23, 2021, 135 Stat. 254 .)

1938 FDCA as of April 2025, highlighting addition, under SubCh V Part E, of Emergency Use Authorization, 21 USC 360bbb-3, added 2003.

Title 21 FOOD AND DRUGS -
Chapter 9 - Federal Food Drug and Cosmetic Act (FDCA)
Subchapter V - Drugs and Devices
Part E - General Provisions Relating to Drugs and Devices
Sections 360bbb through 360bbb-8das of April 15, 2025

Highlighting:
21 USC 360bbb - Expanded access to unapproved therapies and diagnostics
21 USC 360bbb-3 - Authorization for medical products for use in emergencies

21 USC CHAPTER 9, SUBCHAPTER V, Part E: General Provisions Relating to Drugs and Devices

From Title 21—FOOD AND DRUGS
CHAPTER 9—FEDERAL FOOD, DRUG, AND COSMETIC ACT
SUBCHAPTER V—DRUGS AND DEVICES

PART E—GENERAL PROVISIONS RELATING TO DRUGS AND DEVICES

FDCA Sec. 351 = 21 USC 360bbb
Expanded access, added 1997

§360bbb. Expanded access to unapproved therapies and diagnostics

(a) Emergency situations

The Secretary may, under appropriate conditions determined by the Secretary, authorize the shipment of investigational drugs or investigational devices for the diagnosis, monitoring, or treatment of a serious disease or condition in emergency situations.

(b) Individual patient access to investigational products intended for serious diseases

Any person, acting through a physician licensed in accordance with State law, may request from a manufacturer or distributor, and any manufacturer or distributor may, after complying with the provisions of this subsection, provide to such physician an investigational drug or investigational device for the diagnosis, monitoring, or treatment of a serious disease or condition if—

(1) the licensed physician determines that the person has no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat the disease or condition involved, and that the probable risk to the person from the investigational drug or investigational device is not greater than the probable risk from the disease or condition;

(2) the Secretary determines that there is sufficient evidence of safety and effectiveness to support the use of the investigational drug or investigational device in the case described in paragraph (1);

(3) the Secretary determines that provision of the investigational drug or investigational device will not interfere with the initiation, conduct, or completion of clinical investigations to support marketing approval; and

(4) the sponsor, or clinical investigator, of the investigational drug or investigational device submits to the Secretary a clinical protocol consistent with the provisions of section 355(i) or 360j(g) of this title, including any regulations promulgated under section 355(i) or 360j(g) of this title, describing the use of the investigational drug or investigational device in a single patient or a small group of patients.

(c) Treatment investigational new drug applications and treatment investigational device exemptions

Upon submission by a sponsor or a physician of a protocol intended to provide widespread access to an investigational drug or investigational device for eligible patients (referred to in this subsection as an "expanded access protocol"), the Secretary shall permit such investigational drug or investigational device to be made available for expanded access under a treatment investigational new drug application or treatment investigational device exemption if the Secretary determines that—

(1) under the treatment investigational new drug application or treatment investigational device exemption, the investigational drug or investigational device is intended for use in the diagnosis, monitoring, or treatment of a serious or immediately life-threatening disease or condition;

(2) there is no comparable or satisfactory alternative therapy available to diagnose, monitor, or treat that stage of disease or condition in the population of patients to which the investigational drug or investigational device is intended to be administered;

(3)(A) the investigational drug or investigational device is under investigation in a controlled clinical trial for the use described in paragraph (1) under an investigational drug application in effect under section 355(i) of this title or investigational device exemption in effect under section 360j(g) of this title; or

(B) all clinical trials necessary for approval of that use of the investigational drug or investigational device have been completed;

(4) the sponsor of the controlled clinical trials is actively pursuing marketing approval of the investigational drug or investigational device for the use described in paragraph (1) with due diligence;

(5) in the case of an investigational drug or investigational device described in paragraph (3)(A), the provision of the investigational drug or investigational device will not interfere with the enrollment of patients in ongoing clinical investigations under section 355(i) or 360j(g) of this title;

(6) in the case of serious diseases, there is sufficient evidence of safety and effectiveness to support the use described in paragraph (1); and

(7) in the case of immediately life-threatening diseases, the available scientific evidence, taken as a whole, provides a reasonable basis to conclude that the investigational drug or investigational device may be effective for its intended use and would not expose patients to an unreasonable and significant risk of illness or injury.

A protocol submitted under this subsection shall be subject to the provisions of section 355(i) or 360j(g) of this title, including regulations promulgated under section 355(i) or 360j(g) of this title. The Secretary may inform national, State, and local medical associations and societies, voluntary health associations, and other appropriate persons about the availability of an investigational drug or investigational device under expanded access protocols submitted under this subsection. The information provided by the Secretary, in accordance with the preceding sentence, shall be the same type of information that is required by section 282(i)(3) of title 42.

(d) Termination

The Secretary may, at any time, with respect to a sponsor, physician, manufacturer, or distributor described in this section, terminate expanded access provided under this section for an investigational drug or investigational device if the requirements under this section are no longer met.

(e) Definitions

In this section, the terms "investigational drug", "investigational device", "treatment investigational new drug application", and "treatment investigational device exemption" shall have the meanings given the terms in regulations prescribed by the Secretary.

(June 25, 1938, ch. 675, §561, as added Pub. L. 105–115, title IV, §402, Nov. 21, 1997, 111 Stat. 2365; amended Pub. L. 109–482, title I, §102(f)(2), Jan. 15, 2007, 120 Stat. 3685.)

EDITORIAL NOTES

AMENDMENTS

2007—Subsec. (c). Pub. L. 109–482 substituted "section 282(i)(3)" for "section 282(j)(3)" in concluding provisions.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE OF 2007 AMENDMENT

Amendment by Pub. L. 109–482 applicable only with respect to amounts appropriated for fiscal year 2007 or subsequent fiscal years, see section 109 of Pub. L. 109–482, set out as a note under section 281 of Title 42, The Public Health and Welfare.

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

INVESTIGATIONAL DRUGS

Pub. L. 115–52, title VI, §610(a), (b), Aug. 18, 2017, 131 Stat. 1051, 1053, provided that:

"(a) PATIENT ACCESS TO INVESTIGATIONAL DRUGS.—

"(1) PUBLIC MEETING.—

"(A) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the 'Secretary'), acting through the Commissioner of Food and Drugs, in coordination with the Director of the National Institutes of Health, and in consultation with patients, health care providers, drug sponsors, bioethicists, and other stakeholders, shall, not later than 270 days after the date of enactment of this Act [Aug. 18, 2007], convene a public meeting to discuss clinical trial inclusion and exclusion criteria to inform the guidance under paragraph (3). The Secretary shall inform the Comptroller General of the United States of the date when the public meeting will take place.

"(B) TOPICS.—The Secretary shall make available on the internet website of the Food and Drug Administration a report on the topics discussed at the meeting described in subparagraph (A) within 90 days of such meeting. Such topics shall include discussion of—

"(i) the rationale for, and potential barriers for patients created by, research clinical trial inclusion and exclusion criteria;

"(ii) how appropriate patient populations can benefit from the results of trials that employ alternative designs;

"(iii) barriers to participation in clinical trials, including—

"(I) information regarding any potential risks and benefits of participation;

"(II) regulatory, geographical, and socioeconomic barriers; and

"(III) the impact of exclusion criteria on the enrollment in clinical trials of particular populations, including infants and children, pregnant and lactating women, seniors, individuals with advanced disease, and individuals with co-morbid conditions;

"(iv) clinical trial designs and methods, including expanded access trials, that increase enrollment of more diverse patient populations, when appropriate, while facilitating the collection of data to establish safe use and support substantial evidence of effectiveness, including data obtained from expanded access trials; and

"(v) how changes to clinical trial inclusion and exclusion criteria may impact the complexity and length of clinical trials, the data necessary to demonstrate safety and effectiveness, and potential approaches to mitigating those impacts.

"(2) REPORT.—Not later than 1 year after the Secretary issues the report under paragraph (1)(B), the Comptroller General of the United States shall report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on individual access to investigational drugs through the expanded access program under section 561(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb(b)). The report shall include—

"(A) a description of actions taken by manufacturers and distributors under section 561A of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–0);

"(B) consideration of whether Form FDA 3926 and the guidance documents titled 'Expanded Access to Investigational Drugs for Treatment Use—Questions and Answers' and

'Individual Patient Expanded Access Applications: Form FDA 3926', issued by the Food and Drug Administration in June 2016, have reduced application burden with respect to individuals and physicians seeking access to investigational new drugs pursuant to section 561(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) and improved clarity for patients, physicians, and drug manufacturers about such process;

"(C) consideration of whether the guidance or regulations issued to implement section 561 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb) have improved access for individual patients to investigational drugs who do not qualify for clinical trials of such investigational drugs, and what barriers to such access remain;

"(D) an assessment of methods patients and health care providers use to engage with the Food and Drug Administration or drug sponsors on expanded access; and

"(E) an analysis of the Secretary's report under paragraph (1)(B).

"(3) GUIDANCE.—

"(A) IN GENERAL.—Not later than 1 year after the publication of the report under paragraph (1)(B), the Secretary, acting through the Commissioner of Food and Drugs, shall issue one or more draft guidances regarding eligibility criteria for clinical trials. Not later than 1 year after the public comment period on each such draft guidance ends, the Secretary shall issue a revised draft guidance or final guidance.

"(B) CONTENTS.—The guidance documents described in subparagraph (A) shall address methodological approaches that a manufacturer or sponsor of an investigation of a new drug may take to—

"(i) broaden eligibility criteria for clinical trials and expanded access trials, especially with respect to drugs for the treatment of serious and life-threatening conditions or diseases for which there is an unmet medical need;

"(ii) develop eligibility criteria for, and increase trial recruitment to, clinical trials so that enrollment in such trials more accurately reflects the patients most likely to receive the drug, as applicable and as appropriate, while establishing safe use and supporting findings of substantial evidence of effectiveness; and

"(iii) use the criteria described in clauses (i) and (ii) in a manner that is appropriate for drugs intended for the treatment of rare diseases or conditions.

"(b) IMPROVING INSTITUTIONAL REVIEW BOARD REVIEW OF SINGLE PATIENT EXPANDED ACCESS PROTOCOL.—Not later than 1 year after the date of enactment of this Act [Aug. 18, 2017], the Secretary, acting through the Commissioner of Food and Drugs, shall issue guidance or regulations, or revise existing guidance or regulations, to streamline the institutional review board review of individual patient expanded access protocols submitted under [section] 561(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb(b)). To facilitate the use of expanded access protocols, any guidance or regulations so issued or revised may include a description of the process for any person acting through a physician licensed in accordance with State law to request that an institutional review board chair (or designated member of the institutional review board) review a single patient expanded access protocol submitted under such section 561(b) for a drug. The Secretary shall update any relevant forms associated with individual patient expanded access requests under such section 561(b) as necessary."

§360bbb–0. Expanded access policy required for investigational drugs

(a) In general

The manufacturer or distributor of one or more investigational drugs for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions shall make available the policy of the manufacturer or distributor on evaluating and responding to requests submitted under section 360bbb(b) of this title for provision of such a drug.

(b) Public availability of expanded access policy

The policies under subsection (a) shall be made public and readily available, such as by posting such policies on a publicly available Internet website. Such policies may be generally applicable to all investigational drugs of such manufacturer or distributor.

(c) Content of policy

A policy described in subsection (a) shall include—

(1) contact information for the manufacturer or distributor to facilitate communication about requests described in subsection (a);

(2) procedures for making such requests;

(3) the general criteria the manufacturer or distributor will use to evaluate such requests for individual patients, and for responses to such requests;

(4) the length of time the manufacturer or distributor anticipates will be necessary to acknowledge receipt of such requests; and

(5) a hyperlink or other reference to the clinical trial record containing information about the expanded access for such drug that is required under section 282(j)(2)(A)(ii)(II)(gg) of title 42.

(d) No guarantee of access

The posting of policies by manufacturers and distributors under subsection (a) shall not serve as a guarantee of access to any specific investigational drug by any individual patient.

(e) Revised policy

Nothing in this section shall prevent a manufacturer or distributor from revising a policy required under this section at any time.

(f) Application

This section shall apply to a manufacturer or distributor with respect to an investigational drug beginning on the earlier of—

(1) the first initiation of a phase 2 or phase 3 study (as such terms are defined in section 312.21(b) and (c) of title 21, Code of Federal Regulations (or any successor regulations)) with respect to such investigational drug; or

(2) as applicable, 15 days after the drug receives a designation as a breakthrough therapy, fast track product, or regenerative advanced therapy under subsection (a), (b), or (g), respectively, of section 356 of this title.

(June 25, 1938, ch. 675, §561A, as added Pub. L. 114–255, div. A, title III, §3032, Dec. 13, 2016, 130 Stat. 1100; amended Pub. L. 115–52, title VI, §610(c), Aug. 18, 2017, 131 Stat. 1053.)

EDITORIAL NOTES

AMENDMENTS

2017—Subsec. (f). Pub. L. 115–52 substituted "earlier" for "later" in introductory provisions, added par. (2), redesignated former par. (2) as (1), and struck out former par. (1) which read as follows: "the date that is 60 calendar days after December 13, 2016; or".

§360bbb–0a. Investigational drugs for use by eligible patients

(a) Definitions

For purposes of this section—

(1) the term "eligible patient" means a patient—

(A) who has been diagnosed with a life-threatening disease or condition (as defined in section 312.81 of title 21, Code of Federal Regulations (or any successor regulations));

(B) who has exhausted approved treatment options and is unable to participate in a clinical trial involving the eligible investigational drug, as certified by a physician, who—

(i) is in good standing with the physician's licensing organization or board; and

(ii) will not be compensated directly by the manufacturer for so certifying; and

(C) who has provided to the treating physician written informed consent regarding the eligible investigational drug, or, as applicable, on whose behalf a legally authorized representative of the patient has provided such consent;

(2) the term "eligible investigational drug" means an investigational drug (as such term is used in section 360bbb of this title)—

(A) for which a Phase 1 clinical trial has been completed;

(B) that has not been approved or licensed for any use under section 355 of this title or section 351 of the Public Health Service Act [42 U.S.C. 262];

(C)(i) for which an application has been filed under section 355(b) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)]; or

(ii) that is under investigation in a clinical trial that—

(I) is intended to form the primary basis of a claim of effectiveness in support of approval or licensure under section 355 of this title or section 351 of the Public Health Service Act [42 U.S.C. 262]; and

(II) is the subject of an active investigational new drug application under section 355(i) of this title or section 351(a)(3) of the Public Health Service Act [42 U.S.C. 262(a)(3)], as applicable; and

(D) the active development or production of which is ongoing and has not been discontinued by the manufacturer or placed on clinical hold under section 355(i) of this title; and

(3) the term "phase 1 trial" means a phase 1 clinical investigation of a drug as described in section 312.21 of title 21, Code of Federal Regulations (or any successor regulations).

(b) Exemptions

Eligible investigational drugs provided to eligible patients in compliance with this section are exempt from sections 352(f), 353(b)(4), 355(a), and 355(i) of this title, section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)], and parts 50, 56, and 312 of title 21, Code of Federal Regulations (or any successor regulations), provided that the sponsor of such eligible investigational drug or any person who manufactures, distributes, prescribes, dispenses, introduces or delivers for introduction into interstate commerce, or provides to an eligible patient an eligible investigational drug pursuant to this section is in compliance with the applicable requirements set forth in sections 312.6, 312.7, and 312.8(d)(1) of title 21, Code of Federal Regulations (or any successor regulations) that apply to investigational drugs.

(c) Use of clinical outcomes

(1) In general

Notwithstanding any other provision of this chapter, the Public Health Service Act [42 U.S.C. 201 et seq.], or any other provision of Federal law, the Secretary may not use a clinical outcome associated with the use of an eligible investigational drug pursuant to this section to delay or adversely affect the review or approval of such drug under section 355 of this title or section 351 of the Public Health Service Act [42 U.S.C. 262] unless—

(A) the Secretary makes a determination, in accordance with paragraph (2), that use of such clinical outcome is critical to determining the safety of the eligible investigational drug; or

(B) the sponsor requests use of such outcomes.

(2) Limitation

If the Secretary makes a determination under paragraph (1)(A), the Secretary shall provide written notice of such determination to the sponsor, including a public health justification for such determination, and such notice shall be made part of the administrative record. Such determination shall not be delegated below the director of the agency center that is charged with the premarket review of the eligible investigational drug.

(d) Reporting

(1) In general

The manufacturer or sponsor of an eligible investigational drug shall submit to the Secretary an annual summary of any use of such drug under this section. The summary shall include the number of doses supplied, the number of patients treated, the uses for which the drug was made available, and any known serious adverse events. The Secretary shall specify by regulation the deadline of submission of such annual summary and may amend section 312.33 of title 21, Code of Federal Regulations (or any successor regulations) to require the submission of such annual summary in conjunction with the annual report for an applicable investigational new drug application for such drug.

(2) Posting of information

The Secretary shall post an annual summary report of the use of this section on the internet website of the Food and Drug Administration, including the number of drugs for which clinical outcomes associated with the use of an eligible investigational drug pursuant to this section was—

(A) used in accordance with subsection (c)(1)(A);

(B) used in accordance with subsection (c)(1)(B); and

(C) not used in the review of an application under section 355 of this title or section 351 of the Public Health Service Act [42 U.S.C. 262].

(June 25, 1938, ch. 675, §561B, as added Pub. L. 115–176, §2(a), May 30, 2018, 132 Stat. 1372.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (c)(1), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

STATUTORY NOTES AND RELATED SUBSIDIARIES

LIMITATION OF LIABILITY

Pub. L. 115–176, §2(b), May 30, 2018, 132 Stat. 1374, provided that:

"(1) ALLEGED ACTS OR OMISSIONS.—With respect to any alleged act or omission with respect to an eligible investigational drug provided to an eligible patient pursuant to section 561B of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–0a] and in compliance with such section, no liability in a cause of action shall lie against—

"(A) a sponsor or manufacturer; or

"(B) a prescriber, dispenser, or other individual entity (other than a sponsor or manufacturer), unless the relevant conduct constitutes reckless or willful misconduct, gross negligence, or an intentional tort under any applicable State law.

"(2) DETERMINATION NOT TO PROVIDE DRUG.—No liability shall lie against a sponsor manufacturer, prescriber, dispenser or other individual entity for its determination not to provide access to an eligible investigational drug under section 561B of the Federal Food, Drug, and Cosmetic Act.

"(3) LIMITATION.—Except as set forth in paragraphs (1) and (2), nothing in this section shall be construed to modify or otherwise affect the right of any person to bring a private action under any State or Federal product liability, tort, consumer protection, or warranty law."

§360bbb–1. Dispute resolution

If, regarding an obligation concerning drugs or devices under this Act or section 351 of the Public Health Service Act [42 U.S.C. 262], there is a scientific controversy between the Secretary and a person who is a sponsor, applicant, or manufacturer and no specific provision of the Act involved, including a regulation promulgated under such Act, provides a right of review of the matter in controversy, the Secretary shall, by regulation, establish a procedure under which such sponsor, applicant, or manufacturer may request a review of such controversy, including a review by an appropriate scientific advisory panel described in section 355(n) of this title or an advisory committee described in section 360e(g)(2)(B) of this title. Any such review shall take place in a timely manner. The Secretary shall promulgate such regulations within 1 year after November 21, 1997.

(June 25, 1938, ch. 675, §562, as added Pub. L. 105–115, title IV, §404, Nov. 21, 1997, 111 Stat. 2368.)

EDITORIAL NOTES

REFERENCES IN TEXT

This Act, referred to in text, is the Federal Food, Drug, and Cosmetic Act, act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to this chapter. For complete classification of this Act to the Code, see section 301 of this title and Tables.

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

§360bbb–2. Classification of products

(a) Request

A person who submits an application or submission (including a petition, notification, and any other similar form of request) under this chapter for a product, may submit a request to the Secretary respecting the classification of the product as a drug, biological product, device, or a combination product subject to section 353(g) of this title or respecting the component of the Food and Drug Administration that will regulate the product. In submitting the request, the person shall recommend a classification for the product, or a component to regulate the product, as appropriate.

(b) Statement

Not later than 60 days after the receipt of the request described in subsection (a), the Secretary shall determine the classification of the product under subsection (a), or the component of the Food and Drug Administration that will regulate the product, and shall provide to the person a written statement that identifies such classification or such component, and the reasons for such determination. The Secretary may not modify such statement except with the written consent of the person, or for public health reasons based on scientific evidence.

(c) Inaction of Secretary

If the Secretary does not provide the statement within the 60-day period described in subsection (b), the recommendation made by the person under subsection (a) shall be considered to be a final determination by the Secretary of such classification of the product, or the component of the Food and Drug Administration that will regulate the product, as applicable, and may not be modified by the Secretary except with the written consent of the person, or for public health reasons based on scientific evidence.

(June 25, 1938, ch. 675, §563, as added Pub. L. 105–115, title IV, §416, Nov. 21, 1997, 111 Stat. 2378.)

STATUTORY NOTES AND RELATED SUBSIDIARIES

EFFECTIVE DATE

Section effective 90 days after Nov. 21, 1997, except as otherwise provided, see section 501 of Pub. L. 105–115, set out as an Effective Date of 1997 Amendment note under section 321 of this title.

FDCA Sec. 564 = 21 USC 360bbb-3
Emergency Use Authorization (EUA)
Added 2003

§360bbb–3. Authorization for medical products for use in emergencies

(a) In general

(1) Emergency uses

Notwithstanding any provision of this chapter and section 351 of the Public Health Service Act [42 U.S.C. 262], and subject to the provisions of this section, the Secretary may authorize the introduction into interstate commerce, during the effective period of a declaration under subsection (b), of a drug, device, or biological product intended for use in an actual or potential emergency (referred to in this section as an "emergency use").

(2) Approval status of product

An authorization under paragraph (1) may authorize an emergency use of a product that—

(A) is not approved, licensed, or cleared for commercial distribution under section 355, 360(k), 360b, or 360e of this title or section 351 of the Public Health Service Act [42 U.S.C. 262] or conditionally approved under section 360ccc of this title (referred to in this section as an "unapproved product"); or

(B) is approved, conditionally approved under section 360ccc of this title, licensed, or cleared under such a provision, but which use is not under such provision an approved, conditionally approved under section 360ccc of this title, licensed, or cleared use of the product (referred to in this section as an "unapproved use of an approved product").

(3) Relation to other uses

An emergency use authorized under paragraph (1) for a product is in addition to any other use that is authorized for the product under a section of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.] referred to in paragraph (2)(A).

(4) Definitions

For purposes of this section:

(A) The term "biological product" has the meaning given such term in section 351 of the Public Health Service Act [42 U.S.C. 262].
(B) The term "emergency use" has the meaning indicated for such term in paragraph (1).
(C) The term "product" means a drug, device, or biological product.
(D) The term "unapproved product" has the meaning indicated for such term in paragraph (2)(A).
(E) The term "unapproved use of an approved product" has the meaning indicated for such term in paragraph (2)(B).

(b) Declaration of emergency or threat justifying emergency authorized use

(1) In general

The Secretary may make a declaration that the circumstances exist justifying the authorization under this subsection for a product on the basis of—

(A) a determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a biological, chemical, radiological, or nuclear agent or agents;

(B) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with—

(i) a biological, chemical, radiological, or nuclear agent or agents; or
(ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces;

(C) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a biological, chemical, radiological, or nuclear agent or agents, or a disease or condition that may be attributable to such agent or agents; or

(D) the identification of a material threat pursuant to section 319F–2 of the Public Health Service Act [42 U.S.C. 247d–6b] sufficient to affect national security or the health and security of United States citizens living abroad.

(2) Termination of declaration

(A) In general

A declaration under this subsection shall terminate upon the earlier of—

(i) a determination by the Secretary, in consultation as appropriate with the Secretary of Homeland Security or the Secretary of Defense, that the circumstances described in paragraph (1) have ceased to exist; or
(ii) a change in the approval status of the product such that the circumstances described in subsection (a)(2) have ceased to exist.

(B) Disposition of product

If an authorization under this section with respect to an unapproved product ceases to be effective as a result of a termination under subparagraph (A) of this paragraph, the Secretary shall consult with the manufacturer of such product with respect to the appropriate disposition of the product.

(3) Advance notice of termination

The Secretary shall provide advance notice that a declaration under this subsection will be terminated. The period of advance notice shall be a period reasonably determined to provide—

(A) in the case of an unapproved product, a sufficient period for disposition of the product, including the return of such product (except such quantities of product as are necessary to provide for continued use consistent with subsection (f)(2)) to the manufacturer (in the case of a manufacturer that chooses to have such product returned); and
(B) in the case of an unapproved use of an approved product, a sufficient period for the disposition of any labeling, or any information under subsection (e)(2)(B)(ii), as the case may be, that was provided with respect to the emergency use involved.

(4) Publication

The Secretary shall promptly publish in the Federal Register each declaration, determination, and advance notice of termination under this subsection.

(5) Explanation by Secretary

If an authorization under this section with respect to an unapproved product or an unapproved use of an approved product has been in effect for more than 1 year, the Secretary shall provide in writing to the sponsor of such product an explanation of the scientific, regulatory, or other obstacles to approval, licensure, or clearance of such product or use, including specific actions to be taken by the Secretary and the sponsor to overcome such obstacles.

(6) Military emergencies

In the case of a determination described in paragraph (1)(B), the Secretary shall determine, within 45 calendar days of such determination, whether to make a declaration under paragraph (1), and, if appropriate, shall promptly make such a declaration.

(c) Criteria for issuance of authorization

The Secretary may issue an authorization under this section with respect to the emergency use of a product only if, after consultation with the Assistant Secretary for Preparedness and Response, the Director of the National Institutes of Health, and the Director of the Centers for Disease Control and Prevention (to the extent feasible and appropriate given the applicable circumstances described in subsection (b)(1)), the Secretary concludes—

(1) that an agent referred to in a declaration under subsection (b) can cause a serious or life-threatening disease or condition;
(2) that, based on the totality of scientific evidence available to the Secretary, including data from adequate and well-controlled clinical trials, if available, it is reasonable to believe that—
(A) the product may be effective in diagnosing, treating, or preventing—
(i) such disease or condition; or
(ii) a serious or life-threatening disease or condition caused by a product authorized under this section, approved or cleared under this chapter, or licensed under section 351 of the Public Health Service Act [42 U.S.C. 262], for diagnosing, treating, or preventing such a disease or condition caused by such an agent; and

(B) the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product, taking into consideration the material threat posed by the agent or agents identified in a declaration under subsection (b)(1)(D), if applicable;

(3) that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition;
(4) in the case of a determination described in subsection (b)(1)(B)(ii), that the request for emergency use is made by the Secretary of Defense; and
(5) that such other criteria as the Secretary may by regulation prescribe are satisfied.

(d) Scope of authorization

An authorization of a product under this section shall state—

(1) each disease or condition that the product may be used to diagnose, prevent, or treat within the scope of the authorization;
(2) the Secretary's conclusions, made under subsection (c)(2)(B), that the known and potential benefits of the product, when used to diagnose, prevent, or treat such disease or condition, outweigh the known and potential risks of the product; and
(3) the Secretary's conclusions, made under subsection (c), concerning the safety and potential effectiveness of the product in diagnosing, preventing, or treating such diseases or conditions, including, to the extent practicable given the circumstances of the emergency, an assessment of the available scientific evidence.

(e) Conditions of authorization

(1) Unapproved product

(A) Required conditions

With respect to the emergency use of an unapproved product, the Secretary, to the extent practicable given the applicable circumstances described in subsection (b)(1), shall, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) Appropriate conditions designed to ensure that health care professionals administering the product are informed—
(I) that the Secretary has authorized the emergency use of the product;
(II) of the significant known and potential benefits and risks of the emergency use of the product, and of the extent to which such benefits and risks are unknown; and
(III) of the alternatives to the product that are available, and of their benefits and risks.

(ii) Appropriate conditions designed to ensure that individuals to whom the product is administered are informed—
(I) that the Secretary has authorized the emergency use of the product;
(II) of the significant known and potential benefits and risks of such use, and of the extent to which such benefits and risks are unknown; and
(III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.

(iii) Appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the product.
(iv) For manufacturers of the product, appropriate conditions concerning recordkeeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

(B) Authority for additional conditions

With respect to the emergency use of an unapproved product, the Secretary may, for a person who carries out any activity for which the authorization is issued, establish such conditions on an authorization under this section as the Secretary finds necessary or appropriate to protect the public health, including the following:

(i) Appropriate conditions on which entities may distribute the product with respect to the emergency use of the product (including limitation to distribution by government entities), and on how distribution is to be performed.

(ii) Appropriate conditions on who may administer the product with respect to the emergency use of the product, and on the categories of individuals to whom, and the circumstances under which, the product may be administered with respect to such use.

(iii) Appropriate conditions with respect to collection and analysis of information concerning the safety and effectiveness of the product with respect to the use of such product during the period when the authorization is in effect and a reasonable time following such period.

(iv) For persons other than manufacturers of the product, appropriate conditions concerning recordkeeping and reporting, including records access by the Secretary, with respect to the emergency use of the product.

(2) Unapproved use

With respect to the emergency use of a product that is an unapproved use of an approved product:

(A) For a person who carries out any activity for which the authorization is issued, the Secretary shall, to the extent practicable given the applicable circumstances described in subsection (b)(1), establish conditions described in clauses (i) and (ii) of paragraph (1)(A), and may establish conditions described in clauses (iii) and (iv) of such paragraph or in paragraph (1)(B).

(B)(i) If the authorization under this section regarding the emergency use authorizes a change in the labeling of the product, but the manufacturer of the product chooses not to make such change, such authorization may not authorize distributors of the product or any other person to alter or obscure the labeling provided by the manufacturer, except as provided in section 360bbb–3a of this title with respect to authorized changes to the product expiration date.

(ii) In the circumstances described in clause (i), for a person who does not manufacture the product and who chooses to act under this clause, an authorization under this section regarding the emergency use shall, to the extent practicable given the circumstances of the emergency, authorize such person to provide appropriate information with respect to such product in addition to the labeling provided by the manufacturer, subject to compliance with clause (i). While the authorization under this section is effective, such additional information shall not be considered labeling for purposes of section 352 of this title.

(C) In establishing conditions under this paragraph with respect to the distribution and administration of the product for the unapproved use, the Secretary shall not impose conditions that would restrict distribution or administration of the product when distributed or administered for the approved use.

(3) Good manufacturing practice; prescription

With respect to the emergency use of a product for which an authorization under this section is issued (whether an unapproved product or an unapproved use of an approved product), the Secretary may waive or limit, to the extent appropriate given the applicable circumstances described in subsection (b)(1)—

(A) requirements regarding current good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this chapter, including such requirements established under section 351 or 360j(f)(1) of this title, and including relevant conditions prescribed with respect to the product by an order under section 360j(f)(2) of this title;

(B) requirements established under subsection (b) or (f) of section 353 of this title or under section 354 of this title; and

(C) requirements established under section 360j(e) of this title.

(4) Advertising

The Secretary may establish conditions on advertisements and other promotional descriptive printed matter that relate to the emergency use of a product for which an authorization under this section is issued (whether an unapproved product or an unapproved use of an approved product), including, as appropriate—

(A) with respect to drugs and biological products, requirements applicable to prescription drugs pursuant to section 352(n) of this title; or

(B) with respect to devices, requirements applicable to restricted devices pursuant to section 352(r) of this title.

(f) Duration of authorization

(1) In general

Except as provided in paragraph (2), an authorization under this section shall be effective until the earlier of the termination of the declaration under subsection (b) or a revocation under subsection (g).

(2) Continued use after end of effective period

Notwithstanding the termination of the declaration under subsection (b) or a revocation under subsection (g), an authorization shall continue to be effective to provide for continued use of an unapproved product with respect to a patient to whom, or an animal to which, it was administered during the period described by paragraph (1), to the extent found necessary by such patient's attending physician or by the veterinarian caring for such animal, as applicable.

(g) Review and revocation of authorization

(1) Review

The Secretary shall periodically review the circumstances and the appropriateness of an authorization under this section. As part of such review, the Secretary shall regularly review the progress made with respect to the approval, conditional approval under section 360ccc of this title, licensure, or clearance of—

(A) an unapproved product for which an authorization was issued under this section; or

(B) an unapproved use of an approved product for which an authorization was issued under this section.

(2) Revision and revocation

The Secretary may revise or revoke an authorization under this section if—

(A) the circumstances described under subsection (b)(1) no longer exist;

(B) the criteria under subsection (c) for issuance of such authorization are no longer met; or

(C) other circumstances make such revision or revocation appropriate to protect the public health or safety.

(h) Publication; confidential information

(1) Publication

The Secretary shall promptly publish on the internet website of the Food and Drug Administration and in the Federal Register a notice of each authorization, and each termination or revocation of an authorization under this section, and an explanation of the reasons therefor (which may include a summary of data or information that has been submitted to the Secretary in an application, request, or submission under this section or section 355(b), 355(i), 355(j), 360b(b), 360b(j), 360b(n), 360e, 360(k), 360c(f)(2), 360j(g), 360j(m), 360ccc, or 360ccc–1 of this title, or section 351(a) or 351(k) of the Public Health Service Act [42 U.S.C. 262(a), (k)], even if such summary may reveal the existence of such an application, request, or submission, or data contained in such application, request, or submission). The Secretary shall make any revisions to an authorization under this section available on the Internet Web site of the Food and Drug Administration, which may include a summary of the data and information supporting such revisions.

(2) Confidential information

Nothing in this section alters or amends section 1905 of title 18 or section 552(b)(4) of title 5. Information made publicly available by the Secretary in accordance with paragraph (1) shall be considered a disclosure authorized by law for purposes of section 1905 of title 18 [1]

(i) Actions committed to agency discretion

Actions under the authority of this section by the Secretary, by the Secretary of Defense, or by the Secretary of Homeland Security are committed to agency discretion.

(j) Rules of construction

The following applies with respect to this section:

(1) Nothing in this section impairs the authority of the President as Commander in Chief of the Armed Forces of the United States under article II, section 2 of the United States Constitution.

(2) Nothing in this section impairs the authority of the Secretary of Defense with respect to the Department of Defense, including the armed forces, under other provisions of Federal law.

(3) Nothing in this section (including any exercise of authority by a manufacturer under subsection (e)(2)) impairs the authority of the United States to use or manage quantities of a product that are owned or controlled by the United States (including quantities in the stockpile maintained under section 319F–2 of the Public Health Service Act [42 U.S.C. 247d–6b]).

(4) Nothing in this section shall be construed as authorizing a delay in the review or other consideration by the Secretary of any application or submission pending before the Food and Drug Administration for a product for which an authorization under this section is issued.

(k) Relation to other provisions

If a product is the subject of an authorization under this section, the use of such product within the scope of the authorization shall not be considered to constitute a clinical investigation for purposes of section 355(i), 360b(j), or 360j(g) of this title or any other provision of this chapter or section 351 of the Public Health Service Act [42 U.S.C. 262].

(l) Option to carry out authorized activities

Nothing in this section provides the Secretary any authority to require any person to carry out any activity that becomes lawful pursuant to an authorization under this section, and no person is required to inform the Secretary that the person will not be carrying out such activity, except that a manufacturer of a sole-source unapproved product authorized for emergency use shall report to the Secretary within a reasonable period of time after the issuance by the Secretary of such authorization if such manufacturer does not intend to carry out any activity under the authorization. This section only has legal effect on a person who carries out an activity for which an authorization under this section is issued. This section does not modify or affect activities carried out pursuant to other provisions of this chapter or section 351 of the Public Health Service Act [42 U.S.C. 262]. Nothing in this subsection may be construed as restricting the Secretary from imposing conditions on persons who carry out any activity pursuant to an authorization under this section.

(m) Categorization of laboratory tests associated with devices subject to authorization

(1) In general

In issuing an authorization under this section with respect to a device, the Secretary may, subject to the provisions of this section, determine that a laboratory examination or procedure associated with such device shall be deemed, for purposes of section 353 of the Public Health Service Act [42 U.S.C. 263a], to be in a particular category of examinations and procedures (including the category described by subsection (d)(3) of such section) if, based on the totality of scientific evidence available to the Secretary—

(A) such categorization would be beneficial to protecting the public health; and

(B) the known and potential benefits of such categorization under the circumstances of the authorization outweigh the known and potential risks of the categorization.

(2) Conditions of determination

The Secretary may establish appropriate conditions on the performance of the examination or procedure pursuant to such determination.

(3) Effective period

A determination under this subsection shall be effective for purposes of section 353 of the Public Health Service Act [42 U.S.C. 263a] notwithstanding any other provision of that section during the effective period of the relevant declaration under subsection (b).

(June 25, 1938, ch. 675, §564, as added Pub. L. 108–136, div. A, title XVI, §1603(a), Nov. 24, 2003, 117 Stat. 1684; amended Pub. L. 108–276, §4(a), July 21, 2004, 118 Stat. 853; Pub. L. 113–5, title III, §302(a), Mar. 13, 2013, 127 Stat. 179; Pub. L. 114–255, div. A, title III, §3088(a), Dec. 13, 2016, 130 Stat. 1148; Pub. L. 115–92, §1(a), Dec. 12, 2017, 131 Stat. 2023; Pub. L. 117–328, div. FF, title II, §2504,

Dec. 29, 2022, 136 Stat. 5802.)

Editorial Notes

References in Text

The Public Health Service Act, referred to in subsec. (a)(3), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

Amendments

2022—Subsec. (h)(1). Pub. L. 117–328, §2504(1)(A), (C), inserted "on the internet website of the Food and Drug Administration and" after "promptly publish" and ", which may include a summary of the data and information supporting such revisions" before period at end of second sentence.

Pub. L. 117–328, §2504(1)(B), which directed substitution of "application, request, or submission under this section or section 355(b), 355(i), 355(j), 360b(b), 360b(j), 360b(n), 360e, 360(k), 360c(f)(2), 360j(g), 360j(m), 360ccc, or 360ccc–1 of this title, or section 351(a) or 351(k) of the Public Health Service Act, even if such summary may reveal the existence of such an application, request, or submission, or data contained in such application, request, or submission" for "application under section 355(i), 360b(j), or 360j(g) of this title, even if such summary may indirectly reveal the existence of such application", was executed by making the substitution for "application under section 355(i) 360b(j), or 360j(g) of this title, even if such summary may indirectly reveal the existence of such application", to reflect the probable intent of Congress.

Subsec. (h)(2). Pub. L. 117–328, §2504(2), inserted at end "Information made publicly available by the Secretary in accordance with paragraph (1) shall be considered a disclosure authorized by law for purposes of section 1905 of title 18".

2017—Subsec. (b)(1)(B). Pub. L. 115–92, §1(a)(1)(A), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: "a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces of attack with a biological, chemical, radiological, or nuclear agent or agents;".

Subsec. (b)(6). Pub. L. 115–92, §1(a)(1)(B), added par. (6).

Subsec. (c)(4), (5). Pub. L. 115–92, §1(a)(2), added par. (4) and redesignated former par. (4) as (5).

2016—Subsec. (a)(2)(A). Pub. L. 114–255, §3088(a)(1)(A), substituted "360b, or 360e" for "or 360e" and inserted "or conditionally approved under section 360ccc of this title" after "Public Health Service Act".

Subsec. (a)(2)(B). Pub. L. 114–255, §3088(a)(1)(B), inserted "conditionally approved under section 360ccc of this title," after "approved," in two places.

Subsec. (b)(4). Pub. L. 114–255, §3088(a)(2), struck out second comma after "determination".

Subsec. (e)(3)(B). Pub. L. 114–255, §3088(a)(3), substituted "subsection (b) or (f) of section 353 of this title or under section 354 of this title" for "section 353(b) of this title".

Subsec. (f)(2). Pub. L. 114–255, §3088(a)(4), inserted ", or an animal to which," after "to a patient to whom" and "or by the veterinarian caring for such animal, as applicable" after "attending physician".

Subsec. (g)(1). Pub. L. 114–255, §3088(a)(5), inserted "conditional approval under section 360ccc of this title," after "approval,".

Subsec. (h)(1). Pub. L. 114–255, §3088(a)(6), substituted "360b(j), or 360j(g) of this title" for "or section 360j(g) of this title".

Subsec. (k). Pub. L. 114–255, §3088(a)(7), substituted "360b(j), or 360j(g) of this title" for "section 360j(g) of this title,".

2013—Subsec. (a)(1). Pub. L. 113–5, §302(a)(1)(A), substituted "any provision of this chapter" for "sections 355, 360(k), and 360e of this title".

Subsec. (a)(2)(A). Pub. L. 113–5, §302(a)(1)(B), substituted "under section 355, 360(k), or 360e of this title or section 351 of the Public Health Service Act" for "under a provision of law referred to in such paragraph".

Subsec. (a)(3). Pub. L. 113–5, §302(a)(1)(C), substituted "a section of this chapter or the Public Health Service Act referred to in paragraph (2)(A)" for "a provision of law referred to in such paragraph".

Subsec. (b). Pub. L. 113–5, §302(a)(2)(A), inserted "or threat justifying emergency authorized use" after "emergency" in heading.

Subsec. (b)(1). Pub. L. 113–5, §302(a)(2)(B), substituted "may make a declaration that the circumstances exist" for "may declare an emergency" in introductory provisions, struck out "specified" before "biological" in subpars. (A) and (B), added subpar. (D), and amended subpar. (C) generally. Prior to amendment, subpar. (C) read as follows: "a determination by the Secretary of a public health emergency under section 319 of the Public Health Service Act that affects, or has a significant potential to affect, national security, and that involves a specified biological, chemical, radiological, or nuclear agent or agents, or a specified disease or condition that may be attributable to such agent or agents."

Subsec. (b)(2)(A)(ii). Pub. L. 113–5, §302(a)(2)(C)(i), amended cl. (ii) generally. Prior to amendment, cl. (ii) read as follows: "the expiration of the one-year period beginning on the date on which the declaration is made."

Subsec. (b)(2)(B), (C). Pub. L. 113–5, §302(a)(2)(C)(ii), (iii), redesignated subpar. (C) as (B) and struck out former subpar. (B). Prior to amendment, text of subpar. (B) read as follows: "Notwithstanding subparagraph (A), the Secretary may renew a declaration under this subsection, and this paragraph shall apply to any such renewal."

Subsec. (b)(4). Pub. L. 113–5, §302(a)(2)(D), substituted ", and advance notice of termination under this subsection" for "advance notice of termination, and renewal under this subsection".

Subsec. (b)(5). Pub. L. 113–5, §302(a)(2)(E), added par. (5).

Subsec. (c). Pub. L. 113–5, §302(a)(3)(A), in introductory provisions, inserted "the Assistant Secretary for Preparedness and Response," after "consultation with" and substituted "Director of the National Institutes of Health, and" for "Director of the National Institutes of Health and" and "applicable circumstances described in subsection (b)(1)" for "circumstances of the emergency involved".

Subsec. (c)(1). Pub. L. 113–5, §302(a)(3)(B), substituted "referred to" for "specified".

Subsec. (c)(2)(B). Pub. L. 113–5, §302(a)(3)(C), inserted ", taking into consideration the material threat posed by the agent or agents identified in a declaration under subsection (b)(1)(D), if applicable" after "risks of the product".

Subsec. (d)(3). Pub. L. 113–5, §302(a)(4), inserted ", to the extent practicable given the circumstances of the emergency," after "including".

Subsec. (e)(1)(A). Pub. L. 113–5, §302(a)(5)(A), substituted "applicable circumstances described in subsection (b)(1)" for "circumstances of the emergency" in introductory provisions.

Subsec. (e)(1)(B)(iii). Pub. L. 113–5, §302(a)(5)(B), amended cl. (iii) generally. Prior to amendment, cl. (iii) read as follows: "Appropriate conditions with respect to the collection and analysis of information, during the period when the authorization is in effect, concerning the safety and effectiveness of the product with respect to the emergency use of such product."

Subsec. (e)(2)(A). Pub. L. 113–5, §302(a)(5)(C)(i), substituted "person" for "manufacturer of the product" and "applicable circumstances described in subsection (b)(1)" for "circumstances of the emergency" and inserted "or in paragraph (1)(B)" before period at end.

Subsec. (e)(2)(B)(i). Pub. L. 113–5, §302(a)(5)(C)(ii), inserted ", except as provided in section 360bbb–3a of this title with respect to authorized changes to the product expiration date" before period at end.

Subsec. (e)(2)(C). Pub. L. 113–5, §302(a)(5)(C)(iii), amended subpar. (C) generally. Prior to amendment, subpar. (C) read as follows: "The Secretary may establish with respect to the distribution and administration of the product for the unapproved use conditions no more restrictive than those established by the Secretary with respect to the distribution and administration of the product for the approved use."

Subsec. (e)(3). Pub. L. 113–5, §302(a)(5)(D), amended par. (3) generally. Prior to amendment, text read as follows: "With respect to the emergency use of a product for which an authorization under this section is issued (whether an unapproved product or an unapproved use of an approved product), the Secretary may waive or limit, to the extent appropriate given the circumstances of the emergency, requirements regarding current good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this chapter, including such requirements established under section 351 of this title."

Subsec. (g). Pub. L. 113–5, §302(a)(6)(A), substituted "Review and revocation" for "Revocation" in heading.

Subsec. (g)(1). Pub. L. 113–5, §302(a)(6)(B), inserted at end "As part of such review, the Secretary shall regularly review the progress made with respect to the approval, licensure, or clearance of—

"(A) an unapproved product for which an authorization was issued under this section; or

"(B) an unapproved use of an approved product for which an authorization was issued under this section."

Subsec. (g)(2). Pub. L. 113–5, §302(a)(6)(C), amended par. (2) generally. Prior to amendment, text read as follows: "The Secretary may revoke an authorization under this section if the criteria under subsection (c) of this section for issuance of such authorization are no longer met or other circumstances make such revocation appropriate to protect the public health or safety."

Subsec. (h)(1). Pub. L. 113–5, §302(a)(7), inserted at end "The Secretary shall make any revisions to an authorization under this section available on the Internet Web site of the Food and Drug Administration."

Subsec. (j)(4). Pub. L. 113–5, §302(a)(8), added par. (4).

Subsec. (m). Pub. L. 113–5, §302(a)(9), added subsec. (m).

2004—Pub. L. 108–276 amended section generally, substituting provisions of subsecs. (a) to (l) for similar former provisions, except for additional provisions in subsec. (b)(1) allowing Secretary to authorize use of medical products in actual or potential domestic and public health emergencies in addition to actual or potential military emergencies.

Executive Documents

Making General Use Respirators Available

Memorandum of President of the United States, Mar. 11, 2020, 85 F.R. 15049, provided:

Memorandum for the Secretary of Health and Human Services [and] the Secretary of Labor

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

It is the policy of the United States to take proactive measures to prepare for and respond to public health threats, including the public health emergency involving Coronavirus Disease 2019 (COVID–19), which was declared by the Secretary of Health and Human Services on February 4, 2020, pursuant to section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3). We must ensure that our healthcare providers have full access to the products they need. On March 10, 2020, the Secretary of Health and Human Services took action by issuing a declaration pursuant to section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d), which will help bring products necessary for addressing the epidemic to healthcare providers across the Nation. Unfortunately, at present, public health experts anticipate shortages in the supply of personal respiratory devices (respirators) available for use by

healthcare workers in mitigating further transmission of COVID–19.

To help prevent the spread of COVID–19, the Secretary of Health and Human Services shall take all appropriate and necessary steps with respect to general use respirators to facilitate their emergency use by healthcare personnel in healthcare facilities and elsewhere, including under the authorities granted by section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d) and section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–3). Additionally, the Secretary of Labor shall consider all appropriate and necessary steps to increase the availability of respirators.

The Secretary of Health and Human Services is authorized and directed to publish this memorandum in the Federal Register.

DONALD J. TRUMP.

[1] *So in original. Probably should be followed by a period.*

§360bbb–3a. Emergency use of medical products

(a) Definitions

In this section:

(1) Eligible product

The term "eligible product" means a product that—

(A) is approved or cleared under this subchapter, conditionally approved under section 360ccc of this title, or licensed under section 351 of the Public Health Service Act [42 U.S.C. 262];

(B)(i) is intended for use to prevent, diagnose, or treat a disease or condition involving a biological, chemical, radiological, or nuclear agent or agents; or

(ii) is intended for use to prevent, diagnose, or treat a serious or life-threatening disease or condition caused by a product described in clause (i); and

(C) is intended for use during the circumstances under which—

(i) a determination described in subparagraph (A), (B), or (C) of section 360bbb–3(b)(1) of this title has been made by the Secretary of Homeland Security, the Secretary of Defense, or the Secretary, respectively; or

(ii) the identification of a material threat described in subparagraph (D) of section 360bbb–3(b)(1) of this title has been made pursuant to section 319F–2 of the Public Health Service Act [42 U.S.C. 247d–6b].

(2) Product

The term "product" means a drug, device, or biological product.

(b) Expiration dating

(1) In general

The Secretary may extend the expiration date and authorize the introduction or delivery for introduction into interstate commerce of an eligible product after the expiration date provided by the manufacturer if—

(A) the expiration date extension is intended to support the United States ability to protect—

(i) the public health; or

(ii) military preparedness and effectiveness; and

(B) the expiration date extension is supported by an appropriate scientific evaluation that is conducted or accepted by the Secretary.

(2) Requirements and conditions

Any extension of an expiration date under paragraph (1) shall, as part of the extension, identify—

(A) each specific lot, batch, or other unit of the product for which extended expiration is authorized;

(B) the duration of the extension; and

(C) any other requirements or conditions as the Secretary may deem appropriate for the protection of the public health, which may include requirements for, or conditions on, product sampling, storage, packaging or repackaging, transport, labeling, notice to product recipients, recordkeeping, periodic testing or retesting, or product disposition.

(3) Effect

Notwithstanding any other provision of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.], an eligible product shall not be considered an unapproved product (as defined in section 360bbb–3(a)(2)(A) of this title) and shall not be deemed adulterated or misbranded under this chapter because, with respect to such product, the Secretary has, under paragraph (1), extended the expiration date and authorized the introduction or delivery for introduction into interstate commerce of such product after the expiration date provided by the manufacturer.

(4) Expiration date

For purposes of this subsection, the term "expiration date" means the date established through appropriate stability testing required by the regulations issued by the Secretary to ensure that the product meets applicable standards of identity, strength, quality, and purity at the time of use.

(c) Current good manufacturing practice

(1) In general

The Secretary may, when the circumstances of a domestic, military, or public health emergency or material threat described in subsection (a)(1)(C) so warrant, authorize, with respect to an eligible product, deviations from current good manufacturing practice requirements otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this chapter, including requirements under section 351 or 360j(f)(1) of this title or applicable conditions prescribed with respect to the eligible product by an order under section 360j(f)(2) of this title.

(2) Effect

Notwithstanding any other provision of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.], an eligible product shall not be considered an unapproved product (as defined in section 360bbb–3(a)(2)(A) of this title) and shall not be deemed adulterated or misbranded under this chapter because, with respect to such product, the Secretary has authorized deviations from current good manufacturing practices under paragraph (1).

(d) Emergency dispensing

The requirements of subsections (b) and (f) of section 353, section 354, and section 360j(e) of this title shall not apply to an eligible product, and the product shall not be considered an unapproved product (as defined in section 360bbb–3(a)(2)(A) of this title) and shall not be deemed adulterated or misbranded under this chapter because it is dispensed without an individual prescription, if—

(1) the product is dispensed during the circumstances described in subsection (a)(1)(C); and

(2) such dispensing without an individual prescription occurs—

(A) as permitted under the law of the State in which the product is dispensed; or

(B) in accordance with an order issued by the Secretary, for the purposes and duration of the circumstances described in subsection (a)(1)(C).

(e) Emergency use instructions

(1) In general

The Secretary, acting through an appropriate official within the Department of Health and Human Services, may create and issue emergency use instructions to inform health care providers or individuals to whom an eligible product is to be administered concerning such product's approved, licensed, or cleared conditions of use.

(2) Effect

Notwithstanding any other provisions of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.], a product shall not be considered an unapproved product and shall not be deemed adulterated or misbranded under this chapter because of the issuance of emergency use instructions under paragraph (1) with respect to such product or the introduction or delivery for introduction of such product into interstate commerce accompanied by such instructions—

(A) during an emergency response to an actual emergency that is the basis for a determination described in subsection (a)(1)(C); or

(B) by a government entity (including a Federal, State, local, or tribal government entity), or a person acting on behalf of such a government entity, in preparation for an emergency response.

(June 25, 1938, ch. 675, §564A, as added Pub. L. 113–5, title III, §302(b), Mar. 13, 2013, 127 Stat. 183; amended Pub. L. 114–255, div. A, title III, §3088(c), Dec. 13, 2016, 130 Stat. 1149; Pub. L. 116–22, title VII, §705(c), June 24, 2019, 133 Stat. 964.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsecs. (b)(3), (c)(2), and (e)(2), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

AMENDMENTS

2019—Subsec. (e)(2)(A). Pub. L. 116–22 substituted "subsection (a)(1)(C)" for "subsection (a)(1)(C)(i)".

2016—Subsec. (a)(1)(A). Pub. L. 114–255, §3088(c)(1), inserted ", conditionally approved under section 360ccc of this title," after "subchapter".

Subsec. (d). Pub. L. 114–255, §3088(c)(2), substituted "subsections (b) and (f) of section 353, section 354, and section 360j(e) of this title" for "sections 353(b) and 360j(e) of this title" in introductory provisions.

§360bbb–3b. Products held for emergency use

It is not a violation of any section of this chapter or of the Public Health Service Act [42 U.S.C. 201 et seq.] for a government entity (including a Federal, State, local, or tribal government entity), or a person acting on behalf of such a government entity, to introduce into interstate commerce a product (as defined in section 360bbb–3(a)(4) of this title) intended for emergency use, if that product—

(1) is intended to be held and not used; and
(2) is held and not used, unless and until that product—
(A) is approved, cleared, or licensed under section 355, 360(k), 360b, or 360e of this title or section 351 of the Public Health Service Act [42 U.S.C. 262] or conditionally approved under section 360ccc of this title;
(B) is authorized for investigational use under section 355, 360b, or 360j of this title or section 351 of the Public Health Service Act [42 U.S.C. 262]; or
(C) is authorized for use under section 360bbb–3 of this title or section 360bbb–3a of this title.

(June 25, 1938, ch. 675, §564B, as added Pub. L. 113–5, title III, §302(d), Mar. 13, 2013, 127 Stat. 185; amended Pub. L. 114–255, div. A, title III, §3088(d), Dec. 13, 2016, 130 Stat. 1149; Pub. L. 116–22, title VII, §705(d), June 24, 2019, 133 Stat. 964.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Public Health Service Act, referred to in text, is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

AMENDMENTS

2019—Par. (2)(B). Pub. L. 116–22, §705(d)(1), inserted comma after "355".
Par. (2)(C). Pub. L. 116–22, §705(d)(2), inserted "or section 360bbb–3a of this title" before period at end.
2016—Par. (2)(A). Pub. L. 114–255, §3088(d)(1), substituted "360b, or 360e of this title" for "or 360e of this title" and inserted "or conditionally approved under section 360ccc of this title" after "Public Health Service Act".
Par. (2)(B). Pub. L. 114–255, §3088(d)(2), substituted "360b, or 360j of this title" for "or 360j of this title".

§360bbb–3c. Expedited development and review of medical products for emergency uses

(1) In general

The Secretary of Defense may request that the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, take actions to expedite the development of a medical product, review of investigational new drug applications under section 355(i) of this title, review of investigational device exemptions under section 360j(g) of this title, and review of applications for approval and clearance of medical products under sections 355, 360(k), and 360e of this title and section 262 of title 42, including applications for licensing of vaccines or blood as biological products under such section 262 of title 42, or applications for review of regenerative medicine advanced therapy products under section 356(g) of this title, if there is a military emergency, or significant potential for a military emergency, involving a specific and imminently life-threatening risk to United States military forces of attack with an agent or agents, and the medical product that is the subject of such application, submission, or notification would be reasonably likely to diagnose, prevent, treat, or mitigate such life-threatening risk.

(2) Actions

Upon a request by the Secretary of Defense under paragraph (1), the Secretary of Health and Human Services, acting through the Commissioner of Food and Drugs, shall take action to expedite the development and review of an applicable application or notification with respect to a medical product described in paragraph (1), which may include, as appropriate—
(A) holding meetings with the sponsor and the review team throughout the development of the medical product;
(B) providing timely advice to, and interactive communication with, the sponsor regarding the development of the medical product to ensure that the development program to gather the nonclinical and clinical data necessary for approval or clearance is as efficient as practicable;
(C) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;
(D) assigning a cross-disciplinary project lead for the review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor;
(E) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment;
(F) applying any applicable Food and Drug Administration program intended to expedite the development and review of a medical product; and
(G) in appropriate circumstances, permitting expanded access to the medical product during the investigational phase, in accordance with applicable requirements of the Food and Drug Administration.

(3) Enhanced collaboration and communication

In order to facilitate enhanced collaboration and communication with respect to the most current priorities of the Department of Defense—
(A) the Food and Drug Administration shall meet with the Department of Defense and any other appropriate development partners, such as the Biomedical Advanced Research and Development Authority, on a semi-annual basis for the purposes of conducting a full review of the relevant products in the Department of Defense portfolio; and
(B) the Director of the Center for Biologics Evaluation and Research shall meet quarterly with the Department of Defense to discuss the development status of regenerative medicine advanced therapy, blood, and vaccine medical products and projects that are the highest priorities to the Department of Defense (which may include freeze dried plasma products and platelet alternatives),

unless the Secretary of Defense determines that any such meetings are not necessary.

(4) Medical product

In this subsection, the term "medical product" means a drug (as defined in section 321 of this title), a device (as defined in such section 321 of this title), or a biological product (as defined in section 262 of title 42).

(Pub. L. 115–92, §1(b), Dec. 12, 2017, 131 Stat. 2023.)

EDITORIAL NOTES

CODIFICATION

Section was enacted as part of Pub. L. 115–92, and not as part of the Federal Food, Drug, and Cosmetic Act which comprises this chapter.

§360bbb–4. Countermeasure development, review, and technical assistance

(a) Definitions

In this section—
(1) the term "countermeasure" means a qualified countermeasure, a security countermeasure, and a qualified pandemic or epidemic product;
(2) the term "qualified countermeasure" has the meaning given such term in section 247d–6a of title 42;
(3) the term "security countermeasure" has the meaning given such term in section 247d–6b of title 42; and
(4) the term "qualified pandemic or epidemic product" means a product that meets the definition given such term in section 247d–6d of title 42 and—
(A) that has been identified by the Department of Health and Human Services or the Department of Defense as receiving funding directly related to addressing chemical, biological, radiological, or nuclear threats, including pandemic influenza; or
(B) is included under this paragraph pursuant to a determination by the Secretary.

(b) General duties

In order to accelerate the development, stockpiling, approval, licensure, and clearance of qualified countermeasures, security countermeasures, and qualified pandemic or epidemic products, the Secretary, in consultation with the Assistant Secretary for Preparedness and Response, shall—
(1) ensure the appropriate involvement of Food and Drug Administration personnel in interagency activities related to countermeasure advanced research and development, consistent with sections 247d–6, 247d–6a, 247d–6b, 247d–6d, 247d–7e, and 300hh–10 of title 42;
(2) ensure the appropriate involvement and consultation of Food and Drug Administration personnel in any flexible manufacturing activities carried out under section 247d–7e of title 42, including with respect to meeting regulatory requirements set forth in this chapter;
(3) promote countermeasure expertise within the Food and Drug Administration by—
(A) ensuring that Food and Drug Administration personnel involved in reviewing countermeasures for approval, licensure, or clearance are informed by the Assistant Secretary for Preparedness and Response on the material threat assessment conducted under section 247d–6b of title 42 for the agent or agents for which the countermeasure under review is intended;
(B) training Food and Drug Administration personnel regarding review of countermeasures for approval, licensure, or clearance;
(C) holding public meetings at least twice annually to encourage the exchange of scientific ideas; and
(D) establishing protocols to ensure that countermeasure reviewers have sufficient training or experience with countermeasures;

(4) maintain teams, composed of Food and Drug Administration personnel with expertise on countermeasures, including specific countermeasures, populations with special clinical needs (including children and pregnant women that may use countermeasures, as applicable and appropriate), classes or groups of countermeasures, or other countermeasure-related technologies and capabilities, that shall—
(A) consult with countermeasure experts, including countermeasure sponsors and applicants, to identify and help resolve scientific issues related to the approval, licensure, or clearance of countermeasures, through workshops or public meetings; and
(B) improve and advance the science relating to the development of new tools, standards, and approaches to assessing and evaluating countermeasures—
(i) in order to inform the process for countermeasure approval, clearance, and licensure; and
(ii) with respect to the development of countermeasures for populations with special clinical needs, including children and pregnant women, in order to meet the needs of such populations, as necessary and appropriate; and

(5) establish within the Food and Drug Administration a team of experts on manufacturing and regulatory activities (including compliance with current Good Manufacturing Practice) to provide both off-site and on-site technical assistance to the manufacturers of qualified countermeasures (as defined in section 247d–6a of title 42), security countermeasures (as defined in section 247d–6b of title 42), or vaccines, at the request of such a manufacturer and at the discretion of the Secretary, if the Secretary determines that a shortage or potential shortage may occur in the United States in the supply of such vaccines or

countermeasures and that the provision of such assistance would be beneficial in helping alleviate or avert such shortage.

(c) Final guidance on development of animal models

(1) In general

Not later than 1 year after March 13, 2013, the Secretary shall provide final guidance to industry regarding the development of animal models to support approval, clearance, or licensure of countermeasures referred to in subsection (a) when human efficacy studies are not ethical or feasible.

(2) Authority to extend deadline

The Secretary may extend the deadline for providing final guidance under paragraph (1) by not more than 6 months upon submission by the Secretary of a report on the status of such guidance to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate.

(d) Development and animal modeling procedures

(1) Availability of animal model meetings

To facilitate the timely development of animal models and support the development, stockpiling, licensure, approval, and clearance of countermeasures, the Secretary shall, not later than 180 days after March 13, 2013, establish a procedure by which a sponsor or applicant that is developing a countermeasure for which human efficacy studies are not ethical or practicable, and that has an approved investigational new drug application or investigational device exemption, may request and receive—

(A) a meeting to discuss proposed animal model development activities; and

(B) a meeting prior to initiating pivotal animal studies.

(2) Pediatric models

To facilitate the development and selection of animal models that could translate to pediatric studies, any meeting conducted under paragraph (1) shall include discussion of animal models for pediatric populations, as appropriate.

(e) Review and approval of countermeasures

(1) Material threat

When evaluating an application or submission for approval, licensure, or clearance of a countermeasure, the Secretary shall take into account the material threat posed by the chemical, biological, radiological, or nuclear agent or agents identified under section 247d–6b of title 42 for which the countermeasure under review is intended.

(2) Review expertise

When practicable and appropriate, teams of Food and Drug Administration personnel reviewing applications or submissions described under paragraph (1) shall include a reviewer with sufficient training or experience with countermeasures pursuant to the protocols established under subsection (b)(3)(D).

(f) Regulatory management plan

(1) Definition

In this subsection, the term "eligible countermeasure" means—

(A) a security countermeasure with respect to which the Secretary has entered into a procurement contract under section 247d–6b(c) of title 42; or

(B) a countermeasure with respect to which the Biomedical Advanced Research and Development Authority has provided funding under section 247d–7e of title 42 for advanced research and development.

(2) Regulatory management plan process

The Secretary, in consultation with the Assistant Secretary for Preparedness and Response and the Director of the Biomedical Advanced Research and Development Authority, shall establish a formal process for obtaining scientific feedback and interactions regarding the development and regulatory review of eligible countermeasures by facilitating the development of written regulatory management plans in accordance with this subsection.

(3) Publication

The Secretary shall make available on the internet website of the Food and Drug Administration information regarding regulatory management plans, including—

(A) the process by which an applicant may submit a request for a regulatory management plan;

(B) the timeframe by which the Secretary is required to respond to such request;

(C) the information required for the submission of such request;

(D) a description of the types of development milestones and performance targets that could be discussed and included in such plans; and

(E) contact information for beginning the regulatory management plan process.

(4) Submission of request and proposed plan by sponsor or applicant

(A) In general

A sponsor or applicant of an eligible countermeasure may initiate the process described under paragraph (2) upon submission of a written request to the Secretary. Such request shall include a proposed regulatory management plan.

(B) Timing of submission

A sponsor or applicant may submit a written request under subparagraph (A) after the eligible countermeasure has an investigational new drug or investigational device exemption in effect.

(C) Response by Secretary

The Secretary shall direct the Food and Drug Administration, upon submission of a written request by a sponsor or applicant under subparagraph (A), to work with the sponsor or applicant to agree on a regulatory management plan within a reasonable time not to exceed 90 days. If the Secretary determines that no plan can be agreed upon, the Secretary shall provide to the sponsor or applicant, in writing, the scientific or regulatory rationale why such agreement cannot be reached.

(5) Plan

The content of a regulatory management plan agreed to by the Secretary and a sponsor or applicant shall include—

(A) an agreement between the Secretary and the sponsor or applicant regarding developmental milestones that will trigger responses by the Secretary as described in subparagraph (B);

(B) performance targets and goals for timely and appropriate responses by the Secretary to the triggers described under subparagraph (A), including meetings between the Secretary and the sponsor or applicant, written feedback, decisions by the Secretary, and other activities carried out as part of the development and review process; and

(C) an agreement on how the plan shall be modified, if needed.

(6) Milestones and performance targets

The developmental milestones described in paragraph (5)(A) and the performance targets and goals described in paragraph (5)(B) shall include—

(A) feedback from the Secretary regarding the data required to support the approval, clearance, or licensure of the eligible countermeasure involved;

(B) feedback from the Secretary regarding the data necessary to inform any authorization under section 360bbb–3 of this title;

(C) feedback from the Secretary regarding the data necessary to support the positioning and delivery of the eligible countermeasure, including to the Strategic National Stockpile;

(D) feedback from the Secretary regarding the data necessary to support the submission of protocols for review under section 355(b)(5)(B) of this title;

(E) feedback from the Secretary regarding any gaps in scientific knowledge that will need resolution prior to approval, licensure, or clearance of the eligible countermeasure and plans for conducting the necessary scientific research;

(F) identification of the population for which the countermeasure sponsor or applicant seeks approval, licensure, or clearance and the population for which desired labeling would not be appropriate, if known; and

(G) as necessary and appropriate, and to the extent practicable, a plan for demonstrating safety and effectiveness in pediatric populations, and for developing pediatric dosing, formulation, and administration with respect to the eligible countermeasure, provided that such plan would not delay authorization under section 360bbb–3 of this title, approval, licensure, or clearance for adults.

(7) Prioritization

(A) Plans for security countermeasures

The Secretary shall establish regulatory management plans for all security countermeasures for which a request is submitted under paragraph (4)(A).

(B) Plans for other eligible countermeasures

The Secretary shall determine whether resources are available to establish regulatory management plans for eligible countermeasures that are not security countermeasures. If resources are available to establish regulatory management plans for eligible countermeasures that are not security countermeasures, and if resources are not available to establish regulatory management plans for all eligible countermeasures for which requests have been submitted, the Director of the Biomedical Advanced Research and Development Authority, in consultation with the Commissioner, shall prioritize which eligible countermeasures may receive regulatory management plans.

(g) Annual report

Not later than 180 days after March 13, 2013, and annually thereafter, the Secretary shall make publicly available on the Web site of the Food and Drug Administration a report that details the countermeasure development and review activities of the Food and Drug Administration, including—

(1) with respect to the development of new tools, standards, and approaches to assess and evaluate countermeasures—

(A) the identification of the priorities of the Food and Drug Administration and the progress made on such priorities; and

(B) the identification of scientific gaps that impede the development, approval, licensure, or clearance of countermeasures for populations with special clinical needs, including children and pregnant women, and the progress made on resolving these challenges;

(2) with respect to countermeasures for which a regulatory management plan has been agreed upon under subsection (f), the extent to which the performance targets and goals set forth in subsection (f)(4)(B) and the regulatory management plan have been met, including, for each such countermeasure—

(A) whether the regulatory management plan was completed within the required timeframe, and the length of time taken to complete such plan;

(B) whether the Secretary adhered to the timely and appropriate response times set forth in such plan; and

(C) explanations for any failure to meet such performance targets and goals;

(3) the number of regulatory teams established pursuant to subsection (b)(4), the number of products, classes of products, or technologies assigned to each such team, and the number of, type of, and any

progress made as a result of consultations carried out under subsection (b)(4)(A);
(4) an estimate of resources obligated to countermeasure development and regulatory assessment, including—
(A) Center-specific objectives and accomplishments; and
(B) the number of full-time equivalent employees of the Food and Drug Administration who directly support the review of countermeasures;

(5) the number of countermeasure applications and submissions submitted, the number of countermeasures approved, licensed, or cleared, the status of remaining submitted applications and submissions, and the number of each type of authorization issued pursuant to section 360bbb–3 of this title;
(6) the number of written requests for a regulatory management plan submitted under subsection (f)(3)(A), the number of regulatory management plans developed, and the number of such plans developed for security countermeasures; and
(7) the number, type, and frequency of meetings between the Food and Drug Administration and—
(A) sponsors of a countermeasure as defined in subsection (a); or
(B) another agency engaged in development or management of portfolios for such countermeasures, including the Centers for Disease Control and Prevention, the Biomedical Advanced Research and Development Authority, the National Institutes of Health, and the appropriate agencies of the Department of Defense.

(h) Accelerating countermeasure development and review during an emergency

(1) Acceleration of countermeasure development and review

The Secretary may, at the request of the sponsor of a countermeasure, during a domestic, military, or public health emergency or material threat described in section 360bbb–3a(a)(1)(C) of this title, expedite the development and review of countermeasures that are intended to address such domestic, military, or public health emergency or material threat for approval, licensure, clearance, or authorization under this title or section 262 of title 42.

(2) Actions

The actions to expedite the development and review of a countermeasure under paragraph (1) may include the following:
(A) Expedited review of submissions made by sponsors of countermeasures to the Food and Drug Administration, including rolling submissions of countermeasure applications and other submissions.
(B) Expedited and increased engagement with sponsors regarding countermeasure development and manufacturing, including—
(i) holding meetings with the sponsor and the review team and providing timely advice to, and interactive communication with, the sponsor regarding the development of the countermeasure to ensure that the development program to gather the nonclinical and clinical data necessary for approval, licensure, clearance, or authorization is as efficient as practicable;
(ii) involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review;
(iii) assigning a cross-disciplinary project lead for the review team to facilitate;
(iv) taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment; and
(v) streamlining the review of approved, licensed, cleared, or authorized countermeasures to treat or prevent new or emerging threats, including the review of any changes to such countermeasures.

(C) Expedited issuance of guidance documents and publication of other regulatory information regarding countermeasure development and manufacturing.
(D) Other steps to expedite the development and review of a countermeasure application submitted for approval, licensure, clearance, or authorization, as the Secretary determines appropriate.

(3) Limitation of effect

Nothing in this subsection shall be construed to require the Secretary to grant, or take any other action related to, a request of a sponsor to expedite the development and review of a countermeasure for approval, licensure, clearance, or authorization under paragraph (1).

(i) Third party evaluation of tests used during an emergency

(1) In general

For purposes of conducting evaluations regarding whether an in vitro diagnostic product (as defined in section 809.3 of title 21, Code of Federal Regulations (or any successor regulations)) for which a request for emergency use authorization is submitted under section 360bbb–3 of this title meets the criteria for issuance of such authorization, the Secretary may, as appropriate, consult with persons with appropriate expertise with respect to such evaluations or enter into cooperative agreements or contracts with such persons under which such persons conduct such evaluations and make such recommendations, including, as appropriate, evaluations and recommendations regarding the scope of authorization and conditions of authorization.

(2) Requirements regarding evaluations and recommendations

(A) In general

In evaluating and making recommendations to the Secretary regarding the validity, accuracy, and reliability of in vitro diagnostic products, as described in paragraph (1), a person shall consider and document whether the relevant criteria under subsection (c)(2) of section 360bbb–3 of this title for issuance of authorization under such section are met with respect to the in vitro diagnostic product.

(B) Written recommendations

Recommendations made by a person under this subsection shall be submitted to the Secretary in writing, and shall include the reasons for such recommendation and other information that may be requested by the Secretary.

(3) Rule of construction

Nothing in this subsection shall be construed to require the Secretary to consult with, or enter into cooperative agreements or contracts with, persons as described in paragraph (1) for purposes of authorizing an in vitro diagnostic product or otherwise affecting the emergency use authorization authorities under this section or section 360bbb–3 of this title.

(June 25, 1938, ch. 675, §565, as added Pub. L. 109–417, title IV, §404, Dec. 19, 2006, 120 Stat. 2875; amended Pub. L. 113–5, title III, §§303–306, Mar. 13, 2013, 127 Stat. 185–190; Pub. L. 116–22, title V, §503, June 24, 2019, 133 Stat. 951; Pub. L. 117–328, div. FF, title II, §§2501, 2502(a), Dec. 29, 2022, 136 Stat. 5796, 5797.)

Editorial Notes

Amendments

2022—Subsec. (h). Pub. L. 117–328, §2501, added subsec. (h).
Subsec. (i). Pub. L. 117–328, §2502(a), added subsec. (i).
2019—Subsec. (f)(3) to (5). Pub. L. 116–22, §503(1), (2), added par. (3) and redesignated former pars. (3) and (4) as (4) and (5), respectively. Former par. (5) redesignated (6).
Subsec. (f)(6). Pub. L. 116–22, §503(1), (3), redesignated par. (5) as (6) and, in introductory provisions, substituted "paragraph (5)(A)" for "paragraph (4)(A)" and "paragraph (5)(B)" for "paragraph (4)(B)". Former par. (6) redesignated (7).
Subsec. (f)(7). Pub. L. 116–22, §503(1), redesignated par. (6) as (7).
Subsec. (f)(7)(A). Pub. L. 116–22, §503(4), substituted "paragraph (4)(A)" for "paragraph (3)(A)".
2013—Pub. L. 113–5, §304(1), substituted "Countermeasure development, review, and technical assistance" for "Technical assistance" in section catchline.
Pub. L. 113–5, §303, designated existing provisions as subsec. (b) and inserted heading.
Subsec. (a). Pub. L. 113–5, §303, added subsec. (a).
Subsec. (b). Pub. L. 113–5, §304(2), reenacted heading without change, substituted "In order to accelerate the development, stockpiling, approval, licensure, and clearance of qualified countermeasures, security countermeasures, and qualified pandemic or epidemic products, the Secretary, in consultation with the Assistant Secretary for Preparedness and Response, shall—" for "The Secretary, in consultation with the Commissioner of Food and Drugs, shall", added pars. (1) to (4), and designated remainder of existing provisions as par. (5).
Subsecs. (c) to (e). Pub. L. 113–5, §304(3), added subsecs. (c) to (e).
Subsec. (f). Pub. L. 113–5, §305, added subsec. (f).
Subsec. (g). Pub. L. 113–5, §306, added subsec. (g).

Statutory Notes and Related Subsidiaries

Guidance

Pub. L. 117–328, div. FF, title II, §2502(b), Dec. 29, 2022, 136 Stat. 5798, provided that: "Not later than 1 year after the date of enactment of this Act [Dec. 29, 2022], the Secretary of Health and Human Services (referred to in this subsection as the 'Secretary') shall issue draft guidance on consultations with persons under subsection (i) of section 565 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–4), as added by subsection (a), including considerations concerning conflicts of interest, compensation arrangements, and information sharing. Not later than 1 year after the public comment period on such draft guidance ends, the Secretary shall issue a revised draft guidance or final guidance."

Predictable Review Timelines of Vaccines by the Advisory Committee on Immunization Practices

Pub. L. 114–255, div. A, title III, §3091, Dec. 13, 2016, 130 Stat. 1149, provided that:
"(a) Consideration of New Vaccines.—Upon the licensure of any vaccine or any new indication for a vaccine, the Advisory Committee on Immunization Practices (in this section referred to as the 'Advisory Committee') shall, as appropriate, consider the use of the vaccine at its next regularly scheduled meeting.
"(b) Additional Information.—If the Advisory Committee does not make a recommendation with respect to the use of a vaccine at the Advisory Committee's first regularly scheduled meeting after the licensure of the vaccine or any new indication for the vaccine, the Advisory Committee shall provide an update on the status of such committee's review.
"(c) Consideration for Breakthrough Therapies and for Potential Use During Public Health Emergency.—The Advisory Committee shall make recommendations with respect to the use of certain vaccines in a timely manner, as appropriate, including vaccines that—
"(1) are designated as a breakthrough therapy under section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) and licensed under section 351 of the Public Health Service Act (42 U.S.C. 262); or
"(2) could be used in a public health emergency.
"(d) Definition.—In this section, the terms 'Advisory Committee on Immunization Practices' and 'Advisory Committee' mean the Advisory Committee on Immunization Practices established by the Secretary pursuant to section 222 of the Public Health Service Act (42 U.S.C. 217a), acting through the Director of the Centers for Disease Control and Prevention."

§360bbb–4a. Priority review to encourage treatments for agents that present national security threats

(a) Definitions

In this section:

(1) Human drug application

The term "human drug application" has the meaning given such term in section 379g(1) of this title.

(2) Priority review

The term "priority review", with respect to a human drug application, means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures in the Food and Drug Administration and goals identified in the letters described in section 101(b) of the Food and Drug Administration Safety and Innovation Act.

(3) Priority review voucher

The term "priority review voucher" means a voucher issued by the Secretary to the sponsor of a material threat medical countermeasure application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] after the date of approval of the material threat medical countermeasure application.

(4) Material threat medical countermeasure application

The term "material threat medical countermeasure application" means an application that—

(A) is a human drug application for a drug intended for use—

(i) to prevent, or treat harm from a biological, chemical, radiological, or nuclear agent identified as a material threat under section 319F–2(c)(2)(A)(ii) of the Public Health Service Act [42 U.S.C. 247d–6b(c)(2)(A)(ii)]; or

(ii) to mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, or biological product against such agent; and

(B) the Secretary determines eligible for priority review;

(C) is approved after December 13, 2016; and

(D) is for—

(i) a human drug, no active moiety (as defined by the Secretary in section 314.3 of title 21, Code of Federal Regulations (or any successor regulations)) of which has been approved in any other application under section 355(b)(1) of this title; or

(ii) a biological product, no active ingredient of which has been approved in any other application under section 351 of the Public Health Service Act [42 U.S.C. 262].

(b) Priority review voucher

(1) In general

The Secretary shall award a priority review voucher to the sponsor of a material threat medical countermeasure application upon approval by the Secretary of such material threat medical countermeasure application.

(2) Transferability

The sponsor of a material threat medical countermeasure application that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher to a sponsor of a human drug for which an application under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] will be submitted after the date of the approval of the material threat medical countermeasure application. There is no limit on the number of times a priority review voucher may be transferred before such voucher is used.

(3) Notification

(A) In general

The sponsor of a human drug application shall notify the Secretary not later than 90 calendar days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally binding commitment to pay for the user fee to be assessed in accordance with this section.

(B) Transfer after notice

The sponsor of a human drug application that provides notification of the intent of such sponsor to use the voucher for the human drug application under subparagraph (A) may transfer the voucher after such notification is provided, if such sponsor has not yet submitted the human drug application described in the notification.

(c) Priority review user fee

(1) In general

The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under subchapter VII.

(2) Fee amount

The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the average cost incurred by the agency in the review of a human drug application subject to priority review in the previous fiscal year.

(3) Annual fee setting

The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2016, for that fiscal year, the amount of the priority review user fee.

(4) Payment

(A) In general

The priority review user fee required by this subsection shall be due upon the submission of a human drug application under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] for which the priority review voucher is used.

(B) Complete application

An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary's procedures for paying such fees.

(C) No waivers, exemptions, reductions, or refunds

The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

(5) Offsetting collections

Fees collected pursuant to this subsection for any fiscal year—

(A) [1] shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

(6) [2] shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.

(d) Notice of issuance of voucher and approval of products under voucher

The Secretary shall publish a notice in the Federal Register and on the Internet website of the Food and Drug Administration not later than 30 calendar days after the occurrence of each of the following:

(1) The Secretary issues a priority review voucher under this section.

(2) The Secretary approves a drug pursuant to an application submitted under section 355(b) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] for which the sponsor of the application used a priority review voucher issued under this section.

(e) Eligibility for other programs

Nothing in this section precludes a sponsor who seeks a priority review voucher under this section from participating in any other incentive program, including under this chapter, except that no sponsor of a material threat medical countermeasure application may receive more than one priority review voucher issued under any section of this chapter with respect to such drug.

(f) Relation to other provisions

The provisions of this section shall supplement, not supplant, any other provisions of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.] that encourage the development of medical countermeasures.

(g) Sunset

The Secretary may not award any priority review vouchers under subsection (b) after October 1, 2023.

(June 25, 1938, ch. 675, §565A, as added Pub. L. 114–255, div. A, title III, §3086, Dec. 13, 2016, 130 Stat. 1144; Pub. L. 117–9, §1(a)(5), Apr. 23, 2021, 135 Stat. 258.)

Editorial Notes

References in Text

Section 101(b) of the Food and Drug Administration Safety and Innovation Act, referred to in subsec. (a)(2), is section 101(b) of Pub. L. 112–144, which is set out as a note under section 379g of this title.

The Public Health Service Act, referred to in subsec. (f), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

AMENDMENTS

2021—Subsec. (a)(4)(D). Pub. L. 117–9 amended subpar. (D) generally. Prior to amendment, subpar. (D) read as follows: "is for a human drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act."

[1] *So in original. No subpar. (B) has been enacted.*

[2] *So in original. Probably should be designated as subpar. (B).*

§360bbb–4b. Medical countermeasure master files

(a) Applicability of reference

(1) In general

A person may submit data and information in a master file to the Secretary with the intent to reference, or to authorize, in writing, another person to reference, such data or information to support a medical countermeasure submission (including a supplement or amendment to any such submission), without requiring the master file holder to disclose the data and information to any such persons authorized to reference the master file. Such data and information shall be available for reference by the master file holder or by a person authorized by the master file holder, in accordance with applicable privacy and confidentiality protocols and regulations.

(2) Reference of certain master files

In the case that data or information within a medical countermeasure master file is used only to support the conditional approval of an application filed under section 360ccc of this title, such master file may be relied upon to support the effectiveness of a product that is the subject of a subsequent medical countermeasure submission only if such application is supplemented by additional data or information to support review and approval in a manner consistent with the standards applicable to such review and approval for such countermeasure, qualified countermeasure, or qualified pandemic or epidemic product.

(b) Medical countermeasure master file content

(1) In general

A master file under this section may include data or information to support—

(A) the development of medical countermeasure submissions to support the approval, licensure, classification, clearance, conditional approval, or authorization of one or more security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products; and

(B) the manufacture of security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products.

(2) Required updates

The Secretary may require, as appropriate, that the master file holder ensure that the contents of such master file are updated during the time such master file is referenced for a medical countermeasure submission.

(c) Sponsor reference

(1) In general

Each incorporation of data or information within a medical countermeasure master file shall describe the incorporated material in a manner in which the Secretary determines appropriate and that permits the review of such information within such master file without necessitating resubmission of such data or information. Master files shall be submitted in an electronic format in accordance with sections 360b(b)(4), 360ccc(a)(4), and 379k–1 of this title, as applicable, and as specified in applicable guidance.

(2) Reference by a master file holder

A master file holder that is the sponsor of a medical countermeasure submission shall notify the Secretary in writing of the intent to reference the medical countermeasure master file as a part of the submission.

(3) Reference by an authorized person

A person submitting an application for review may, where the Secretary determines appropriate, incorporate by reference all or part of the contents of a medical countermeasure master file, if the master file holder authorizes the incorporation in writing.

(d) Acknowledgment of and reliance upon a master file by the Secretary

(1) In general

The Secretary shall provide the master file holder with a written notification indicating that the Secretary has reviewed and relied upon specified data or information within a master file and the purposes for which such data or information was incorporated by reference if the Secretary has reviewed and relied upon such specified data or information to support the approval, classification, conditional approval, clearance, licensure, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product. The Secretary may rely upon the data and information within the medical countermeasure master file for which such written notification was provided in additional applications, as applicable and appropriate and upon the request of the master file holder so notified in writing or by an authorized person of such holder.

(2) Certain applications

If the Secretary has reviewed and relied upon specified data or information within a medical countermeasure master file to support the conditional approval of an application under section 360ccc of this title to subsequently support the approval, clearance, licensure, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product, the Secretary shall provide a brief written description to the master file holder regarding the elements of the application fulfilled by the data or information within the master file and how such data or information contained in such application meets the standards of evidence under subsection (c) or (d) of section 355 of this title, subsection (d) of section 360b of this title, or section 351 of the Public Health Service Act [42 U.S.C. 262] (as applicable), which shall not include any trade secret or confidential commercial information.

(e) Rules of construction

Nothing in this section shall be construed to—

(1) limit the authority of the Secretary to approve, license, clear, conditionally approve, or authorize drugs, biological products, or devices pursuant to, as applicable, this Act [this chapter] or section 351 of the Public Health Service Act [42 U.S.C. 262] (as such applicable Act is in effect on the day before June 24, 2019), including the standards of evidence, and applicable conditions, for approval under the applicable Act;

(2) alter the standards of evidence with respect to approval, licensure, or clearance, as applicable, of drugs, biological products, or devices under this Act [this chapter] or section 351 of the Public Health Service Act [42 U.S.C. 262], including, as applicable, the substantial evidence standards under sections 355(d) and 360b(d) of this title and section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)]; or

(3) alter the authority of the Secretary under this Act [this chapter] or the Public Health Service Act [42 U.S.C. 201 et seq.] to determine the types of data or information previously submitted by a sponsor or any other person that may be incorporated by reference in an application, request, or notification for a drug, biological product, or device submitted under sections 355(i), 355(b), 355(j), 360b(b)(1), 360b(b)(2), 360b(j), 360bbb–3, 360ccc, 360j(g), 360e(c), 360c(f)(2), or 360(k) of this title, or subsection (a) or (k) of section 351 of the Public Health Service Act [42 U.S.C. 262], including a supplement or amendment to any such submission, and the requirements associated with such reference.

(f) Definitions

In this section:

(1) The term "master file holder" means a person who submits data and information to the Secretary with the intent to reference or authorize another person to reference such data or information to support a medical countermeasure submission, as described in subsection (a).

(2) The term "medical countermeasure submission" means an investigational new drug application under section 355(i) of this title, a new drug application under section 355(b) of this title, or an abbreviated new drug application under section 355(j) of this title, a biological product license application under section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] or a biosimilar biological product license application under section 351(k) of the Public Health Service Act [42 U.S.C. 262(k)], a new animal drug application under section 360b(b)(1) of this title or abbreviated new animal drug application under section 360b(b)(2) of this title, an application for conditional approval of a new animal drug under section 360ccc of this title, an investigational device application under section 360j(g) of this title, an application with respect to a device under section 360e(c) of this title, a request for classification of a device under section 360c(f)(2) of this title, a notification with respect to a device under section 360(k) of this title, or a request for an emergency use authorization under section 360bbb–3 of this title to support—

(A) the approval, licensure, classification, clearance, conditional approval, or authorization of a security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product; or

(B) a new indication to an approved security countermeasure, qualified countermeasure, or qualified pandemic or epidemic product.

(3) The terms "qualified countermeasure", "security countermeasure", and "qualified pandemic or epidemic product" have the meanings given such terms in sections 319F–1, 319F–2, and 319F–3, respectively, of the Public Health Service Act [42 U.S.C. 247d–6a, 247d–6b, 247d–6d].

(June 25, 1938, ch. 675, §565B, as added Pub. L. 116–22, title VI, §603(b), June 24, 2019, 133 Stat. 953.)

EDITORIAL NOTES

REFERENCES IN TEXT

This Act, referred to in subsec. (e), is the Federal Food, Drug, and Cosmetic Act, act June 25, 1938, ch. 675, 52 Stat. 1040, which is classified generally to this chapter (§301 et seq.). For complete classification of this Act to the Code, see section 301 of this title and Tables.

The Public Health Service Act, referred to in subsec. (e)(3), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

STATUTORY NOTES AND RELATED SUBSIDIARIES

MEDICAL COUNTERMEASURE MASTER FILES

Pub. L. 116–22, title VI, §603, June 24, 2019, 133 Stat. 953, provided that:

"(a) IN GENERAL.—The purpose of this section (including section 565B of the Federal Food, Drug, and Cosmetic Act [this section], as added by subsection (b)) is to support and advance the development or manufacture of security countermeasures, qualified countermeasures, and qualified pandemic or epidemic products by facilitating and encouraging submission of data and information to support the development of such products, and through clarifying the authority to cross-reference to data and information previously submitted to the Secretary of Health and Human Services (referred to in this section as the 'Secretary'), including data and information submitted to medical countermeasure master files or other master files.

"(b) MEDICAL COUNTERMEASURE MASTER FILES.—[Enacted this section.]

"(c) STAKEHOLDER INPUT.—Not later than 18 months after the date of enactment of this Act [June 24, 2019], the Secretary, acting through the Commissioner of Food and Drugs and in consultation with the Assistant Secretary for Preparedness and Response, shall solicit input from stakeholders, including stakeholders developing security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products, and stakeholders developing technologies to assist in the development of such countermeasures with respect to how the Food and Drug Administration can advance the use of tools and technologies to support and advance the development or manufacture of security countermeasures, qualified countermeasures, and qualified pandemic or epidemic products, including through reliance on cross-referenced data and information contained within master files and submissions previously submitted to the Secretary as set forth in section 565B of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b).

"(d) GUIDANCE.—Not later than 2 years after the date of enactment of this Act, the Secretary, acting through the Commissioner of Food and Drugs, shall publish draft guidance about how reliance on cross-referenced data and information contained within master files under section 565B of the Federal Food, Drug, and Cosmetic Act, as added by subsection (b) or submissions otherwise submitted to the Secretary may be used for specific tools or technologies (including platform technologies) that have the potential to support and advance the development or manufacture of security countermeasures, qualified countermeasures, and qualified pandemic or epidemic products. The Secretary, acting through the Commissioner of Food and Drugs, shall publish the final guidance not later than 3 years after the enactment of this Act."

§360bbb–5. Critical Path Public-Private Partnerships

(a) Establishment

The Secretary, acting through the Commissioner of Food and Drugs, may enter into collaborative agreements, to be known as Critical Path Public-Private Partnerships, with one or more eligible entities to implement the Critical Path Initiative of the Food and Drug Administration by developing innovative, collaborative projects in research, education, and outreach for the purpose of fostering medical product innovation, enabling the acceleration of medical product development, manufacturing, and translational therapeutics, and enhancing medical product safety.

(b) Eligible entity

In this section, the term "eligible entity" means an entity that meets each of the following:

(1) The entity is—

(A) an institution of higher education (as such term is defined in section 1001 of title 20) or a consortium of such institutions; or

(B) an organization described in section 501(c)(3) of title 26 and exempt from tax under section 501(a) of such title.

(2) The entity has experienced personnel and clinical and other technical expertise in the biomedical sciences, which may include graduate training programs in areas relevant to priorities of the Critical Path Initiative.

(3) The entity demonstrates to the Secretary's satisfaction that the entity is capable of—

(A) developing and critically evaluating tools, methods, and processes—

(i) to increase efficiency, predictability, and productivity of medical product development; and

(ii) to more accurately identify the benefits and risks of new and existing medical products;

(B) establishing partnerships, consortia, and collaborations with health care practitioners and other providers of health care goods or services; pharmacists; pharmacy benefit managers and purchasers; health maintenance organizations and other managed health care organizations; health care insurers; government agencies; patients and consumers; manufacturers of prescription drugs, biological products, diagnostic technologies, and devices; and academic scientists; and

(C) securing funding for the projects of a Critical Path Public-Private Partnership from Federal and nonfederal governmental sources, foundations, and private individuals.

(c) Funding

The Secretary may not enter into a collaborative agreement under subsection (a) unless the eligible entity involved provides an assurance that the entity will not accept funding for a Critical Path Public-Private Partnership project from any organization that manufactures or distributes products regulated by the Food and Drug Administration unless the entity provides assurances in its agreement with the Food and Drug Administration that the results of the Critical Path Public-Private Partnership project will not be influenced by any source of funding.

(d) Annual report

Not later than 18 months after September 27, 2007, and annually thereafter, the Secretary, in collaboration with the parties to each Critical Path Public-Private Partnership, shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives—

(1) reviewing the operations and activities of the Partnerships in the previous year; and

(2) addressing such other issues relating to this section as the Secretary determines to be appropriate.

(e) Definition

In this section, the term "medical product" includes a drug, a biological product as defined in section 262 of title 42, a device, and any combination of such products.

(f) Authorization of appropriations

To carry out this section, there is authorized to be appropriated $1,380,822 for the period beginning on October 1, 2022 and ending on December 23, 2022.[1]

(June 25, 1938, ch. 675, §566, as added Pub. L. 110–85, title VI, §603, Sept. 27, 2007, 121 Stat. 898; amended Pub. L. 112–144, title XI, §1102, July 9, 2012, 126 Stat. 1108; Pub. L. 115–52, title VI, §602, Aug. 18, 2017, 131 Stat. 1048; Pub. L. 117–180, div. F, title V, §5005, Sept. 30, 2022, 136 Stat. 2167; Pub. L. 117–229, div. C, title III, §301, Dec. 16, 2022, 136 Stat. 2311; Pub. L. 117–328, div. FF, title III, §3101, Dec. 29, 2022, 136 Stat. 5807.)

EDITORIAL NOTES

AMENDMENTS

2022—Subsec. (f). Pub. L. 117–328, which directed the substitution of "$6,000,000 for each of fiscal years 2023 through 2027" for "$1,265,753 for the period beginning on October 1, 2022 and ending on December 23, 2022", could not be executed because "$1,265,753" did not appear after the intervening amendment by section 301 of Pub. L. 117–229. See below.

Pub. L. 117–229 substituted "$1,380,822 for the period beginning on October 1, 2022 and ending on December 23, 2022" for "$1,265,753 for the period beginning on October 1, 2022 and ending on December 16, 2022".

Pub. L. 117–180 substituted "$1,265,753 for the period beginning on October 1, 2022 and ending on December 16, 2022" for "$6,000,000 for each of fiscal years 2018 through 2022".

2017—Subsec. (f). Pub. L. 115–52 substituted "2018 through 2022" for "2013 through 2017".

2012—Subsec. (f). Pub. L. 112–144 amended subsec. (f) generally. Prior to amendment, text read as follows: "To carry out this section, there are authorized to be appropriated $5,000,000 for fiscal year 2008 and such sums as may be necessary for each of fiscal years 2009 through 2012."

[1] *See 2022 Amendment notes below.*

§360bbb–5a. Emerging technology program

(a) Program establishment

(1) In general

The Secretary shall establish a program to support the adoption of, and improve the development of, innovative approaches to drug design and manufacturing.

(2) Actions

In carrying out the program under paragraph (1), the Secretary may—

(A) facilitate and increase communication between public and private entities, consortia, and individuals with respect to innovative drug product design and manufacturing;

(B) solicit information regarding, and conduct or support research on, innovative approaches to drug product design and manufacturing;

(C) convene meetings with representatives of industry, academia, other Federal agencies, international agencies, and other interested persons, as appropriate;

(D) convene working groups to support drug product design and manufacturing research and development;

(E) support education and training for regulatory staff and scientists related to innovative approaches to drug product design and manufacturing;

(F) advance regulatory science related to the development and review of innovative approaches to drug product design and manufacturing;

(G) convene or participate in working groups to support the harmonization of international regulatory requirements related to innovative approaches to drug product design and manufacturing; and

(H) award grants or contracts to carry out or support the program under paragraph (1).

(3) Grants and contracts

To seek a grant or contract under this section, an entity shall submit an application—

(A) in such form and manner as the Secretary may require; and

(B) containing such information as the Secretary may require, including a description of—

(i) how the entity will conduct the activities to be supported through the grant or contract; and

(ii) how such activities will further research and development related to, or adoption of, innovative approaches to drug product design and manufacturing.

(b) Guidance

The Secretary shall—

(1) issue or update guidance to help facilitate the adoption of, and advance the development of, innovative approaches to drug product design and manufacturing; and

(2) include in such guidance descriptions of—
(A) any regulatory requirements related to the development or review of technologies related to innovative approaches to drug product design and manufacturing, including updates and improvements to such technologies after product approval; and
(B) data that can be used to demonstrate the identity, safety, purity, and potency of drugs manufactured using such technologies.

(c) Report to Congress

Not later than 4 years after December 29, 2022, the Secretary shall submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Health, Education, Labor, and Pensions of the Senate a report containing—
(1) an annual accounting of the allocation of funds made available to carry out this section;
(2) a description of how Food and Drug Administration staff were utilized to carry out this section and, as applicable, any challenges or limitations related to staffing;
(3) the number of public meetings held or participated in by the Food and Drug Administration pursuant to this section, including meetings convened as part of a working group described in subparagraph (D) or (G) of subsection (a)(2), and the topics of each such meeting; and
(4) the number of drug products approved or licensed, after December 29, 2022, using an innovative approach to drug product design and manufacturing.

(June 25, 1938, ch. 675, §566A, as added Pub. L. 117–328, div. FF, title III, §3203, Dec. 29, 2022, 136 Stat. 5814.)

§360bbb–6. Risk communication

(a) Advisory Committee on Risk Communication

(1) In general

The Secretary shall establish an advisory committee to be known as the "Advisory Committee on Risk Communication" (referred to in this section as the "Committee").

(2) Duties of Committee

The Committee shall advise the Commissioner on methods to effectively communicate risks associated with the products regulated by the Food and Drug Administration.

(3) Members

The Secretary shall ensure that the Committee is composed of experts on risk communication, experts on the risks described in subsection (b), and representatives of patient, consumer, and health professional organizations.

(4) Permanence of Committee

Section 1013 of title 5 shall not apply to the Committee established under this subsection.

(b) Partnerships for risk communication

(1) In general

The Secretary shall partner with professional medical societies, medical schools, academic medical centers, and other stakeholders to develop robust and multi-faceted systems for communication to health care providers about emerging postmarket drug risks.

(2) Partnerships

The systems developed under paragraph (1) shall—
(A) account for the diversity among physicians in terms of practice, willingness to adopt technology, and medical specialty; and
(B) include the use of existing communication channels, including electronic communications, in place at the Food and Drug Administration.

(June 25, 1938, ch. 675, §567, as added Pub. L. 110–85, title IX, §917, Sept. 27, 2007, 121 Stat. 960; amended Pub. L. 117–286, §4(a)(157), Dec. 27, 2022, 136 Stat. 4323.)

Editorial Notes

Amendments

2022—Subsec. (a)(4). Pub. L. 117–286 substituted "Section 1013 of title 5" for "Section 14 of the Federal Advisory Committee Act".

§360bbb–7. Notification

(a) Notification to Secretary

With respect to a drug, the Secretary may require notification to the Secretary by a regulated person if the regulated person knows—
(1) that the use of such drug in the United States may result in serious injury or death;
(2) of a significant loss or known theft of such drug intended for use in the United States; or
(3) that—
(A) such drug has been or is being counterfeited; and
(B)(i) the counterfeit product is in commerce in the United States or could be reasonably expected to be introduced into commerce in the United States; or
(ii) such drug has been or is being imported into the United States or may reasonably be expected to be offered for import into the United States.

(b) Manner of notification

Notification under this section shall be made in such manner and by such means as the Secretary may specify by regulation or guidance.

(c) Savings clause

Nothing in this section shall be construed as limiting any other authority of the Secretary to require notifications related to a drug under any other provision of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.].

(d) Definition

In this section, the term "regulated person" means—
(1) a person who is required to register under section 360 or 381(s) of this title;
(2) a wholesale distributor of a drug product; or
(3) any other person that distributes drugs except a person that distributes drugs exclusively for retail sale.

(June 25, 1938, ch. 675, §568, as added Pub. L. 112–144, title VII, §715(b), July 9, 2012, 126 Stat. 1075.)

Editorial Notes

References in Text

The Public Health Service Act, referred to in subsec. (c), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

§360bbb–8. Consultation with external experts on rare diseases, targeted therapies, and genetic targeting of treatments

(a) In general

For the purpose of promoting the efficiency of and informing the review by the Food and Drug Administration of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted, the following shall apply:

(1) Consultation with stakeholders

Consistent with sections X.C and IX.E.4 of the PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017, as referenced in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012, the Secretary shall ensure that opportunities exist, at a time the Secretary determines appropriate, for consultations with stakeholders on the topics described in subsection (b).

(2) Consultation with external experts

(A) In general

The Secretary shall develop and maintain a list of external experts who, because of their special expertise, are qualified to provide advice on rare disease issues, including topics described in subsection (b). The Secretary may, when appropriate to address a specific regulatory question, consult such external experts on issues related to the review of new drugs and biological products for rare diseases and drugs and biological products that are genetically targeted, including the topics described in subsection (b), when such consultation is necessary because the Secretary lacks the specific scientific, medical, or technical expertise necessary for the performance of the Secretary's regulatory responsibilities and the necessary expertise can be provided by the external experts.

(B) External experts

For purposes of subparagraph (A), external experts are individuals who possess scientific or medical training that the Secretary lacks with respect to one or more rare diseases.

(b) Topics for consultation

Topics for consultation pursuant to this section may include—
(1) rare diseases;
(2) the severity of rare diseases;

(3) the unmet medical need associated with rare diseases;
(4) the willingness and ability of individuals with a rare disease to participate in clinical trials;
(5) an assessment of the benefits and risks of therapies to treat rare diseases;
(6) the general design of clinical trials for rare disease populations and subpopulations;
(7) the demographics and the clinical description of patient populations; and
(8) the science of small population studies.

(c) Classification as special government employees

The external experts who are consulted under this section may be considered special government employees, as defined under section 202 of title 18.

(d) Protection of confidential information and trade secrets

(1) Rule of construction

Nothing in this section shall be construed to alter the protections offered by laws, regulations, and policies governing disclosure of confidential commercial or trade secret information, and any other information exempt from disclosure pursuant to section 552(b) of title 5 as such provisions would be applied to consultation with individuals and organizations prior to July 9, 2012.

(2) Consent required for disclosure

The Secretary shall not disclose confidential commercial or trade secret information to an expert consulted under this section without the written consent of the sponsor unless the expert is a special government employee (as defined under section 202 of title 18) or the disclosure is otherwise authorized by law.

(e) Other consultation

Nothing in this section shall be construed to limit the ability of the Secretary to consult with individuals and organizations as authorized prior to July 9, 2012.

(f) No right or obligation

(1) No right to consultation

Nothing in this section shall be construed to create a legal right for a consultation on any matter or require the Secretary to meet with any particular expert or stakeholder.

(2) No altering of goals

Nothing in this section shall be construed to alter agreed upon goals and procedures identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012.

(3) No change to number of review cycles

Nothing in this section is intended to increase the number of review cycles as in effect before July 9, 2012.

(g) No delay in product review

(1) In general

Prior to a consultation with an external expert, as described in this section, relating to an investigational new drug application under section 355(i) of this title, a new drug application under section 355(b) of this title, or a biologics license application under section 262 of title 42, the Director of the Center for Drug Evaluation and Research or the Director of the Center for Biologics Evaluation and Research (or appropriate Division Director), as appropriate, shall determine that—

(A) such consultation will—
(i) facilitate the Secretary's ability to complete the Secretary's review; and
(ii) address outstanding deficiencies in the application; or

(B) the sponsor authorized such consultation.

(2) Limitation

The requirements of this subsection shall apply only in instances where the consultation is undertaken solely under the authority of this section. The requirements of this subsection shall not apply to any consultation initiated under any other authority.

(June 25, 1938, ch. 675, §569, as added Pub. L. 112–144, title IX, §903, July 9, 2012, 126 Stat. 1088; amended Pub. L. 114–255, div. A, title III, §3101(a)(2)(O), Dec. 13, 2016, 130 Stat. 1154; Pub. L. 117–328, div. FF, title III, §3202(e), Dec. 29, 2022, 136 Stat. 5812.)

EDITORIAL NOTES

REFERENCES IN TEXT

Section 101(b) of the Prescription Drug User Fee Amendments of 2012, referred to in subsecs. (a)(1) and (f)(2), is section 101(b) of Pub. L. 112–144, which is set out as a note under section 379g of this title.

AMENDMENTS

2022—Subsec. (b)(8). Pub. L. 117–328 added par. (8).
2016—Subsec. (a)(2)(A). Pub. L. 114–255 substituted "subsection (b)" for "subsection (c)" before period in first sentence.

§360bbb–8a. Optimizing global clinical trials

(a) In general

The Secretary shall—

(1) work with other regulatory authorities of similar standing, medical research companies, and international organizations to foster and encourage uniform, scientifically driven clinical trial standards with respect to medical products around the world; and

(2) enhance the commitment to provide consistent parallel scientific advice to manufacturers seeking simultaneous global development of new medical products in order to—
(A) enhance medical product development;
(B) facilitate the use of foreign data; and
(C) minimize the need to conduct duplicative clinical studies, preclinical studies, or nonclinical studies.

(b) Medical product

In this section, the term "medical product" means a drug, as defined in subsection (g) of section 321 of this title, a device, as defined in subsection (h) of such section, or a biological product, as defined in section 351(i) of the Public Health Service Act [42 U.S.C. 262(i)].

(c) Savings clause

Nothing in this section shall alter the criteria for evaluating the safety or effectiveness of a medical product under this chapter or under the Public Health Service Act [42 U.S.C. 201 et seq.].

(June 25, 1938, ch. 675, §569A, as added Pub. L. 112–144, title XI, §1123, July 9, 2012, 126 Stat. 1113; amended Pub. L. 114–255, div. A, title III, §3101(a)(2)(P), Dec. 13, 2016, 130 Stat. 1154.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (c), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

AMENDMENTS

2016—Subsec. (c). Pub. L. 114–255 inserted "or under the Public Health Service Act" before period at end.

§360bbb–8b. Use of clinical investigation data from outside the United States

(a) In general

In determining whether to approve, license, or clear a drug, biological product, or device pursuant to an application submitted under this subchapter, the Secretary shall accept data from clinical investigations conducted outside of the United States, including the European Union, if the applicant demonstrates that such data are adequate under applicable standards to support approval, licensure, or clearance of the drug, biological product, or device in the United States.

(b) Notice to sponsor

If the Secretary finds under subsection (a) that the data from clinical investigations conducted outside the United States, including in the European Union, are inadequate for the purpose of making a determination on approval, clearance, or licensure of a drug, biological product, or device pursuant to an application submitted under this subchapter, the Secretary shall provide written notice to the sponsor of the application of such finding and include the rationale for such finding.

(June 25, 1938, ch. 675, §569B, as added Pub. L. 112–144, title XI, §1123, July 9, 2012, 126 Stat. 1113; amended Pub. L. 114–255, div. A, title III, §3101(a)(2)(Q), Dec. 13, 2016, 130 Stat. 1155.)

EDITORIAL NOTES

AMENDMENTS

2016—Pub. L. 114–255 substituted "drug, biological product, or device" for "drug or device" wherever appearing.

§360bbb–8c. Patient participation in medical product discussion

(a) Patient engagement in drugs and devices

(1) In general

The Secretary shall develop and implement strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions, including by—

(A) fostering participation of a patient representative who may serve as a special government employee in appropriate agency meetings with medical product sponsors and investigators; and

(B) exploring means to provide for identification of patient representatives who do not have any, or have minimal, financial interests in the medical products industry.

(2) Protection of proprietary information

Nothing in this section shall be construed to alter the protections offered by laws, regulations, or policies governing disclosure of confidential commercial or trade secret information and any other information exempt from disclosure pursuant to section 552(b) of title 5 as such laws, regulations, or policies would apply to consultation with individuals and organizations prior to July 9, 2012.

(3) Other consultation

Nothing in this section shall be construed to limit the ability of the Secretary to consult with individuals and organizations as authorized prior to July 9, 2012.

(4) No right or obligation

Nothing in this section shall be construed to create a legal right for a consultation on any matter or require the Secretary to meet with any particular expert or stakeholder. Nothing in this section shall be construed to alter agreed upon goals and procedures identified in the letters described in section 101(b) of the Prescription Drug User Fee Amendments of 2012. Nothing in this section is intended to increase the number of review cycles as in effect before July 9, 2012.

(5) Financial interest

In this section, the term "financial interest" means a financial interest under section 208(a) of title 18.

(b) Statement of patient experience

(1) In general

Following the approval of an application that was submitted under section 355(b) of this title or section 262(a) of title 42 at least 180 days after December 13, 2016, the Secretary shall make public a brief statement regarding the patient experience data and related information, if any, submitted and reviewed as part of such application.

(2) Data and information

The data and information referred to in paragraph (1) are—

(A) patient experience data;

(B) information on patient-focused drug development tools; and

(C) other relevant information, as determined by the Secretary.

(c) Patient experience data

For purposes of this section, the term "patient experience data" includes data that—

(1) are collected by any persons (including patients, family members and caregivers of patients, patient advocacy organizations, disease research foundations, researchers, and drug manufacturers); and

(2) are intended to provide information about patients' experiences with a disease or condition, including—

(A) the impact (including physical and psychosocial impacts) of such disease or condition, or a related therapy or clinical investigation on patients' lives; and

(B) patient preferences with respect to treatment of such disease or condition.

(June 25, 1938, ch. 675, §569C, as added Pub. L. 112–144, title XI, §1137, July 9, 2012, 126 Stat. 1124; amended Pub. L. 114–255, div. A, title III, §3001, Dec. 13, 2016, 130 Stat. 1083; Pub. L. 115–52, title VI, §605, Aug. 18, 2017, 131 Stat. 1048.)

Editorial Notes

References in Text

Section 101(b) of the Prescription Drug User Fee Amendments of 2012, referred to in subsec. (a)(4), is section 101(b) of Pub. L. 112–144, which is set out as a note under section 379g of this title.

Amendments

2017—Subsec. (c)(2)(A). Pub. L. 115–52 substituted "impact (including physical and psychosocial impacts) of such disease or condition, or a related therapy or clinical investigation" for "impact of such disease or condition, or a related therapy,".

2016—Subsec. (a). Pub. L. 114–255, §3001(1), (2), substituted "Patient engagement in drugs and devices" for "In general" in subsec. heading, designated existing provisions as par. (1) and inserted par. heading, redesignated former pars. (1) and (2) as subpars. (A) and (B), respectively, of par. (1), redesignated subsecs. (b) to (e) as as pars. (2) to (5), respectively, and realigned margins.

Subsecs. (b), (c). Pub. L. 114–255, §3001(3), added subsecs. (b) and (c). Former subsecs. (b) and (c) redesignated pars. (2) and (3), respectively, of subsec. (a).

Subsecs. (d), (e). Pub. L. 114–255, §3001(2), redesignated subsecs. (d) and (e) as pars. (4) and (5), respectively, of subsec. (a).

Statutory Notes and Related Subsidiaries

Patient-Focused Drug Development Guidance

Pub. L. 114–255, div. A, title III, §3002, Dec. 13, 2016, 130 Stat. 1084, provided that:

"(a) Publication of Guidance Documents.—Not later than 180 days after the date of enactment of this Act [Dec. 13, 2016], the Secretary of Health and Human Services (referred to in this section as the 'Secretary'), acting through the Commissioner of Food and Drugs, shall develop a plan to issue draft and final versions of one or more guidance documents, over a period of 5 years, regarding the collection of patient experience data, and the use of such data and related information in drug development. Not later than 18 months after the date of enactment of this Act, the Secretary shall issue a draft version of at least one such guidance document. Not later than 18 months after the public comment period on the draft guidance ends, the Secretary shall issue a revised draft guidance or final guidance.

"(b) Patient Experience Data.—For purposes of this section, the term 'patient experience data' has the meaning given such term in section 569C of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360bbb–8c] (as added by section 3001).

"(c) Contents.—The guidance documents described in subsection (a) shall address—

"(1) methodological approaches that a person seeking to collect patient experience data for submission to, and proposed use by, the Secretary in regulatory decisionmaking may use, that are relevant and objective and ensure that such data are accurate and representative of the intended population, including methods to collect meaningful patient input throughout the drug development process and methodological considerations for data collection, reporting, management, and analysis;

"(2) methodological approaches that may be used to develop and identify what is most important to patients with respect to burden of disease, burden of treatment, and the benefits and risks in the management of the patient's disease;

"(3) approaches to identifying and developing methods to measure impacts to patients that will help facilitate collection of patient experience data in clinical trials;

"(4) methodologies, standards, and technologies to collect and analyze clinical outcome assessments for purposes of regulatory decisionmaking;

"(5) how a person seeking to develop and submit proposed draft guidance relating to patient experience data for consideration by the Secretary may submit such proposed draft guidance to the Secretary;

"(6) the format and content required for submissions under this section to the Secretary, including with respect to the information described in paragraph (1);

"(7) how the Secretary intends to respond to submissions of information described in paragraph (1), if applicable, including any timeframe for response when such submission is not part of a regulatory application or other submission that has an associated timeframe for response; and

"(8) how the Secretary, if appropriate, anticipates using relevant patient experience data and related information, including with respect to the structured risk-benefit assessment framework described in section 505(d) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(d)), to inform regulatory decisionmaking."

Streamlining Patient Input

Pub. L. 114–255, div. A, title III, §3003, Dec. 13, 2016, 130 Stat. 1085, provided that: "Chapter 35 of title 44, United States Code, shall not apply to the collection of information to which a response is voluntary, that is initiated by the Secretary under section 569C of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb–8c) (as amended by section 3001) or section 3002 [set out as a note above]."

§360bbb–8d. Notification, nondistribution, and recall of controlled substances

(a) Order to cease distribution and recall

(1) In general

If the Secretary determines there is a reasonable probability that a controlled substance would cause serious adverse health consequences or death, the Secretary may, after providing the appropriate person with an opportunity to consult with the agency, issue an order requiring manufacturers, importers, distributors, or pharmacists, who distribute such controlled substance to immediately cease distribution of such controlled substance.

(2) Hearing

An order under paragraph (1) shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of issuance of the order, on whether adequate evidence exists to justify an amendment to the order, and what actions are required by such amended order pursuant to subparagraph (3).

(3) Order resolution

After an order is issued according to the process under paragraphs (1) and (2), the Secretary shall, except as provided in paragraph (4)—

(A) vacate the order, if the Secretary determines that inadequate grounds exist to support the actions required by the order;

(B) continue the order ceasing distribution of the controlled substance until a date specified in such order; or

(C) amend the order to require a recall of the controlled substance, including any requirements to notify appropriate persons, a timetable for the recall to occur, and a schedule for updates to be provided to the Secretary regarding such recall.

(4) Risk assessment

If the Secretary determines that the risk of recalling a controlled substance presents a greater health risk than the health risk of not recalling such controlled substance from use, an amended order under subparagraph (B) or (C) of paragraph (3) shall not include either a recall order for, or an order to cease distribution of, such controlled substance, as applicable.

(5) Action following order

Any person who is subject to an order pursuant to subparagraph (B) or (C) of paragraph (3) shall immediately cease distribution of or recall, as applicable, the controlled substance and provide notification as required by such order.

(b) Notice to persons affected

If the Secretary determines necessary, the Secretary may require the person subject to an order pursuant to paragraph (1) or an amended order pursuant to subparagraph (B) or (C) of paragraph (3) to provide either a notice of a recall order for, or an order to cease distribution of, such controlled substance, as applicable, under this section to appropriate persons, including persons who manufacture, distribute, import, or offer for sale such product that is the subject of an order and to the public. In providing such notice, the Secretary may use the assistance of health professionals who prescribed or dispensed such controlled substances.

(c) Nondelegation

An order described in subsection (a)(3) shall be ordered by the Secretary or an official designated by the Secretary. An official may not be so designated under this section unless the official is the Director of the Center for Drug Evaluation and Research or an official senior to such Director.

(d) Savings clause

Nothing contained in this section shall be construed as limiting—

(1) the authority of the Secretary to issue an order to cease distribution of, or to recall, any drug under any other provision of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.]; or

(2) the ability of the Secretary to request any person to perform a voluntary activity related to any drug subject to this chapter or the Public Health Service Act.

(June 25, 1938, ch. 675, §569D, as added Pub. L. 115–271, title III, §3012(b), Oct. 24, 2018, 132 Stat. 3935.)

EDITORIAL NOTES

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (d), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

1944 PHSA as of April 2025, highlighting Quarantine and Inspection, Regulations to control communicable diseases, 42 USC 264; communicable diseases designated by President EO, no physical evidence required. 2002 amendments added “precommunicable stage” language.

Title 42, PUBLIC HEALTH SERVICE ACT -
Chapter 6A - Public Health Service
PART G - Quarantine and Inspection
Sections 264 through 272 as of April 15, 2025

Highlighting:
42 USC 264. Regulations to control communicable diseases
42 USC 265. Suspension of entries and imports from designated places to prevent spread of communicable diseases
42 USC 266. Special quarantine powers in time of war

42 USC 264: Regulations to control communicable diseases
Text contains those laws in effect on April 14, 2025

From Title 42-THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A-PUBLIC HEALTH SERVICE
SUBCHAPTER II-GENERAL POWERS AND DUTIES
Part G-Quarantine and Inspection

Jump To:

1944 PHSA Sec. 361 = 42 USC 264

§264. Regulations to control communicable diseases

(a) Promulgation and enforcement by Surgeon General

The Surgeon General, with the approval of the Secretary, is authorized to make and enforce such regulations as in his judgment are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the Surgeon General may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.

(b) Apprehension, detention, or conditional release of individuals

Regulations prescribed under this section shall not provide for the apprehension, detention, or conditional release of individuals except for the purpose of preventing the introduction, transmission, or spread of such communicable diseases as may be specified from time to time in Executive orders of the President upon the recommendation of the Secretary, in consultation with the Surgeon General,[1].

(c) Application of regulations to persons entering from foreign countries

Except as provided in subsection (d), regulations prescribed under this section, insofar as they provide for the apprehension, detention, examination, or conditional release of individuals, shall be applicable only to individuals coming into a State or possession from a foreign country or a possession.

(d) Apprehension and examination of persons reasonably believed to be infected

(1) Regulations prescribed under this section may provide for the apprehension and examination of any individual reasonably believed to be infected with a communicable disease in a qualifying stage and (A) to be moving or about to move from a State to another State; or (B) to be a probable source of infection to individuals who, while infected with such disease in a qualifying stage, will be moving from a State to another State. Such regulations may provide that if upon examination any such individual is found to be infected, he may be detained for such time and in such manner as may be reasonably necessary. For purposes of this subsection, the term "State" includes, in addition to the several States, only the District of Columbia.

(2) For purposes of this subsection, the term "qualifying stage", with respect to a communicable disease, means that such disease-

(A) is in a communicable stage; or

(B) is in a precommunicable stage, if the disease would be likely to cause a public health emergency if transmitted to other individuals.

(e) Preemption

Nothing in this section or section 266 of this title, or the regulations promulgated under such sections, may be construed as superseding any provision under State law (including regulations and including provisions established by political subdivisions of States), except to the extent that such a provision conflicts with an exercise of Federal authority under this section or section 266 of this title.

(July 1, 1944, ch. 373, title III, §361, 58 Stat. 703 ; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 86–624, §29(c), July 12, 1960, 74 Stat. 419 ; Pub. L. 94–317, title III, §301(b)(1), June 23, 1976, 90 Stat. 707 ; Pub. L. 107–188, title I, §142(a)(1), (2), (b)(1), (c), June 12, 2002, 116 Stat. 626 , 627.)

Editorial Notes

Amendments

2002-Pub. L. 107–188, §142(a)(1), (2), (b)(1), and (c), which directed certain amendments to section 361 of the Public Health Act, was executed by making the amendments to this section, which is section 361 of the Public Health Service Act, to reflect the probable intent of Congress. See below.

Subsec. (b). Pub. L. 107–188, §142(a)(1), substituted "Executive orders of the President upon the recommendation of the Secretary, in consultation with the Surgeon General," for "Executive orders of the President upon the recommendation of the National Advisory Health Council and the Surgeon General".

Subsec. (d). Pub. L. 107–188, §142(a)(2), (b)(1), substituted in first sentence "Regulations" for "On recommendation of the National Advisory Health Council, regulations", "in a qualifying stage" for "in a communicable stage" in two places, designated existing text as par. (1) and substituted "(A)" and "(B)" for "(1)" and "(2)", respectively, and added par. (2).

Subsec. (e). Pub. L. 107–188, §142(c), added subsec. (e).

1976-Subsec. (d). Pub. L. 94–317 inserted provision defining "State" to include, in addition to the several States, only the District of Columbia.

1960-Subsec. (c). Pub. L. 86–624 struck out reference to Territory of Hawaii.

Statutory Notes and Related Subsidiaries

Change of Name

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsecs. (a) and (b) pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

Effective Date of 1960 Amendment

Amendment by Pub. L. 86–624 effective Aug. 21, 1959, see section 47(f) of Pub. L. 86–624, set out as a note under section 201 of this title.

Extension of Eviction Moratorium

Pub. L. 116–260, div. N, title V, §502, Dec. 27, 2020, 134 Stat. 2078 , provided that: "The order issued by the Centers for Disease Control and Prevention under section 361 of the Public Health Service Act (42 U.S.C. 264), entitled 'Temporary Halt in Residential Evictions To Prevent the Further Spread of COVID–19' (85 Fed. Reg. 55292 (September 4, 2020)[)] is extended through January 31, 2021, notwithstanding the effective dates specified in such Order."

Evaluation of Public Health Authorities

Pub. L. 110–392, title I, §121, Oct. 13, 2008, 122 Stat. 4200 , provided that:

"(a) In General.-Not later than 180 days after the date of enactment of the Comprehensive Tuberculosis Elimination Act of 2008 [Oct. 13, 2008], the Secretary of Health and Human Services shall prepare and submit to the appropriate committees of Congress a report that evaluates and provides recommendations on changes needed to Federal and State public health authorities to address current disease containment challenges such as isolation and quarantine.

"(b) Contents of Evaluation.-The report described in subsection (a) shall include-

"(1) an evaluation of the effectiveness of current policies to detain patients with active tuberculosis;

"(2) an evaluation of whether Federal laws should be strengthened to expressly address the movement of individuals with active tuberculosis; and

"(3) specific legislative recommendations for changes to Federal laws, if any.

"(c) Update of Quarantine Regulations.-Not later than 240 days after the date of enactment of this Act [Oct. 13, 2008], the Secretary of Health and Human Services shall promulgate regulations to update the current interstate and foreign quarantine regulations found in parts 70 and 71 of title 42, Code of Federal Regulations."

Executive Documents

Transfer of Functions

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

Functions of Federal Security Administrator transferred to Secretary of Health, Education, and Welfare and all agencies of Federal Security Agency transferred to Department of Health, Education, and Welfare by section 5 of Reorg. Plan No. 1 of 1953, set out as a note under section 3501 of this title. Federal Security Agency and office of Administrator abolished by section 8 of Reorg. Plan No. 1 of 1953.

Executive Order No. 12452

Ex. Ord. No. 12452, Dec. 22, 1983, 48 F.R. 56927, which specified certain communicable diseases for regulations providing for the apprehension, detention, or conditional release of individuals to prevent the introduction, transmission, or spread of such diseases, was revoked by Ex. Ord. No. 13295, §5, Apr. 4, 2003, 68 F.R. 17255, set out below.

EX. ORD. NO. 13295. REVISED LIST OF QUARANTINABLE COMMUNICABLE DISEASES

Ex. Ord. No. 13295, Apr. 4, 2003, 68 F.R. 17255, as amended by Ex. Ord. No. 13375, §1, Apr. 1, 2005, 70 F.R. 17299; Ex. Ord. No. 13674, §1, July 31, 2014, 79 F.R. 45671; Ex. Ord. No. 14047, Sept. 17, 2021, 86 F.R. 52591, provided:

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 361(b) of the Public Health Service Act (42 U.S.C. 264(b)), it is hereby ordered as follows:

SECTION 1. Based upon the recommendation of the Secretary of Health and Human Services (the "Secretary"), in consultation with the Surgeon General, and for the purpose of specifying certain communicable diseases for regulations providing for the apprehension, detention, or conditional release of individuals to prevent the introduction, transmission, or spread of suspected communicable diseases, the following communicable diseases are hereby specified pursuant to section 361(b) of the Public Health Service Act:

(a) Cholera; Diphtheria; infectious Tuberculosis; Measles; Plague; Smallpox; Yellow Fever; and Viral Hemorrhagic Fevers (Lassa, Marburg, Ebola, Crimean-Congo, South American, and others not yet isolated or named).

(b) Severe acute respiratory syndromes, which are diseases that are associated with fever and signs and symptoms of pneumonia or other respiratory illness, are capable of being transmitted from person to person, and that either are causing, or have the potential to cause, a pandemic, or, upon infection, are highly likely to cause mortality or serious morbidity if not properly controlled. This subsection does not apply to influenza.

(c) Influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause, a pandemic.

SEC. 2. The Secretary, in the Secretary's discretion, shall determine whether a particular condition constitutes a communicable disease of the type specified in section 1 of this order.

SEC. 3. The functions of the President under sections 362 and 364(a) of the Public Health Service Act (42 U.S.C. 265 and 267(a)) are assigned to the Secretary.

SEC. 4. This order is not intended to, and does not, create any right or benefit enforceable at law or equity by any party against the United States, its departments, agencies, entities, officers, employees or agents, or any other person.

SEC. 5. Executive Order 12452 of December 22, 1983, is hereby revoked.

[1] *So in original. The comma probably should not appear.*

42 USC 265: Suspension of entries and imports from designated places to prevent spread of communicable diseases
Text contains those laws in effect on April 14, 2025

From Title 42-THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A-PUBLIC HEALTH SERVICE
SUBCHAPTER II-GENERAL POWERS AND DUTIES
Part G-Quarantine and Inspection
Jump To:
Source Credit
Miscellaneous
Change of Name

1944 PHSA Sec. 362 = 42 USC 265

§265. Suspension of entries and imports from designated places to prevent spread of communicable diseases

Whenever the Surgeon General determines that by reason of the existence of any communicable disease in a foreign country there is serious danger of the introduction of such disease into the United States, and that this danger is so increased by the introduction of persons or property from such country that a suspension of the right to introduce such persons and property is required in the interest of the public health, the Surgeon General, in accordance with regulations approved by the President, shall have the power to prohibit, in whole or in part, the introduction of persons and property from such countries or places as he shall designate in order to avert such danger, and for such period of time as he may deem necessary for such purpose.

(July 1, 1944, ch. 373, title III, §362, 58 Stat. 704 .)

Statutory Notes and Related Subsidiaries

Change of Name

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

Executive Documents

Transfer of Functions

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

Delegation of Functions

For assignment of functions of President under this section, see section 3 of Ex. Ord. No. 13295, Apr. 4, 2003, 68 F.R. 17255, set out as a note under section 264 of this title.

42 USC 266: Special quarantine powers in time of war
Text contains those laws in effect on April 14, 2025

From Title 42-THE PUBLIC HEALTH AND WELFARE
CHAPTER 6A-PUBLIC HEALTH SERVICE
SUBCHAPTER II-GENERAL POWERS AND DUTIES
Part G-Quarantine and Inspection

Jump To:

1944 PHSA Sec. 363 = 42 USC 266

§266. Special quarantine powers in time of war

To protect the military and naval forces and war workers of the United States, in time of war, against any communicable disease specified in Executive orders as provided in subsection (b) of section 264 of this title, the Secretary, in consultation with the Surgeon General, is authorized to provide by regulations for the apprehension and examination, in time of war, of any individual reasonably believed (1) to be infected with such disease and (2) to be a probable source of infection to members of the armed forces of the United States or to individuals engaged in the production or transportation of arms, munitions, ships, food, clothing, or other supplies for the armed forces. Such regulations may provide that if upon examination any such individual is found to be so infected, he may be detained for such time and in such manner as may be reasonably necessary.

(July 1, 1944, ch. 373, title III, §363, 58 Stat. 704 ; Pub. L. 107–188, title I, §142(a)(3), (b)(2), June 12, 2002, 116 Stat. 626 , 627.)

Editorial Notes

Amendments

2002-Pub. L. 107–188, which directed substitution of "the Secretary, in consultation with the Surgeon General," for "the Surgeon General, on recommendation of the National Advisory Health Council," and striking out of "in a communicable stage" after "(1) to be infected with such disease", in section 363 of the Public Health Act, was executed to this section, which is section 363 of the Public Health Service Act, to reflect the probable intent of Congress.

Statutory Notes and Related Subsidiaries

Change of Name

"Secretary of Health and Human Services" substituted in text for "Secretary of Health, Education, and Welfare" pursuant to section 509(b) of Pub. L. 96–88, which is classified to section 3508(b) of Title 20, Education.

Termination of War and Emergencies

Joint Res. July 25, 1947, ch. 327, §3, 61 Stat. 451 , provided that in the interpretation of this section, the date July 25, 1947, shall be deemed to be the date of termination of any state of war theretofore declared by Congress and of the national emergencies proclaimed by the President on Sept. 8, 1939, and May 27, 1941.

Executive Documents

Transfer of Functions

Office of Surgeon General abolished by section 3 of Reorg. Plan No. 3 of 1966, eff. June 25, 1966, 31 F.R. 8855, 80 Stat. 1610, and functions thereof transferred to Secretary of Health, Education, and Welfare by section 1 of Reorg. Plan No. 3 of 1966, set out as a note under section 202 of this title. Office of Surgeon General reestablished within the Office of the Assistant Secretary for Health, see Notice of Department of Health and Human Services, Office of the Assistant Secretary for Health, Mar. 30, 1987, 52 F.R. 11754.

Regulations, 42 CFR 70 - Interstate quarantine.
Implementation of 42 USC 264-272 and related.

Title 42 —Public Health
Chapter I —Public Health Service, Department of Health and Human Services
Subchapter F —Quarantine, Inspection, Licensing

PART 70—INTERSTATE QUARANTINE

Authority: Secs. 215 and 311 of the Public Health Service (PHS) Act, as amended (42 U.S.C. 216, 243); section 361-369, PHS Act, as amended (42 U.S.C. 264-272); 31 U.S.C. 9701.

Source: 65 FR 49908, Aug. 16, 2000, unless otherwise noted.

§ 70.1 General definitions.

As used in this part, terms shall have the following meaning:

Airline means any air carrier or foreign air carrier providing air transportation as that term is defined in 49 U.S.C. 40102(a)(2), (a)(5), and (a)(21).

Apprehension means the temporary taking into custody of an individual or group for purposes of determining whether Federal quarantine, isolation, or conditional release is warranted.

CDC means the Centers for Disease Control and Prevention, Department of Health and Human Services.

Communicable diseases means illnesses due to infectious agents or their toxic products, which may be transmitted from a reservoir to a susceptible host either directly as from an infected person or animal or indirectly through the agency of an intermediate plant or animal host, vector, or the inanimate environment.

Communicable period means the period or periods during which the etiologic agent may be transferred directly or indirectly from the body of the infected person or animal to the body of another.

Communicable stage means the stage during which an infectious agent may be transmitted either directly or indirectly from an infected individual to another individual.

Conditional release means the temporary supervision by a public health official (or designee) of an individual or group, who may have been exposed to a quarantinable communicable disease to determine the risk of disease spread and includes public health supervision through in-person visits, telephone, or through electronic or Internet-based monitoring.

Contaminated environment means the presence of an infectious agent on a surface, including on inanimate articles, or in a substance, including food, water, or in the air.

Conveyance means an aircraft, train, road vehicle, vessel (as defined in this section) or other means of transport, including military.

Director means the Director, Centers for Disease Control and Prevention, Department of Health and Human Services, or another authorized representative as approved by the CDC Director or the Secretary of HHS.

Electronic or Internet-based monitoring means mechanisms or technologies allowing for the temporary public health supervision of an individual under conditional release and may include communication through electronic mail, SMS texts, video or audio conference, webcam technologies, integrated voice-response systems, entry of information into a Web-based forum, wearable tracking technologies, and other mechanisms or technologies as determined by the Director or supervising health authority.

Ill person means an individual who:

(1) Has a fever (a measured temperature of 100.4 °F [38 °C] or greater, or feels warm to the touch, or gives a history of feeling feverish) accompanied by one or more of the following: Skin rash, difficulty breathing, persistent cough, decreased consciousness or confusion of recent onset, new unexplained bruising or bleeding (without previous injury), persistent diarrhea, persistent vomiting (other than air sickness), headache with stiff neck, appears obviously unwell; or

(2) Has a fever that has persisted for more than 48 hours; or

(3) Has symptoms or other indications of communicable disease, as the CDC may announce through posting of a notice in the FEDERAL REGISTER.

Incubation period means the time from the moment of exposure to an infectious agent that causes a communicable disease until signs and symptoms of the communicable disease appear in the individual or, if signs and symptoms do not appear, the latest date signs and symptoms could reasonably be expected to appear. For a quarantinable communicable disease, incubation period means the precommunicable stage.

Indigent means an individual whose annual family income is below 200% of the applicable poverty guidelines updated periodically in the FEDERAL REGISTER by the U.S. Department of Health and Human Services under the authority of 42 U.S.C. 9902(2) or, if no income is earned, liquid assets totaling less than 15% of the applicable poverty guidelines.

Interstate traffic

(1) Means:

(i) The movement of any conveyance or the transportation of persons or property, including any portion of such movement or transportation that is entirely within a State or possession—

(ii) From a point of origin in any State or possession to a point of destination in any other State or possession; or

(iii) Between a point of origin and a point of destination in the same State or possession but through any other State, possession, or contiguous foreign country.

(2) Interstate traffic does not include the following:

(i) The movement of any conveyance which is solely for the purpose of unloading persons or property transported from a foreign country, or loading persons or property for transportation to a foreign country.

(ii) The movement of any conveyance which is solely for the purpose of effecting its repair, reconstruction, rehabilitation, or storage.

Isolation means the separation of an individual or group reasonably believed to be infected with a quarantinable communicable disease from those who are healthy to prevent the spread of the quarantinable communicable disease.

Master or operator with respect to a vessel, means the sea crew member with responsibility for vessel operation and navigation, or a similar individual with responsibility for a conveyance. Consistent with the definition of "operate" in 14 CFR 1.1, "operator" means, with respect to aircraft, any person who uses, causes to use, or authorizes to use an aircraft, for the purpose (except as provided in 14 CFR 91.13) of air navigation including the piloting of an aircraft, with or without the right of legal control (as owner, lessee, or otherwise).

Medical examination means the assessment of an individual by an authorized and licensed health worker to determine the individual's health status and potential public health risk to others and may include the taking of a medical history, a physical examination, and collection of human biological samples for laboratory testing as may be needed to diagnose or confirm the presence or extent of infection with a quarantinable communicable disease.

Medical reviewer means a physician, nurse practitioner, or similar medical professional qualified in the diagnosis and treatment of infectious diseases who is appointed by the Secretary or Director to conduct medical reviews under this part and may include an HHS or CDC employee, provided that the employee differs from the CDC official who issued the Federal order for quarantine, isolation, or conditional release.

Non-invasive means procedures conducted by an authorized public health worker (*i.e.,* an individual with education and training in the field of public health) or another individual with suitable public health training and includes the visual examination of the ear, nose, and mouth; temperature assessments using an ear, oral, cutaneous, or noncontact thermometer, or thermal imaging; and other procedures not involving the puncture or incision of the skin or insertion of an instrument or foreign material into the body or a body cavity excluding the ear, nose, and mouth.

Possession means U.S. Territory.

Precommunicable stage means the stage beginning upon an individual's earliest opportunity for exposure to an infectious agent and ending upon the individual entering or reentering the communicable stage of the disease or, if the individual does not enter the communicable stage, the latest date at which the individual could reasonably be expected to have the potential to enter or reenter the communicable stage.

Public health emergency as used in this part means:

(1) Any communicable disease event as determined by the Director with either documented or significant potential for regional, national, or international communicable disease spread or that is highly likely to cause death or serious illness if not properly controlled; or

(2) Any communicable disease event described in a declaration by the Secretary pursuant to 319(a) of the Public Health Service Act (42 U.S.C. 247d (a)); or

(3) Any communicable disease event the occurrence of which is notified to the World Health Organization, in accordance with Articles 6 and 7 of the International Health Regulations, as one that may constitute a Public Health Emergency of International Concern; or

(4) Any communicable disease event the occurrence of which is determined by the Director-General of the World Health Organization, in accordance with Article 12 of the International Health Regulations, to constitute a Public Health Emergency of International Concern; or

(5) Any communicable disease event for which the Director-General of the World Health Organization, in accordance with Articles 15 or 16 of the International Health Regulations, has issued temporary or standing recommendations for purposes of preventing or promptly detecting the occurrence or reoccurrence of the communicable disease.

Public health prevention measures means the assessment of an individual through non-invasive procedures and other means, such as observation, questioning, review of travel documents, records review, and other non-invasive means, to determine the individual's health status and potential public health risk to others.

Qualifying stage is statutorily defined (42 U.S.C. 264(d)(2)) to mean:

(1) The communicable stage of a quarantinable communicable disease; or

(2) The precommunicable stage of the quarantinable communicable disease, but only if the quarantinable communicable disease would be likely to cause a public health emergency if transmitted to other individuals.

Quarantine means the separation of an individual or group reasonably believed to have been exposed to a quarantinable communicable disease, but who are not yet ill, from others who have not been so exposed, to prevent the possible spread of the quarantinable communicable disease.

Quarantinable communicable disease means any of the communicable diseases listed in an Executive Order, as provided under section 361 of the Public Health Service Act. Executive Order 13295, of April 4, 2003, as amended by Executive Order 13375 of April 1, 2005, contains the current revised list of quarantinable communicable diseases, and may be obtained at *http://www.cdc.gov* and *http://www.archives.gov/federal_register*. If this Order is amended, HHS will enforce that amended order immediately and update that Web site.

Reasonably believed to be infected, as applied to an individual, means specific articulable facts upon which a public health officer could reasonably draw the inference that an individual has been exposed, either directly or indirectly, to the infectious agent that causes a quarantinable communicable disease, as through contact with an infected person or an infected person's bodily fluids, a contaminated environment, or through an intermediate host or vector, and that as a consequence of the exposure, the individual is or may be harboring in the body the infectious agent of that quarantinable communicable disease.

Representatives means a physician, nurse practitioner, or similar medical professional qualified in the diagnosis and treatment of infectious diseases, and an attorney who is knowledgeable of public health practices, who are appointed by the Secretary or Director and may include HHS or CDC employees, to assist an indigent individual under Federal quarantine, isolation, or conditional release with a medical review under this part.

Secretary means the Secretary of Health and Human Services (HHS) or any other officer or employee of that Department to whom the authority involved has been delegated.

State means any of the 50 states, plus the District of Columbia.

U.S. Territory means any territory (also known as possessions) of the United States, including American Samoa, Guam, the Northern Mariana Islands, the Commonwealth of Puerto Rico, and the U.S. Virgin Islands.

Vessel means any passenger-carrying, cargo, or towing vessel exclusive of:

Fishing boats including those used for shell-fishing;

Tugs which operate only locally in specific harbors and adjacent waters;

Barges without means of self-propulsion;

Construction-equipment boats and dredges; and

Sand and gravel dredging and handling boats.

[65 FR 49908, Aug. 16, 2000, as amended at 77 FR 75884, Dec. 26, 2012; 82 FR 6968, Jan. 19, 2017]

§ 70.2 Measures in the event of inadequate local control.

Whenever the Director of the Centers for Disease Control and Prevention determines that the measures taken by health authorities of any State or possession (including political subdivisions thereof) are insufficient to prevent the spread of any of the communicable diseases from such State or possession to any other State or possession, he/she may take such measures to prevent such spread of the diseases as he/she deems reasonably necessary, including inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of animals or articles believed to be sources of infection.

§ 70.3 All communicable diseases.

A person who has a communicable disease in the communicable period shall not travel from one State or possession to another without a permit from the health officer of the State, possession, or locality of destination, if such permit is required under the law applicable to the place of destination. Stop-overs other than those necessary for transportation connections shall be considered as places of destination.

§ 70.4 Report of disease.

The master of any vessel or person in charge of any conveyance engaged in interstate traffic, on which a case or suspected case of a communicable disease develops shall, as soon as practicable, notify the local health authority at the next port of call, station, or stop, and shall take such measures to prevent the spread of the disease as the local health authority directs.

§ 70.5 Requirements relating to travelers under a Federal order of isolation, quarantine, or conditional release.

(a) The following provisions are applicable to any individual under a Federal order of isolation, quarantine, or conditional release with regard to a quarantinable communicable disease or to any individual meeting the requirements of paragraph (d), (e), or (f) of this section:

(1) Except as specified under the terms of a Federal conditional release order, no such individual shall travel in interstate traffic or from one State or U.S. territory to another without a written travel permit issued by the Director.

(2) Requests for a travel permit must state the reasons why the travel is being requested, mode of transportation, the places or individuals to be visited, the precautions, if any, to be taken to prevent the potential transmission or spread of the communicable disease, and other information as determined necessary by the Director to assess the individual's health condition and potential for communicable disease spread to others.

(3) The Director will consider all requests for a permit and, taking into consideration the risk of introduction, transmission, or spread of the communicable disease, may condition the permit upon compliance with such precautionary measures as the Director shall prescribe. The Director shall respond to a request for a permit within 5 business days.

(4) An individual to whom a permit has been issued shall retain it in his/her possession throughout the course of his/her authorized travel and comply with all conditions prescribed therein, including presentation of the permit to the operators of conveyances, as required by its terms.

(5) An individual who has had his/her request for a permit denied, or who has had a travel permit suspended or revoked, may submit a written appeal to the Director (excluding the CDC official who denied, suspended, or revoked the permit). The appeal must be in writing, state the factual basis for the appeal, and be submitted to the Director (excluding the CDC official who denied, suspended, or revoked the permit) within 10 calendar days of the denial, suspension, or revocation of the permit. The Director (excluding the CDC official who denied, suspended, or revoked the permit) will issue a written response to the appeal within 3 business days, which shall constitute final agency action.

(b) The operator of any conveyance operating in interstate traffic shall not:

(1) Accept for transportation any individual whom the operator knows, or reasonably should know, to be under a Federal order of isolation, quarantine, or conditional release, unless such an individual presents a permit issued by the Director or a copy of the Federal conditional release order authorizing such travel;

(2) Transport any individual whom the operator knows, or reasonably should know, to be under a Federal order of isolation, quarantine, or conditional release in violation of any of the terms or conditions prescribed in the travel permit or conditional release order issued by the Director.

(c) Whenever a conveyance operating in interstate traffic transports an individual under a Federal order or travel permit, the Director may require that the operator of the conveyance submit the conveyance to inspection, sanitary measures, and other measures, as the Director deems necessary to prevent the possible spread of communicable disease.

(d) The Director may additionally apply the provisions in paragraphs (a) through (c) of this section to individuals traveling entirely intrastate and to conveyances that transport such individuals upon the request of a State or local health authority of jurisdiction. The Director shall consider the State or local health authority's request for assistance and taking into consideration the risk of introduction, transmission, or spread of the communicable disease, grant or deny, in his/her discretion, the request for assistance.

(e) The Director may additionally apply the provisions in paragraphs (a) through of this section (c) to individuals traveling interstate or entirely intrastate and to conveyances that transport such individuals whenever the Director makes a determination under 42 CFR 70.2 that based on the existence of inadequate local control such measures are needed to prevent the spread of any of the communicable diseases from such State or U.S. territory to any other State or U.S. territory.

(f) The Director may additionally apply the provisions in paragraphs (a) through (c) of this section to individuals under a State or local order, or written agreement, for quarantine, isolation, or conditional release and to conveyances that may transport such individuals, upon the request of a State or local health authority of jurisdiction or whenever the Director makes a determination of inadequate local control under 42 CFR 70.2. The Director shall consider the State or local health authority's request for assistance and taking into consideration the risk of introduction, transmission, or spread of the communicable disease, grant or deny, in his/her discretion, the request for assistance.

(g) The Director may exempt individuals and non-public conveyances, such as ambulances, air ambulance flights, or private vehicles, from the requirements of this section.

[82 FR 6970, Jan. 19, 2017]

§ 70.6 Apprehension and detention of persons with quarantinable communicable diseases.

(a) The Director may authorize the apprehension, medical examination, quarantine, isolation, or conditional release of any individual for the purpose of preventing the introduction, transmission, and spread of quarantinable communicable diseases, as specified by Executive Order, based upon a finding that:

(1) The individual is reasonably believed to be infected with a quarantinable communicable disease in a qualifying stage and is moving or about to move from a State into another State; or

(2) The individual is reasonably believed to be infected with a quarantinable communicable disease in a qualifying stage and constitutes a probable source of infection to other individuals who may be moving from a State into another State.

(b) The Director will arrange for adequate food and water, appropriate accommodation, appropriate medical treatment, and means of necessary communication for individuals who are apprehended or held in quarantine or isolation under this part.

[82 FR 6971, Jan. 19, 2017]

§ 70.7 Responsibility with respect to minors, wards, and patients.

A parent, guardian, physician, nurse, or other such person shall not transport, or procure or furnish transportation for any minor child or ward, patient or other such person who is in the communicable period of a communicable disease, except in accordance with provisions of this part.

§ 70.8 Members of military and naval forces.

The provisions of §§ 70.3, 70.4, 70.5, 70.7, and this section shall not apply to members of the military or naval forces, and medical care or hospital beneficiaries of the Army, Navy, Veterans' Administration, or Public Health Service, when traveling under competent orders: *Provided,* That in the case of persons otherwise subject to the provisions of § 70.5 the authority authorizing the travel requires precautions to prevent the possible transmission of infection to others during the travel period.

§ 70.9 Vaccination clinics.

(a) The Director may establish vaccination clinics, through contract or otherwise, authorized to administer vaccines and/or other prophylaxis.

(b) A vaccination fee may be charged for individuals not enrolled in Medicare Part B to cover costs associated with administration of the vaccine and/or other prophylaxis. Such fee is to be collected at the time that the vaccine is administered. The vaccination fee, if imposed, is shown in the following table:

Vaccine	Effective dates	Amount
Fluarix	[1] 1/25/05	[2] $25.00

[1] *Continuing for one year.*

[2] *$7.00 for the vaccine and $18.00 for administration.*

[70 FR 3493, Jan. 25, 2005]

§ 70.10 Public health prevention measures to detect communicable disease.

(a) The Director may conduct public health prevention measures at U.S. airports, seaports, railway stations, bus terminals, and other locations where individuals may gather to engage in interstate travel, through non-invasive procedures determined appropriate by the Director to detect the presence of communicable diseases.

(b) As part of the public health prevention measures, the Director may require individuals to provide contact information such as U.S. and foreign addresses, telephone numbers, email addresses, and other contact information, as well as information concerning their intended destination, health status, known or possible exposure history, and travel history.

[82 FR 6971, Jan. 19, 2017]

§ 70.11 Report of death or illness onboard aircraft operated by an airline.

(a) The pilot in command of an aircraft operated by an airline who is conducting a commercial passenger flight in interstate traffic under a regular schedule shall report as soon as practicable to the Director the occurrence onboard of any deaths or the presence of ill persons among passengers or crew and take such measures as the Director may direct to prevent the potential spread of the communicable disease, provided that such measures do not affect the airworthiness of the aircraft or the safety of flight operations.

(b) The pilot in command of an aircraft operated by an airline who reports in accordance with paragraph (a) of this section shall be deemed to satisfy the reporting obligation under 42 CFR 70.4.

[82 FR 6971, Jan. 19, 2017]

§ 70.12 Medical examinations.

(a) The Director may require an individual to undergo a medical examination as part of a Federal order for quarantine, isolation, or conditional release for a quarantinable communicable disease.

(b) The Director shall promptly arrange for the medical examination to be conducted when one is required under this section and shall as part of the Federal order advise the individual that the medical examination shall be conducted by an authorized and licensed health worker, and with prior informed consent.

(c) As part of the medical examination, the Director may require an individual to provide information and undergo such testing as may be reasonably necessary to diagnose or confirm the presence or extent of infection with a quarantinable communicable disease.

(d) Individuals reasonably believed to be infected based on the results of a medical examination may be isolated, or if such results are inconclusive or unavailable, individuals may be quarantined or conditionally released in accordance with this part.

[82 FR 6971, Jan. 19, 2017]

§ 70.13 Payment for care and treatment.

(a) The Director may authorize payment for the care and treatment of individuals subject to medical examination, quarantine, isolation, and conditional release, subject to paragraphs (b) through (h) of this section.

(b) Payment for care and treatment shall be in the CDC's sole discretion and subject to the availability of appropriations.

(c) Payment shall be secondary to the obligation of the United States or any third-party (*i.e.,* any State or local governmental entity, private insurance carrier, or employer), under any other law or contractual agreement, to pay for such care and treatment, and shall be paid by the Director only after all third-party payers have made payment in satisfaction of their obligations.

(d) Payment may include costs for providing ambulance or other medical transportation when such services are deemed necessary by the Director for the individual's care and treatment.

(e) Payment shall be limited to those amounts the hospital, medical facility, or medical transportation service would customarily bill the Medicare system using the International Classification of Diseases, Clinical Modification (ICD-CM), and relevant regulations promulgated by the Centers for Medicare and Medicaid Services in existence at the time of billing.

(f) For quarantinable communicable diseases, payment shall be limited to costs for services and items reasonable and necessary for the care and treatment of the individual or group for the time period beginning when the Director refers the individual or group to the hospital or medical facility and ends when, as determined by the Director, the period of apprehension, quarantine, isolation, or conditional release expires.

(g) For diseases other than those described in paragraph (f) of this section, such payment shall be limited to costs for services and items reasonable and necessary for care and treatment of the individual for the time period that begins when the Director refers the individual to the hospital or medical facility and ends when the individual's condition is diagnosed, as determined by the Director, as an illness other than a quarantinable communicable disease.

(h) For ambulance or other medical transportation, payment shall be limited to the costs for such services and other items reasonable and necessary for the individual's safe medical transport.

[82 FR 6971, Jan. 19, 2017]

§ 70.14 Requirements relating to the issuance of a Federal order for quarantine, isolation, or conditional release.

(a) A Federal order authorizing quarantine, isolation, or conditional release shall be in writing, signed by the Director, and contain the following information:

(1) The identity of the individual or group subject to the order;

(2) The location of the quarantine or isolation or, in the case of conditional release, the entity to who and means by which the individual shall report for public health supervision;

(3) An explanation of the factual basis underlying the Director's reasonable belief that the individual is in the qualifying stage of a quarantinable communicable disease;

(4) An explanation of the factual basis underlying the Director's reasonable belief that the individual is moving or about to move from one State into another or constitutes a probable source of infection to others who may be moving from one State into another;

(5) An explanation that the Federal order will be reassessed no later than 72 hours after it has been served and an explanation of the medical review of the Federal order pursuant to this part, including the right to request a medical review, present witnesses and testimony at the medical review, and to

be represented at the medical review by either an advocate (*e.g.,* an attorney, family member, or physician) at the individual's own expense, or, if indigent, to have representatives appointed at the government's expense;

(6) An explanation of the criminal penalties for violating a Federal order of quarantine, isolation, or conditional release; and

(7) An explanation that if a medical examination is required as part of the Federal order that the examination will be conducted by an authorized and licensed health worker, and with prior informed consent.

(b) A Federal order authorizing quarantine, isolation, or conditional release shall be served on the individual no later than 72 hours after the individual has been apprehended, except that the Federal order may be published or posted in a conspicuous location if the Federal order is applicable to a group of individuals and individual service would be impracticable.

(c) The Director shall arrange for translation or interpretation services of the Federal order as needed.

(d) Nothing in this section shall affect the constitutional or statutory rights of individuals to obtain judicial review of their Federal detention.

[82 FR 6971, Jan. 19, 2017]

§ 70.15 Mandatory reassessment of a Federal order for quarantine, isolation, or conditional release.

(a) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall reassess the need to continue the quarantine, isolation, or conditional release of an individual no later than 72 hours after the service of the Federal order.

(b) As part of the reassessment, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall review all records considered in issuing the Federal order, including travel records, records evidencing exposure or infection with a quarantinable communicable disease, as well as any relevant new information.

(c) As part of the reassessment, and where applicable, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall consider and make a determination regarding whether less restrictive alternatives would adequately serve to protect the public health.

(d) At the conclusion of the reassessment, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall promptly issue and serve a written Federal order directing that the quarantine, isolation, or conditional release be continued, modified, or rescinded.

(e) In the event that the Director orders that the quarantine, isolation, or conditional release be continued or modified, the written Federal order shall explain the process for requesting a medical review under this part.

(f) The Director's written Federal order shall be promptly served on the individual, except that the Federal order may be served by publication or by posting in a conspicuous location if the Federal order is applicable to a group of individuals and individual service would be impracticable.

(g) The Director shall arrange for translation or interpretation services of the Federal order as needed.

[82 FR 6971, Jan. 19, 2017]

§ 70.16 Medical review of a Federal order for quarantine, isolation, or conditional release.

(a) The Director shall, as soon as practicable, arrange for a medical review upon a request by an individual under Federal quarantine, isolation, or conditional release.

(b) A request for a medical review may only occur after the Director's mandatory reassessment under section 70.15 and following the service of a Federal order continuing or modifying the quarantine, isolation, or conditional release.

(c) The medical review shall be for the purpose of ascertaining whether the Director has a reasonable belief that the individual is infected with a quarantinable communicable disease in a qualifying stage.

(d) The Director shall notify the individual in writing of the time and place of the medical review.

(e) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall designate a medical reviewer to review the medical or other evidence presented at the review, make medical or other findings of fact, and issue a recommendation concerning whether the Federal order for quarantine, isolation, or conditional release should be rescinded, continued, or modified.

(f) The individual under Federal quarantine, isolation, or conditional release may authorize an advocate (*e.g.,* an attorney, family member, or physician) at his or her own expense to submit medical or other evidence and, in the medical reviewer's discretion, be allowed to present a reasonable number of medical experts. The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall appoint representatives at government expense to assist the individual for purposes of the medical review upon a request and certification, under penalty of perjury, by that individual that he or she is indigent.

(g) Prior to the convening of the review, the individual or his/her authorized advocate or representatives shall be provided a reasonable opportunity to examine the available medical and other records involved in the medical review that pertain to that individual.

(h) The Director shall take such measures that he/she determines to be reasonably necessary to allow an individual under Federal quarantine or isolation to communicate with any authorized advocate or representatives in such a manner as to prevent the possible spread of the quarantinable communicable disease.

(i) The medical reviewer may order a medical examination of an individual when, in the medical reviewer's professional judgment, such an examination would assist in assessing the individual's medical condition.

(j) As part of the review, and where applicable, the medical reviewer shall consider and accept into the record evidence concerning whether less restrictive alternatives would adequately serve to protect public health.

(k) The medical review shall be conducted by telephone, audio or video conference, or through other means that the medical reviewer determines in his/her discretion are practicable for allowing the individual under quarantine, isolation, or conditional release to participate in the medical review.

(l) At the conclusion of the review, the medical reviewer shall, based upon his or her review of the facts and other evidence made available during the medical review, issue a written report to the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) concerning whether, in the medical reviewer's professional judgment, the Federal quarantine, isolation, or conditional release

should be rescinded, continued, or modified. The written report shall include a determination regarding whether less restrictive alternatives would adequately serve to protect public health. The written report shall be served on the individual and the individual's authorized advocate or representatives.

(m) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall, as soon as practicable, review the written report and any objections that may be submitted by the individual or the individual's authorized advocate or representatives that contest the findings and recommendation contained in the medical reviewer's written report. Upon conclusion of the review, the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) shall promptly issue a written Federal order directing that the quarantine, isolation, or conditional release be continued, modified, or rescinded. In the event that the Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) continues or modifies the Federal quarantine, isolation, or conditional release, the Director's written order shall include a statement that the individual may request that the Director rescind the Federal quarantine, isolation, or conditional release, but based only on a showing of significant, new or changed facts or medical evidence that raise a genuine issue as to whether the individual should continue to be subject to Federal quarantine, isolation, or conditional release. The written Federal order shall be promptly served on the individual and the individual's authorized advocate or representatives, except that the Federal order may be served by publication or by posting in a conspicuous location if applicable to a group of individuals and individual service would be impracticable.

(n) The Director's written order shall not constitute final agency action until it has been served on the individual and the individual's authorized advocate or representatives, or alternatively, if applicable to a group of individuals and individual service would be impracticable, it is published or posted.

(o) The Director (excluding the CDC official who issued the quarantine, isolation, or conditional release order) may order the consolidation of one or more medical reviews if the number of individuals or other factors makes the holding of individual medical reviews impracticable.

(p) The Director may issue additional instructions as may be necessary or desirable governing the conduct of medical reviews.

(q) The Director shall arrange for translation or interpretation services as needed for purposes of this section.

[82 FR 6971, Jan. 19, 2017]

§ 70.17 Administrative records relating to Federal quarantine, isolation, or conditional release.

(a) The administrative record of an individual under Federal quarantine, isolation, or conditional release shall, where applicable, consist of the following:

(1) The Federal order authorizing quarantine, isolation, or conditional release, including any subsequent Federal orders continuing or modifying the quarantine, isolation or conditional release;

(2) Records of any available medical, laboratory, or other epidemiologic information that are in the agency's possession and that were considered in issuing the Federal quarantine, isolation, or conditional release order, or any subsequent Federal orders;

(3) Records submitted by the individual under quarantine, isolation, or conditional release, or by an authorized advocate or representatives, as part of a request for rescission of the Federal quarantine, isolation, or conditional release or as part of a medical review;

(4) The written findings and report of the medical reviewer, including any transcripts of the medical review and any written objections submitted by the individual under Federal quarantine, isolation, or conditional release, or by any authorized advocate or representatives;

(b) An individual subject to a Federal public health order shall upon request be served with a copy of his or her own administrative record in its entirety.

[82 FR 6971, Jan. 19, 2017]

§ 70.18 Penalties.

(a) Persons in violation of this part are subject to a fine of no more than $100,000 if the violation does not result in a death or one year in jail, or both, or a fine of no more than $250,000 if the violation results in a death or one year in jail, or both, or as otherwise provided by law.

(b) Violations by organizations are subject to a fine of no more than $200,000 per event if the violation does not result in a death or $500,000 per event if the violation results in a death or as otherwise provided by law.

[82 FR 6971, Jan. 19, 2017]

Title 42 —Public Health
Chapter I —Public Health Service, Department of Health and Human Services
Subchapter F —Quarantine, Inspection, Licensing

PART 73—SELECT AGENTS AND TOXINS

Authority: 42 U.S.C. 262a.

Source: 70 FR 13316, Mar. 18, 2005, unless otherwise noted.

§ 73.0 Applicability and related requirements.

All individuals and entities that possess SARS-CoV, Lujo virus, or Chapare virus must provide notice to CDC regarding their possession of SARS-CoV, Lujo virus, or Chapare virus on or before December 4, 2012. Currently registered individuals and entities possessing SARS-CoV, Lujo virus, or Chapare virus must meet all the requirements of this part by December 4, 2012. All previously unregistered individuals and entities possessing SARS-CoV, Lujo virus, or Chapare virus must meet all of the requirements of this part by April 3, 2013.

[77 FR 61110, Oct. 5, 2012, as amended at 77 FR 71702, Dec. 4, 2012]

§ 73.1 Definitions.

For purposes of this part:

Administrator means the Administrator, Animal and Plant Health Inspection Service, or any person authorized to act for the Administrator.

Animal and Plant Health Inspection Service (APHIS) means the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture.

Attorney General means the Attorney General of the United States or any person authorized to act for the Attorney General.

Biological agent means any microorganism (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, or any naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance, capable of causing death, disease, or other biological malfunction in a human, an animal, a plant, or another living organism; deterioration of food, water, equipment, supplies, or material of any kind; or deleterious alteration of the environment.

CDC means Centers for Disease Control and Prevention of the Department of Health and Human Services.

Conotoxins means short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$, whereas:

(1) C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges;

(2) The consensus sequence includes known toxins α-MI and α-GI (shown above) as well as α-GIA, Ac1.1a, α-CnIA, α-CnIB;

(3) X_1 = any amino acid(s) or Des-X;

(4) X_2 = Asparagine or Histidine;

(5) P = Proline;

(6) A = Alanine;

(7) G = Glycine;

(8) X_3 = Arginine or Lysine;

(9) X_4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan;

(10) X_5 = Tyrosine, Phenylalanine, or Tryptophan;

(11) X_6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine;

(12) X_7 = Any amino acid(s) or Des X; and

(13) "Des X" = "an amino acid does not have to be present at this position." For example if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.

Diagnosis means the analysis of specimens for the purpose of identifying or confirming the presence or characteristics of a select agent or toxin provided that such analysis is directly related to protecting the public health or safety, animal health or animal products, or plant health or plant products.

Entity means any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity.

HHS means the Department of Health and Human Services.

HHS Secretary means the Secretary of the Department of Health and Human Services or his or her designee, unless otherwise specified.

HHS select agent and/or toxin means a biological agent or toxin included in § 73.3.

Information security means protecting information and information systems from unauthorized access, use, disclosure, disruption, modification, or destruction in order to provide—

(1) Integrity, which means guarding against improper information modification or destruction, and includes ensuring information authenticity;

(2) Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and

(3) Availability, which means ensuring timely and reliable access to and use of information.

Occupational exposure means any reasonably anticipated skin, eye, mucous membrane, parenteral contact, or respiratory aerosol exposure to select agents or toxins that may result from the performance of an employee's duties.

Overlap select agent and/or toxin means a biological agent or toxin listed in § 73.4 and 9 CFR part 121.4.

Principal investigator means the one individual who is designated by the entity to direct a project or program and who is responsible to the entity for the scientific and technical direction of that project or program.

Proficiency testing means the process of determining the competency of an individual or laboratory to perform a specified test or procedure.

Recombinant nucleic acids means:

(1) Molecules that are constructed by joining nucleic acid molecules and that can replicate in a living cell or

(2) Molecules that result from the replication of those described in paragraph (1) of this definition.

Responsible Official means the individual designated by an entity with the authority and control to ensure compliance with the regulations in this part.

Security barrier means a physical structure that is designed to prevent entry by unauthorized persons.

Select agent and/or toxin means unless otherwise specified, all of the biological agents or toxins listed in §§ 73.3 and 73.4.

Specimen means samples of material from humans, animals, plants or the environment or isolates or cultures from such samples for the diagnosis, verification, or proficiency testing.

State means any of the several States of the United States, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the District of Columbia, Guam, the Virgin Islands of the United States, or any other territory or possession of the United States.

Synthetic nucleic acids means:

(1) Molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (*i.e.,* synthetic nucleic acids) or

(2) Molecules that result from the replication of those described in paragraph (1) of this definition.

Toxin means the toxic material or product of plants, animals, microorganisms (including, but not limited to, bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule, whatever their origin and method of production, and includes any poisonous substance or biological product that may be engineered as a result of biotechnology, produced by a living organism; or any poisonous isomer or biological product, homolog, or derivative of such a substance.

United States means all of the States.

USDA means the United States Department of Agriculture.

Validated inactivation procedure means a procedure, whose efficacy is confirmed by data generated from a viability testing protocol, to render a select agent non-viable but allows the select agent to retain characteristics of interest for future use; or to render any nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use.

Viability testing protocol means a protocol to confirm the validated inactivation procedure by demonstrating the material is free of all viable select agent.

Verification means the demonstration of obtaining established performance (e.g., accuracy, precision, and the analytical sensitivity and specificity) specifications for any procedure used for diagnosis.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61110, Oct. 5, 2012; 82 FR 6290, Jan. 19, 2017]

§ 73.2 Purpose and scope.

This part implements the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 setting forth the requirements for possession, use, and transfer of select agents and toxins. The biological agents and toxins listed in this part have the potential to pose a severe threat to public health and safety, to animal health, or to animal products. Overlap select agents and toxins are subject to regulation by both CDC and APHIS.

§ 73.3 HHS select agents and toxins.

(a) Except for exclusions under paragraphs (d) and (e) of this section, the HHS Secretary has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to public health and safety. The select agents and toxins marked with an asterisk (*) are designated as Tier 1 select agents and toxins and are subject to additional requirements as listed in this part.

(b) HHS select agents and toxins[1] are:

(1) Abrin.

(2) *Bacillus cereus* Biovar *anthracis.**

(3) Botulinum neurotoxins.*

(4) Botulinum neurotoxin producing species of *Clostridium.**

(5) Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$).[2]

(6) *Coxiella burnetii.*

(7) Crimean-Congo hemorrhagic fever virus.

(8) Diacetoxyscirpenol.

(9) Eastern equine encephalitis virus.

(10) *Ebolavirus* *

(11) *Francisella tularensis.**

(12) Lassa fever virus.

(13) Lujo virus.

(14) Marburg virus.*

(15) Monkeypox virus.

(16) Reconstructed replication competent forms of the 1918 pandemic influenza A virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 influenza A virus).

(17) Ricin.

(18) *Rickettsia prowazekii.*

(19) Severe acute respiratory syndrome coronavirus (SARS-CoV).

(20) SARS-CoV/SARS-CoV-2 chimeric viruses resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors.

(21) Saxitoxin.

(22) South American hemorrhagic fever virus: Chapare.

(23) South American hemorrhagic fever virus: Guanarito.

(24) South American hemorrhagic fever virus: Junin.

(25) South American hemorrhagic fever virus: Machupo.

(26) South American hemorrhagic fever virus: Sabia.

(27) Staphylococcal enterotoxins (subtypes A,B,C,D,E).

(28) T-2 toxin.

(29) Tetrodotoxin.

(30) Tick-borne encephalitis virus: Far Eastern subtype.

(31) Tick-borne encephalitis virus: Siberian subtype.

(32) Kyasanur Forest disease virus.

(33) Omsk haemorrhagic fever virus.

(34) Variola major virus (Smallpox virus).*

(35) Variola minor virus (Alastrim).*

(36) *Yersinia pestis.**

[1] Please refer to *https://www.selectagents.gov* for current information on historical or proposed nomenclature for the HHS select agents on the list.

[2] C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges; The consensus sequence includes known toxins a-MI and a-GI (shown above) as well as a-GIA, Ac1.1a, a-CnIA, a-CnIB; X1 = any amino acid(s) or Des-X; X2 = Asparagine or Histidine; P = Proline; A = Alanine; G = Glycine; X3 = Arginine or Lysine; X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan; X5 = Tyrosine, Phenylalanine, or Tryptophan; X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine; X7 = Any amino acid(s) or Des X and; “Des X” = “an amino acid does not have to be present at this position.” For example, if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.

(c) Genetic Elements, Recombinant and/or Synthetic Nucleic Acids, and Recombinant and/or Synthetic Organisms:

(1) Nucleic acids that can produce infectious forms of any of the select agent viruses listed in paragraph (b) of this section.

(2) Recombinant and/or Synthetic nucleic acids that encode for the toxic form(s) of any of the toxins listed in paragraph (b) of this section if the nucleic acids:

(i) Can be expressed *in vivo* or *in vitro*, or

(ii) Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro.*

(3) HHS select agents and toxins listed in paragraph (b) of this section that have been genetically modified.

(d) HHS select agents or toxins that meet any of the following criteria are excluded from the requirements of this part:

(1) Any HHS select agent or toxin that is in its naturally occurring environment provided the select agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) Non-viable HHS select agents or nontoxic HHS toxins.

(3) A select agent or toxin that has been subjected to decontamination or a destruction procedure when intended for waste disposal.

(4) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure that is confirmed through a viability testing protocol. Surrogate strains that are known to possess equivalent properties with respect to inactivation can be used to validate an inactivation procedure; however, if there are known strain-to-strain variations in the resistance of a select agent to an inactivation procedure, then an inactivation procedure validated on a lesser resistant strain must also be validated on the more resistant strains.

(5) Material containing a select agent that is subjected to a procedure that removes all viable select agent cells, spores, or virus particles if the material is subjected to a viability testing protocol to ensure that the removal method has rendered the material free of all viable select agent.

(6) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus not subjected to a validated inactivation procedure or material containing a select agent not subjected to a procedure that removes all viable select agent cells, spores, or virus particles if the material is determined by the HHS Secretary to be effectively inactivated or effectively removed. To apply for a determination an individual or entity must submit a written request and supporting scientific information to CDC. A written decision granting or denying the request will be issued.

(7) Except as required in § 73.16(l), the aggregate amount of the toxin under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor does not, at any time, exceed the following amounts: 1000 mg of Abrin; 1 mg of Botulinum neurotoxins; 200 mg of Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$); 10,000 mg of Diacetoxyscirpenol; 1000 mg of Ricin; 500 mg of Saxitoxin; 100 mg of Staphylococcal enterotoxins (subtypes A-E); 10,000 mg of T-2 toxin; or 500 mg of Tetrodotoxin. Provided that,

(i) The toxin is transferred only after the transferor uses due diligence and documents the identification of the recipient and the legitimate need (*e.g.,* prophylactic, protective, bona fide research, or other peaceful purpose) claimed by the recipient to use such toxin. Information to be documented includes, but is not limited to, the recipient identity information, including the recipient's name, institution name, address, telephone number and email address; name of the toxin and the total amount transferred; and the legitimate need claimed by the recipient. Notwithstanding the provisions of paragraph (d) of this section, the HHS Secretary retains the authority to, without prior notification, inspect and copy or request the submission of the due diligence documentation to the CDC.

(ii) Reports to CDC if they detect a known or suspected violation of Federal law or become aware of suspicious activity related to a toxin listed in this part.

(8) An animal inoculated with or exposed to an HHS select toxin.

(9) An HHS select toxin identified in an original food sample or clinical sample.

(10) For those laboratories that are not exempt under § 73.5(a) and § 73.6(a), Botulinum neurotoxin that is produced as a byproduct in the study of Botulinum neurotoxin producing species of *Clostridium* so long as the toxin has not been intentionally cultivated, collected, purified, or otherwise extracted, and the material containing the toxin is rendered non-toxic and disposed of within 30 days of the initiation of the culture.

(11) Waste generated during the delivery of patient care by health care professionals from a patient diagnosed with an illness or condition associated with a select agent, where that waste is decontaminated or transferred for destruction by complying with state and Federal regulations within seven calendar days of the conclusion of patient care.

(12) Madariaga virus and any Clade II Monkeypox provided that the individual or entity can identify that the agent is within the exclusion category.

(e) An attenuated strain of a select agent or a select toxin modified to be less potent or toxic may be excluded from the requirements of this part based upon a determination by the HHS Secretary that the attenuated strain or modified toxin does not pose a severe threat to public health and safety.

(1) To apply for exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be listed on the National Select Agent Registry Web site at *http://www.selectagents.gov/*.

(2) If an excluded attenuated strain or modified toxin is subjected to any manipulation that restores or enhances its virulence or toxic activity, the resulting select agent or toxin will be subject to the requirements of this part.

(3) An individual or entity may make a written request to the HHS Secretary for reconsideration of a decision denying an application for the exclusion of an attenuated strain of a select agent or a select toxin modified to be less potent or toxic. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The HHS Secretary will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

(f) Any HHS select agent or toxin seized by a Federal law enforcement agency will be excluded from the requirements of this part during the period between seizure of the select agent or toxin and the transfer or destruction of such agent or toxin provided that:

(1) As soon as practicable, the Federal law enforcement agency transfers the seized select agent or toxin to an entity eligible to receive such agent or toxin or destroys the agent or toxin by a recognized sterilization or inactivation process,

(2) The Federal law enforcement agency safeguards and secures the seized select agent or toxin against theft, loss, or release, and reports any theft, loss, or release of such agent or toxin, and

(3) The Federal law enforcement agency reports the seizure of the select agent or toxin to CDC or APHIS.

(i) The seizure of *Bacillus cereus* Biovar *anthracis,* Botulinum neurotoxins, Botulinum neurotoxin producing species of *Clostridium*, Ebola viruses, *Francisella tularensis,* Marburg virus, Variola major virus (Smallpox virus), Variola minor (Alastrim), or *Yersinia pestis* must be reported within 24 hours by telephone, facsimile, or e-mail. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after seizure of the select agent or toxin.

(ii) For all other HHS select agents or toxins, APHIS/CDC Form 4 must be submitted within seven calendar days after seizure of the agent or toxin.

(iii) A copy of APHIS/CDC Form 4 must be maintained for three years.

(4) The Federal law enforcement agency reports the final disposition of the select agent or toxin by submission of APHIS/CDC Form 4. A copy of the completed form must be maintained for three years.

[70 FR 13316, Mar. 18, 2005, as amended at 70 FR 61049, Oct. 20, 2005; 73 FR 61365, Oct. 16, 2008; 73 FR 64554, Oct. 30, 2008; 77 FR 61110, Oct. 5, 2012; 79 FR 26861, May 12, 2014; 81 FR 63143, Sept. 14, 2016; 82 FR 6290, Jan. 19, 2017; 86 FR 64081, Nov. 17, 2021; 89 FR 101952, Dec. 17, 2024]

§ 73.4 Overlap select agents and toxins.

(a) Except for exclusions under paragraphs (d) and (e) of this section, the HHS Secretary has determined that the biological agents and toxins listed in this section have the potential to pose a severe threat to public health and safety, to animal health, or to animal products. The select agents and toxins marked with an asterisk (*) are designated as Tier 1 select agents and toxins and are subject to additional requirements as listed in this part.

(b) Overlap select agents and toxins[1] are:

(1) *Bacillus anthracis.**

(2) *Bacillus anthracis* Pasteur strain.

(3) *Burkholderia mallei.**

(4) *Burkholderia pseudomallei.**

(5) Hendra virus.

(6) Nipah virus.*

(7) Rift Valley fever virus.

(8) Venezuelan equine encephalitis virus.

[1] Please refer to *https://www.selectagents.gov* for current information on historical or proposed nomenclature for the Overlap select agents on the list.

(c) Genetic Elements, Recombinant and/or Synthetic Nucleic Acids, and Recombinant and/or Synthetic Organisms:

(1) Nucleic acids that can produce infectious forms of any of the overlap select agent viruses listed in paragraph (b) of this section.

(2) Recombinant and/or synthetic nucleic acids that encode for the toxic form(s) of any overlap toxins listed in paragraph (b) of this section if the nucleic acids:

(i) Can be expressed *in vivo* or *in vitro*, or

(ii) Are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*.

(3) Overlap select agents and toxins listed in paragraph (b) of this section that have been genetically modified.

(d) Overlap select agents or toxins that meet any of the following criteria are excluded from the requirements of this part:

(1) Any overlap select agent or toxin that is in its naturally occurring environment provided that the select agent or toxin has not been intentionally introduced, cultivated, collected, or otherwise extracted from its natural source.

(2) Non-viable overlap select agents or nontoxic overlap toxins.

(3) A select agent or toxin that has been subjected to decontamination or a destruction procedure when intended for waste disposal.

(4) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation procedure that is confirmed through a viability testing protocol. Surrogate strains that are known to possess equivalent properties with respect to inactivation can be used to validate an inactivation procedure; however, if there are known strain-to-strain variations in the resistance of a select agent to an inactivation procedure, then an inactivation procedure validated on a lesser resistant strain must also be validated on the more resistant strains.

(5) Material containing a select agent that is subjected to a procedure that removes all viable select agent cells, spores, or virus particles if the material is subjected to a viability testing protocol to ensure that the removal method has rendered the material free of all viable select agent.

(6) A select agent or regulated nucleic acids that can produce infectious forms of any select agent virus not subjected to a validated inactivation procedure or material containing a select agent not subjected to a procedure that removes all viable select agent cells, spores, or virus particles if the material is determined by the HHS Secretary or Administrator to be effectively inactivated or

effectively removed. To apply for a determination an individual or entity must submit a written request and supporting scientific information to CDC or APHIS. A written decision granting or denying the request will be issued.

(7) An overlap select toxin identified in an original food sample or clinical sample.

(8) Waste generated during the delivery of patient care by health care professionals from a patient diagnosed with an illness or condition associated with a select agent, where that waste is decontaminated or transferred for destruction by complying with state and Federal regulations within seven calendar days of the conclusion of patient care.

(9) Any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC provided that the individual or entity can identify that the agent is within the exclusion category.

(e) An attenuated strain of a select agent, or a select toxin modified to be less potent or toxic, may be excluded from the requirements of this part based upon a determination by the HHS Secretary that the attenuated strain or modified toxin does not pose a severe threat to public health and safety.

(1) To apply for exclusion, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued. An exclusion will be effective upon notification to the applicant. Exclusions will be listed on the National Select Agent Registry Web site at *http://www.selectagents.gov/*.

(2) If an excluded attenuated strain or modified toxin is subjected to any manipulation that restores or enhances its virulence or toxic activity, the resulting select agent or toxin will be subject to the requirements of this part.

(3) An individual or entity may make a written request to the HHS Secretary or Administrator for reconsideration of a decision denying an application for the exclusion of an attenuated strain of a select agent or a select toxin modified to be less potent or toxic. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The HHS Secretary or Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

(f) Any overlap select agent or toxin seized by a Federal law enforcement agency will be excluded from the requirements of this part during the period between seizure of the select agent or toxin and the transfer or destruction of such agent or toxin provided that:

(1) As soon as practicable, the Federal law enforcement agency transfers the seized select agent or toxin to an entity eligible to receive such agent or toxin or destroys the agent or toxin by a recognized sterilization or inactivation process,

(2) The Federal law enforcement agency safeguards and secures the seized select agent or toxin against theft, loss, or release, and reports any theft, loss, or release of such agent or toxin, and

(3) The Federal law enforcement agency reports the seizure of the overlap select agent or toxin to CDC or APHIS.

(i) The seizure of *Bacillus anthracis, Burkholderia mallei* and *Burkholderia pseudomallei* must be reported within 24 hours by telephone, facsimile, or e-mail. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after seizure of the overlap select agent or toxin.

(ii) For all other overlap select agents or toxins, APHIS/CDC Form 4 must be submitted within seven calendar days after seizure of the select agent or toxin.

(iii) A copy of APHIS/CDC Form 4 must be maintained for three years.

(4) The Federal law enforcement agency reports the final disposition of the overlap select agent or toxin by the submission of APHIS/CDC Form 4. A copy of the completed form must be maintained for three years.

[70 FR 13316, Mar. 18, 2005, as amended at 73 FR 61366, Oct. 16, 2008; 77 FR 61111, Oct. 5, 2012; 79 FR 26861, May 12, 2014; 82 FR 6291, Jan. 19, 2017; 89 FR 101952, Dec. 17, 2024]

§ 73.5 Exemptions for HHS select agents and toxins.

(a) Clinical or diagnostic laboratories and other entities that possess, use, or transfer a HHS select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the HHS Secretary, within seven calendar days after identification of the select agent or toxin (except for Botulinum neurotoxin and/or *Staphylococcal* enterotoxin (Subtypes A-E)), or within 30 calendar days after identification of Botulinum neurotoxin and/or *Staphylococcal* enterotoxin (Subtypes A-E), the select agent or toxin is transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization or inactivation process,

(2) The select agent or toxin is secured against theft, loss, or release during the period between identification of the select agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported, and

(3) Unless otherwise directed by the HHS Secretary, the clinical or diagnostic specimens collected from a patient infected with a select agent are transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization or inactivation process within seven calendar days after delivery of patient care by health care professionals has concluded, and

(4) The identification of the agent or toxin is reported to CDC or APHIS, the specimen provider, and to other appropriate authorities when required by Federal, State, or local law by telephone, facsimile, or email. This report must be followed by submission of APHIS/CDC Form 4 to APHIS or CDC within seven calendar days after identification.

(i) The identification of any of the following HHS select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: *Bacillus cereus* Biovar *anthracis,*, Botulinum neurotoxins, Botulinum neurotoxin producing species of *Clostridium*, Ebola viruses, *Francisella tularensis,* Marburg virus, Variola major virus (Smallpox virus), Variola minor (Alastrim), or Yersinia pestis. This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after identification.

(ii) For all other HHS select agents or toxins, APHIS/CDC Form 4 must be submitted within seven calendar days after identification.

(iii) Less stringent reporting may be required based on extraordinary circumstances, such as a widespread outbreak.

(iv) A copy of APHIS/CDC Form 4 must be maintained for three years.

(b) Clinical or diagnostic laboratories and other entities that possess, use, or transfer a HHS select agent or toxin that is contained in a specimen presented for proficiency testing will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the HHS Secretary, within 90 calendar days of receipt, the select agent or toxin is transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization or inactivation process,

(2) The select agent or toxin is secured against theft, loss, or release during the period between identification of the select agent or toxin and transfer or destruction of such agent or toxin, and the theft, loss, or release of such agent or toxin is reported, and

(3) The identification of the select agent or toxin, and its derivative, is reported to CDC or APHIS and to other appropriate authorities when required by Federal, State, or local law. To report the identification of a select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 calendar days of receipt of the select agent or toxin. A copy of the completed form must be maintained for three years.

(c) Unless the HHS Secretary issues an order making specific provisions of this part applicable to protect public health and safety, products that are, bear, or contain listed select agents or toxins that are cleared, approved, licensed, or registered under any of the following laws, are exempt from the provisions of this part insofar as their use meets the requirements of such laws:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*),

(2) Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262),

(3) The Act commonly known as the Virus-Serum-Toxin Act (21 U.S.C. 151-159), or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*).

(d) The HHS Secretary may exempt from the requirements of this part an investigational product that is, bears, or contains a select agent or toxin, when such product is being used in an investigation authorized under any Federal Act and additional regulation under this part is not necessary to protect public health and safety.

(1) To apply for an exemption, an individual or entity must submit a completed APHIS/CDC Form 5.

(2) The HHS Secretary shall make a determination regarding the application within 14 calendar days after receipt, provided the application meets all of the requirements of this section and the application establishes that the investigation has been authorized under the cited Act. A written decision granting or denying the request will be issued.

(3) The applicant must notify CDC or APHIS when an authorization for an investigation no longer exists. This exemption automatically terminates when such authorization is no longer in effect.

(e) The HHS Secretary may temporarily exempt an individual or entity from the requirements of this part based on a determination that the exemption is necessary to provide for the timely participation of the individual or entity in response to a domestic or foreign public health emergency. With respect to the emergency involved, the exemption may not exceed 30 calendar days, except that one extension of an additional 30 calendar days may be granted.

[70 FR 13316, Mar. 18, 2005, as amended at 73 FR 61366, Oct. 16, 2008; 77 FR 61112, Oct. 5, 2012; 82 FR 6292, Jan. 19, 2017]

§ 73.6 Exemptions for overlap select agents and toxins.

(a) Clinical or diagnostic laboratories and other entities that possess, use, or transfer an overlap select agent or toxin that is contained in a specimen presented for diagnosis or verification will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the HHS Secretary or Administrator, within seven calendar days after identification, the select agent or toxin is transferred in accordance with § 73.16 or 9 CFR part 121.16 or destroyed on-site by a recognized sterilization or inactivation process,

(2) The select agent or toxin is secured against theft, loss, or release during the period between identification of the select agent or toxin and transfer or destruction of such agent or toxin, and any theft, loss, or release of such agent or toxin is reported, and

(3) Unless otherwise directed by the HHS Secretary or Administrator, the clinical or diagnostic specimens collected from a patient infected with a select agent are transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization or inactivation process within seven calendar days after delivery of patient care by health care professionals has concluded, and

(4) The identification of the agent or toxin is reported to CDC or APHIS, the specimen provider, and to other appropriate authorities when required by Federal, State, or local law by telephone, facsimile, or email. This report must be followed by submission of APHIS/CDC Form 4 to APHIS or CDC within seven calendar days after identification.

(i) The identification of any of the following overlap select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: *Bacillus anthracis, Burkholderia mallei* and *Burkholderia pseudomallei.* This report must be followed by submission of APHIS/CDC Form 4 within seven calendar days after identification.

(ii) For all other overlap select agents or toxins, APHIS/CDC Form 4 must be submitted within seven calendar days after identification.

(iii) Less stringent reporting may be required based on extraordinary circumstances, such as a widespread outbreak.

(iv) A copy of APHIS/CDC Form 4 must be maintained for three years.

(b) Clinical or diagnostic laboratories and other entities that possess, use, or transfer an overlap select agent or toxin that is contained in a specimen presented for proficiency testing will be exempt from the requirements of this part for such agent or toxin contained in the specimen, provided that:

(1) Unless directed otherwise by the HHS Secretary or Administrator, within 90 calendar days of receipt, the select agent or toxin is transferred in accordance with § 73.16 or 9 CFR part 121.16 or destroyed on-site by a recognized sterilization or inactivation process,

(2) The select agent or toxin is secured against theft, loss, or release during the period between identification of the select agent or toxin and transfer or destruction of such agent or toxin, and the theft, loss, or release of such agent or toxin is reported, and

(3) The identification of the select agent or toxin, and its derivative, is reported to CDC or APHIS and to other appropriate authorities when required by Federal, State, or local law. To report the identification of an overlap select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 calendar days of receipt of the select agent or toxin. A copy of the completed form must be maintained for three years.

(c) Unless the HHS Secretary issues an order making specific provisions of this part applicable to protect public health and safety, products that are, bear, or contain listed select agents or toxins that are cleared, approved, licensed, or registered under any of the following laws, are exempt from the provisions of this part insofar as their use meets the requirements of such laws:

(1) The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*),

(2) Section 351 of the Public Health Service Act pertaining to biological products (42 U.S.C. 262),

(3) The Act commonly known as the Virus-Serum-Toxin Act (21 U.S.C. 151-159), or

(4) The Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 *et seq.*).

(d) The HHS Secretary, after consultation with Administrator, may exempt from the requirements of this part an investigational product that is, bears, or contains an overlap select agent or toxin, may be exempted when such product is being used in an investigation authorized under any Federal Act and additional regulation under this part is not necessary to protect public health and safety.

(1) To apply for an exemption, an individual or entity must submit a completed APHIS/CDC Form 5.

(2) The HHS Secretary shall make a determination regarding the application within 14 calendar days after receipt, provided the application meets all of the requirements of this section and the application establishes that the investigation has been authorized under the cited Act. A written decision granting or denying the request will be issued.

(3) The applicant must notify CDC or APHIS when an authorization for an investigation no longer exists. This exemption automatically terminates when such authorization is no longer in effect.

(e) The HHS Secretary may exempt an individual or entity from the requirements of this part based on a determination that the exemption is necessary to provide for the timely participation of the individual or entity in response to a domestic or foreign public health emergency. The HHS Secretary may extend the exemption once for additional 30 days.

(f) Upon request of the Administrator, the HHS Secretary may exempt an individual or entity from the requirements, in whole or in part, of this part for 30 calendar days if the Administrator has granted the exemption for agricultural emergency. The HHS Secretary may extend the exemption once for an additional 30 calendar days.

[70 FR 13316, Mar. 18, 2005, as amended at 73 FR 61366, Oct. 16, 2008; 77 FR 61112, Oct. 5, 2012; 79 FR 26862, May 12, 2014;82 FR 6292, Jan. 19, 2017]

§ 73.7 Registration and related security risk assessments.

(a) Unless exempted under § 73.5, an individual or entity shall not possess, use, or transfer any HHS select agent or toxin without a certificate of registration issued by the HHS Secretary. Unless exempted under § 73.6 or 9 CFR part 121.6, an individual or entity shall not possess, use, or transfer overlap select agents or toxins, without a certificate of registration issued by the HHS Secretary and Administrator.

(b) As a condition of registration, each entity is required to be in compliance with the requirements of this part for select agents and toxins listed on the registration regardless of whether the entity is in actual possession of the select agent or toxin. With regard to toxins, the entity registered for possession, use or transfer of a toxin must be in compliance with the requirements of this part regardless of the amount of toxin currently in its possession.

(c) As a condition of registration, each entity must designate an individual to be its Responsible Official. While most registrants are likely to be entities, in the event that an individual applies for and is granted a certificate of registration, the individual will be considered the Responsible Official.

(d)

(1) As a condition of registration, the following must be approved by the HHS Secretary or Administrator based on a security risk assessment by the Attorney General:

(i) The individual or entity,

(ii) The Responsible Official, and

(iii) Unless otherwise exempted under this section, any individual who owns or controls the entity.

(2) Federal, State, or local governmental agencies, including public accredited academic institutions, are exempt from the security risk assessments for the entity and the individual who owns or controls such entity.

(3) An individual will be deemed to own or control an entity under the following conditions:[1]

(i) For a private institution of higher education, an individual will be deemed to own or control the entity if the individual is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.

(ii) For entities other than institutions of higher education, an individual will be deemed to own or control the entity if the individual:

(A) Owns 50 percent or more of the entity, or is a holder or owner of 50 percent or more of its voting stock, or

(B) Is in a managerial or executive capacity with regard to the entity's select agents or toxins or with regard to the individuals with access to the select agents or toxins possessed, used, or transferred by the entity.

(4) An entity will be considered to be an institution of higher education if it is an institution of higher education as defined in section 101(a) of the Higher Education Act of 1965 (20 U.S.C. 1001(a)), or is an organization described in 501(c)(3) of the Internal Revenue Code of 1986, as amended (26 U.S.C. 501(c)(3)).

(5) To obtain a security risk assessment, an individual or entity must submit the information necessary to conduct a security risk assessment to the Attorney General.

(e) To apply for a certificate of registration that covers only HHS select agents or toxins, an individual or entity must submit the information requested in the registration application package (APHIS/CDC Form 1) to CDC. To apply for a certificate of registration that does not cover only HHS select agents or toxins (*i.e.,* covers at least one overlap select agent and/or toxin, or covers any combination of HHS select agents and/or toxins and USDA select agents and/or toxins), an individual or entity must submit the information requested in the registration application package (APHIS/CDC Form 1) to CDC or APHIS, but not both.

[1] These conditions may apply to more than one individual.

(f) Prior to the issuance of a certificate of registration, the Responsible Official must promptly provide notification of any changes to the application for registration by submitting the relevant page(s) of the registration application.

(g) The issuance of a certificate of registration may be contingent upon inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared under this part.

(h) A certificate of registration will be valid for one physical location (a room, a building, or a group of buildings) where the Responsible Official will be able to perform the responsibilities required in this part, for specific select agents or toxins, and for specific activities.

(i) A certificate of registration may be amended to reflect changes in circumstances (e.g., replacement of the Responsible Official or other personnel changes, changes in ownership or control of the entity, changes in the activities involving any select agents or toxins, or the addition or removal of select agents or toxins).

(1) Prior to any change, the Responsible Official must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application.

(2) The Responsible Official will be notified in writing if an application to amend a certificate of registration has been approved. Approval of the amendment may be contingent upon an inspection or submission of additional information, such as the security plan, biosafety plan, incident response plan, or any other documents required to be prepared under this part.

(3) No change may be made without such approval.

(j) An entity must immediately notify CDC or APHIS if it loses the services of its Responsible Official. In the event that an entity loses the services of its Responsible Official, an entity may continue to possess or use select agents or toxins only if it appoints as the Responsible Official another individual who has been approved by the HHS Secretary or Administrator following a security risk assessment by the Attorney General and who meets the requirements of this part.

(k) A certificate of registration will be terminated upon the written request of the entity if the entity no longer possesses or uses any select agents or toxins and no longer wishes to be registered.

(l) A certificate of registration will be valid for a maximum of three years.

[70 FR 13316, Mar. 18, 2005, as amended at 82 FR 6292, Jan. 19, 2017]

§ 73.8 Denial, revocation, or suspension of registration.

(a) An application may be denied or a certificate of registration revoked or suspended if:

(1) The individual or entity, the Responsible Official, or an individual who owns or controls the entity is within any of the categories described in 18 U.S.C. 175b,

(2) The individual or entity, the Responsible Official, or an individual who owns or controls the entity as reasonably suspected by any Federal law enforcement or intelligence agency of:

(i) Committing a crime specified in 18 U.S.C. 2332b(g)(5),

(ii) Knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence, or

(iii) Being an agent of a foreign power (as defined in 50 U.S.C. 1801).

(3) The individual or entity does not meet the requirements of this part, or

(4) It is determined that such action is necessary to protect public health and safety.

(b) Upon revocation or suspension of a certificate of registration, the individual or entity must:

(1) Immediately stop all use of each select agent or toxin covered by the revocation or suspension order,

(2) Immediately safeguard and secure each select agent or toxin covered by the revocation or suspension order from theft, loss, or release, and

(3) Comply with all disposition instructions issued by the HHS Secretary for the select agent or toxin covered by the revocation or suspension.

(c) Denial of an application for registration and revocation of registration may be appealed under § 73.20. However, any denial of an application for registration or revocation of a certificate of registration will remain in effect until a final agency decision has been rendered.

§ 73.9 Responsible Official.

(a) An individual or entity required to register under this part must designate an individual to be the Responsible Official. The Responsible Official must:

(1) Be approved by the HHS Secretary or Administrator following a security risk assessment by the Attorney General,

(2) Be familiar with the requirements of this part,

(3) Have authority and responsibility to act on behalf of the entity,

(4) Ensure compliance with the requirements of this part,

(5) Have a physical (and not merely a telephonic or audio/visual) presence at the registered entity to ensure that the entity is in compliance with the select agent regulations and be able to respond in a timely manner to onsite incidents involving select agents and toxins in accordance with the entity's incident response plan, and

(6) Ensure that annual inspections are conducted for each registered space where select agents or toxins are stored or used in order to determine compliance with the requirements of this part. The results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected and the corrections documented.

(7) Ensure that individuals are provided the contact information for the HHS Office of Inspector General Hotline and the USDA Office of Inspector General Hotline so that they may anonymously report any biosafety or security concerns related to select agents and toxins.

(8) Investigate to determine the reason for any failure of a validated inactivation procedure or any failure to remove viable select agent from material. If the Responsible Official is unable to determine the cause of a deviation from a validated inactivation procedure or a viable select agent removal method; or receives a report of any inactivation failure after the movement of material to another location, the Responsible Official must report immediately by telephone or email the inactivation or viable agent removal method failure to CDC or APHIS.

(9) Review, and revise as necessary, each of the entity's validated inactivation procedures or viable select agent removal methods. The review must be conducted annually or after any change in Principal Investigator, change in the validated inactivation procedure or viable select agent removal method, or failure of the validated inactivation procedure or viable select agent removal method. The review must be documented and training must be conducted if there are any changes to the validated inactivation procedure, viable select agent removal method, or viability testing protocol.

(b) An entity may designate one or more individuals to serve as an alternate Responsible Official, who acts for the Responsible Official in his/her absence. These individuals must have the authority and control to ensure compliance with the regulations when acting as the Responsible Official.

(c) The Responsible Official must report the identification and final disposition of any select agent or toxin contained in a specimen presented for diagnosis or verification.

(1) The identification of any of the following select agents or toxins must be immediately reported by telephone, facsimile, or e-mail: *Bacillus anthracis,*, *Bacillus cereus* Biovar *anthracis,"* Botulinum neurotoxins, Botulinum neurotoxin producing species of *Clostridium, Burkholderia mallei, Burkholderia pseudomallei Francisella tularensis,* Ebola viruses, , Marburg virus, Variola major virus (Smallpox virus), Variola minor (Alastrim), or *Yersinia pestis.* The final disposition of the agent or toxin must be reported by submission of APHIS/CDC Form 4 within seven calendar days after identification. A copy of the completed form must be maintained for three years.

(2) To report the identification and final disposition of any other select agent or toxin, APHIS/CDC Form 4 must be submitted within seven calendar days after identification. A copy of the completed form must be maintained for three years.

(3) Less stringent reporting may be required based on extraordinary circumstances, such as a widespread outbreak.

(d) The Responsible Official must report the identification and final disposition of any select agent or toxin contained in a specimen presented for proficiency testing. To report the identification and final disposition of a select agent or toxin, APHIS/CDC Form 4 must be submitted within 90 calendar days of receipt of the agent or toxin. A copy of the completed form must be maintained for three years.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61112, Oct. 5, 2012; 82 FR 6292, Jan. 19, 2017]

§ 73.10 Restricting access to select agents and toxins; security risk assessments.

(a) An individual or entity required to register under this part may not provide an individual access to a select agent or toxin, and an individual may not access a select agent or toxin, unless the individual is approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General.

(b) An individual will be deemed to have access at any point in time if the individual has possession of a select agent or toxin (e.g., ability to carry, use, or manipulate) or the ability to gain possession of a select agent or toxin.

(c) Each individual with access to select agents or toxins must have the appropriate education, training, and/or experience to handle or use such agents or toxins.

(d) To apply for access approval, each individual must submit the information necessary to conduct a security risk assessment to the Attorney General.

(e) A person with a valid approval from the HHS Secretary or Administrator to have access to select agents and toxins may request, through his or her Responsible Official, that the HHS Secretary or Administrator provide their approved access status to another registered individual or entity for a specified period of time. A Responsible Official must immediately notify the Responsible Official of the visited entity if the person's access to select agents and toxins has been terminated.

(f) An individual's security risk assessment may be expedited upon written request by the Responsible Official and a showing of good cause (e.g., public health or agricultural emergencies, national security, or a short term visit by a prominent researcher). A written decision granting or denying the request will be issued.

(g) An individual's access approval will be denied or revoked if the individual is within any of the categories described in 18 U.S.C. 175b,

(h) An individual's access approval may be denied, limited, or revoked if:

(1) The individual is reasonably suspected by any Federal law enforcement or intelligence agency of committing a crime specified in 18 U.S.C. 2332b(g)(5), knowing involvement with an organization that engages in domestic or international terrorism (as defined in 18 U.S.C. 2331) or with any other organization that engages in intentional crimes of violence, or being an agent of a foreign power (as defined in 50 U.S.C. 1801), or

(2) It is determined such action is necessary to protect public health and safety.

(i) An individual may appeal the HHS Secretary's decision to deny, limit, or revoke access approval under § 73.20.

(j) Access approval is valid for a maximum of three years.

(k) The Responsible Official must immediately notify CDC or APHIS when an individual's access to select agents or toxins is terminated by the entity and the reasons therefore.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61112, Oct. 5, 2012; 82 FR 6293, Jan. 19, 2017]

§ 73.11 Security.

(a) An individual or entity required to register under this part must develop and implement a written security plan. The security plan must be sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release.

(b) The security plan must be designed according to a site-specific risk assessment and must provide graded protection in accordance with the risk of the select agent or toxin, given its intended use. A current security plan must be submitted for initial registration, renewal of registration, or when requested.

(c) The security plan must:

(1) Describe procedures for physical security, inventory control, and information systems control,

(2) Contain provisions for the control of access to select agents and toxins including the safeguarding of animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent, against unauthorized access, theft, loss or release.

(3) Contain provisions for routine cleaning, maintenance, and repairs,

(4) Establish procedures for removing unauthorized or suspicious persons,

(5) Describe procedures for addressing loss or compromise of keys, keycards, passwords, combinations, etc. and protocols for changing access permissions or locks following staff changes,

(6) Contain procedures for reporting unauthorized or suspicious persons or activities, loss or theft of select agents or toxins, release of select agents or toxins, or alteration of inventory records, and

(7) Contain provisions for ensuring that all individuals with access approval from the HHS Secretary or Administrator understand and comply with the security procedures.

(8) Describe procedures for how the Responsible Official will be informed of suspicious activity that may be criminal in nature and related to the entity, its personnel, or its select agents or toxins; and describe procedures for how the entity will notify the appropriate Federal, State, or local law enforcement agencies of such activity.

(9) Contain provisions for information security that:

(i) Ensure that all external connections to systems which manage security for the registered space are isolated or have controls that permit only authorized and authenticated users;

(ii) Ensure that authorized and authenticated users are only granted access to select agent and toxin related information, files, equipment (*e.g.,* servers or mass storage devices) and applications as necessary to fulfill their roles and responsibilities, and that access is modified when the user's roles and responsibilities change or when their access to select agents and toxins is suspended or revoked;

(iii) Ensure that controls are in place that are designed to prevent malicious code (such as, but not limited to, computer virus, worms, spyware) from compromising the confidentiality, integrity, or availability of information systems which manage access to spaces registered under this part or records in § 73.17;

(iv) Establish a robust configuration management practice for information systems to include regular patching and updates made to operating systems and individual applications; and

(v) Establish procedures that provide backup security measures in the event that access control systems, surveillance devices, and/or systems that manage the requirements of section 17 of this part are rendered inoperable.

(10) Contain provisions and policies for shipping, receiving, and storage of select agents and toxins, including documented procedures for receiving, monitoring, and shipping of all select agents and toxins. These provisions must provide that an entity will properly secure containers on site and have a written contingency plan for unexpected shipments.

(d) An individual or entity must adhere to the following security requirements or implement measures to achieve an equivalent or greater level of security:

(1) Allow access only to individuals with access approval from the HHS Secretary or Administrator,

(2) Allow individuals not approved for access from the HHS Secretary or Administrator to conduct routine cleaning, maintenance, repairs, or other activities not related to select agents or toxins only when continuously escorted by an approved individual if the potential for access to select agents or toxins exists,

(3) Provide for the control of select agents and toxins by requiring freezers, refrigerators, cabinets, and other containers where select agents or toxins are stored to be secured against unauthorized access (e.g., card access system, lock boxes),

(4) Inspect all suspicious packages before they are brought into or removed from the area where select agents or toxins are used or stored,

(5) Establish a protocol for intra-entity transfers under the supervision of an individual with access approval from the HHS Secretary or Administrator, including chain-of-custody documents and provisions for safeguarding against theft, loss, or release,

(6) Require that individuals with access approval from the HHS Secretary or Administrator refrain from sharing with any other person their unique means of accessing a select agent or toxin (e.g., keycards or passwords),

(7) Require that individuals with access approval from the HHS Secretary or Administrator immediately report any of the following to the Responsible Official:

(i) Any loss or compromise of keys, passwords, combination, etc.,

(ii) Any suspicious persons or activities,

(iii) Any loss or theft of select agents or toxins,

(iv) Any release of a select agent or toxin, and

(v) Any sign that inventory or use records for select agents or toxins have been altered or otherwise compromised, and

(vi) Any loss of computer, hard drive or other data storage device containing information that could be used to gain access to select agents or toxins.

(8) Separate areas where select agents and toxins are stored or used from the public areas of the building.

(e) Entities must conduct complete inventory audits of all affected select agents and toxins in long-term storage when any of the following occur:

(1) Upon the physical relocation of a collection or inventory of select agents or toxins for those select agents or toxins in the collection or inventory;

(2) Upon the departure or arrival of a principal investigator for those select agents and toxins under the control of that principal investigator; or

(3) In the event of a theft or loss of a select agent or toxin, all select agents and toxins under the control of that principal investigator.

(f) In addition to the requirements contained in paragraphs (c) and (d) of this section, the security plan for an individual or entity possessing a Tier 1 select agent or toxin must also:

(1) Describe procedures for conducting a pre-access suitability assessment of persons who will have access to a Tier 1 select agent or toxin;

(2) Describe procedures for how an entity's Responsible Official will coordinate their efforts with the entity's safety and security professionals to ensure security of Tier 1 select agents and toxins and share, as appropriate, relevant information; and

(3) Describe procedures for the ongoing assessment of the suitability of personnel with access to a Tier 1 select agent or toxin. The procedures must include:

(i) Self- and peer-reporting of incidents or conditions that could affect an individual's ability to safely have access to or work with select agents and toxins, or to safeguard select agents and toxins from theft, loss, or release;

(ii) The training of employees with access to Tier 1 select agents and toxins on entity policies and procedures for reporting, evaluation, and corrective actions concerning the assessment of personnel suitability; and

(iii) The ongoing suitability monitoring of individuals with access to Tier 1 select agents and toxins.

(4) Entities with Tier 1 select agents and toxins must prescribe the following security enhancements:

(i) Procedures that will limit access to a Tier 1 select agent or toxin to only those individuals who are approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General, have had an entity-conducted pre-access suitability assessment, and are subject to the entity's procedures for ongoing suitability assessment;

(ii) Procedures that limit access to laboratory and storage facilities outside of normal business hours to only those specifically approved by the Responsible Official or designee;

(iii) Procedures for allowing visitors, their property, and vehicles at the entry and exit points to the registered space, or at other designated points of entry to the building, facility, or compound that are based on the entity's site-specific risk assessment;

(iv) A minimum of three security barriers where each security barrier adds to the delay in reaching secured areas where select agents and toxins are used or stored. One of the security barriers must be monitored in such a way as to detect intentional and unintentional circumventing of established access control measures under all conditions (day/night, severe weather, etc.) The final barrier must limit access to the select agent or toxin to personnel approved by the HHS Secretary or Administrator, following a security risk assessment by the Attorney General.

(v) All registered space or areas that reasonably afford access to the registered space must be protected by an intrusion detection system (IDS) unless physically occupied;

(vi) Personnel monitoring the IDS must be capable of evaluating and interpreting the alarm and alerting the designated security response force or law enforcement;

(vii) For powered access control systems, describe procedures to ensure that security is maintained in the event of the failure of access control systems due to power disruption affecting registered space;

(viii) The entity must:

(A) Determine that the response time for security forces or local police will not exceed 15 minutes where the response time is measured from the time of an intrusion alarm, or report of a security incident, to the arrival of the responders at the first security barrier or;

(B) Provide security barriers that are sufficient to delay unauthorized access until the response force arrives in order to safeguard the select agents and toxins from theft, intentional release, or unauthorized access. The response time is measured from the time of an intrusion alarm, or report of a security incident, to the arrival of the responders at the first security barrier.

(5) Entities that possess Variola major virus and Variola minor virus must have the following additional security requirements:

(i) Require personnel with independent unescorted access to Variola major or Variola minor virus to have a Top Secret security clearance;

(ii) Require Variola major or Variola minor virus storage locations to be under the surveillance of closed circuit television that is monitored;

(iii) After hours access procedures for Variola major or Variola minor virus must require notification of the entity's security staff prior to entry into the Variola laboratory and upon exit;

(iv) Require that observation zones be maintained in outdoor areas adjacent to the physical barrier at the perimeter of the entity and be large enough to permit observation of the activities of people at that barrier in the event of its penetration;

(v) Provide for a minimum of four barriers for the protection of the Variola major or Variola minor virus, one of which must be a perimeter fence;

(vi) Require a numbered picture badge identification subsystem to be used for all individuals who are authorized to access Variola major or Variola minor without escort;

(vii) Require the use, at all times, of properly trained and equipped security force personnel able to interdict threats identified in the site specific risk assessment;

(viii) Identify security force personnel designated to strengthen onsite response capabilities, and that will be onsite and available at all times to carry out their assigned response duties;

(ix) Provide for security patrols to periodically check external areas of the registered areas to include physical barriers and building entrances;

(x) Require that all on-duty security force personnel shall be capable of maintaining continuous communication with support and response assets by way of security operations center;

(xi) Require that Variola major and Variola minor material in long term storage be stored in tamper-evident systems;

(xii) Require that all spaces containing working or permanent Variola major or Variola minor stocks be locked and protected by an intrusion alarm system that will alarm upon the unauthorized entry of a person anywhere into the area;

(xiii) Require that alarms required pursuant to this section annunciate in a continuously manned security operations center located within the facility; and

(xiv) Require that the security operations center shall be located within a building so that the interior is not visible from the perimeter of the protected area.

(g) In developing a security plan, an individual or entity should consider the document entitled, "Security Guidance for Select Agent or Toxin Facilities." This document is available on the National Select Agent Registry at *http://www.selectagents.gov/*.

(h) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident. Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61112, Oct. 5, 2012; 79 FR 26862, May 12, 2014; 82 FR 6293, Jan. 19, 2017]

§ 73.12 Biosafety.

(a) An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. The current biosafety plan must be submitted for initial registration, renewal of registration, or when requested. The biosafety plan must include the following provisions:

(1) The hazardous characteristics of each agent or toxin listed on the entity's registration and the biosafety risk associated with laboratory procedures related to the select agent or toxin;

(2) Safeguards in place with associated work practices to protect entity personnel, the public, and the environment from exposure to the select agent or toxin including, but not limited to: Personal protective equipment and other safety equipment; containment equipment including, but not limited to, biological safety cabinets, animal caging systems, and centrifuge safety containers; and engineering controls and other facility safeguards;

(3) Written procedures for each validated method used for disinfection, decontamination or destruction, as appropriate, of all contaminated or presumptively contaminated materials including, but not limited to: Cultures and other materials related to the propagation of select agents or toxins, items related to the analysis of select agents and toxins, personal protective equipment, animal caging systems and bedding (if applicable), animal carcasses or extracted tissues and fluids (if applicable), laboratory surfaces and equipment, and effluent material; and

(4) Procedures for the handling of select agents and toxins in the same spaces with non-select agents and toxins to prevent unintentional contamination.

(b) The biosafety and containment procedures must be sufficient to contain the select agent or toxin (e.g., physical structure and features of the entity, and operational and procedural safeguards).

(c) In developing a biosafety plan, an individual or entity should consider:

(1) The CDC/NIH publication, "Biosafety in Microbiological and Biomedical Laboratories." This document is available on the National Select Agent Registry Web site at *http://www.selectagents.gov*.

(2) The "NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules," (NIH Guidelines). This document is available on the National Select Agent Registry Web site at *http://www.selectagents.gov*.

(d) The biosafety plan must include an occupational health program for individuals with access to Tier 1 select agents and toxins, and those individuals must be enrolled in the occupational health program.

(e) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident. Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61114, Oct. 5, 2012; 82 FR 6293, Jan. 19, 2017]

§ 73.13 Restricted experiments.

(a) An individual or entity may not conduct, or possess products resulting from, the following experiments unless approved by and conducted in accordance with the conditions prescribed by the HHS Secretary:

(1) Experiments that involve the deliberate transfer of, or selection for, a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the control of disease agents in humans, veterinary medicine, or agriculture.

(2) Experiments involving the deliberate formation of synthetic or recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD[50] <100 ng/kg body weight.

(3) Experiments that involve the creation of SARS-CoV/SARS-CoV-2 chimeric viruses resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors or vice versa.

(b) The HHS Secretary may revoke approval to conduct any of the experiments in paragraph (a) of this section, or revoke or suspend a certificate of registration, if the individual or entity fails to comply with the requirements of this part.

(c) To apply for approval to conduct any of the experiments in paragraph (a) of this section, an individual or entity must submit a written request and supporting scientific information. A written decision granting or denying the request will be issued.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61114, Oct. 5, 2012; 79 FR 26862, May 12, 2014; 86 FR 64081, Nov. 17, 2021]

§ 73.14 Incident response.

(a) An individual or entity required to register under this part must develop and implement a written incident response plan based upon a site specific risk assessment.[2] The incident response plan must be coordinated with any entity-wide plans, kept in the workplace, and available to employees for review. The current incident response plan must be submitted for initial registration, renewal of registration, or when requested.

[2] Nothing in this section is meant to supersede or preempt incident response requirements imposed by other statutes or regulations.

(b) The incident response plan must fully describe the entity's response procedures for the theft, loss, or release of a select agent or toxin; inventory discrepancies; security breaches (including information systems); severe weather and other natural disasters; workplace violence; bomb threats and suspicious packages; and emergencies such as fire, gas leak, explosion, power outage, and other natural and man-made events.

(c) The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent.

(d) The incident response plan must also contain the following information:

(1) The name and contact information (e.g., home and work) for the individual or entity (e.g., responsible official, alternate responsible official(s), biosafety officer, etc.),

(2) The name and contact information for the building owner and/or manager, where applicable,

(3) The name and contact information for tenant offices, where applicable,

(4) The name and contact information for the physical security official for the building, where applicable,

(5) Personnel roles and lines of authority and communication,

(6) Planning and coordination with local emergency responders,

(7) Procedures to be followed by employees performing rescue or medical duties,

(8) Emergency medical treatment and first aid,

(9) A list of personal protective and emergency equipment, and their locations,

(10) Site security and control,

(11) Procedures for emergency evacuation, including type of evacuation, exit route assignments, safe distances, and places of refuge, and

(12) Decontamination procedures.

(e) Entities with Tier 1 select agents and toxins must have the following additional incident response policies or procedures:

(1) The incident response plan must fully describe the entity's response procedures for failure of intrusion detection or alarm system; and

(2) The incident response plan must describe procedures for how the entity will notify the appropriate Federal, State, or local law enforcement agencies of suspicious activity that may be criminal in nature and related to the entity, its personnel, or its select agents or toxins.

(f) The plan must be reviewed annually and revised as necessary. Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plan. The plan must be reviewed and revised, as necessary, after any drill or exercise and after any incident. Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and the names of registered entity personnel participants.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61114, Oct. 5, 2012; 82 FR 6293, Jan. 19, 2017]

§ 73.15 Training.

(a) An individual or entity required to register under this part must provide information and training on biocontainment, biosafety, security (including security awareness), and incident response to:

(1) Each individual with access approval from the HHS Secretary or Administrator. The training must address the particular needs of the individual, the work they will do, and the risks posed by the select agents or toxins. The training must be accomplished prior to the individual's entry into an area where a select agent is handled or stored, or within 12 months of the date the individual was approved by the HHS Secretary or the Administrator for access, whichever is earlier.

(2) Each individual not approved for access to select agents and toxins by the HHS Secretary or Administrator before that individual enters areas under escort where select agents or toxins are handled or stored (*e.g.,* laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.). Training for escorted personnel must be based on the risk associated with accessing areas where select agents and toxins are used and/or stored. The training must be accomplished prior to the individual's entry into where select agents or toxins are handled or stored (*e.g.,* laboratories, growth chambers, animal rooms, greenhouses, storage areas, shipping/receiving areas, production facilities, etc.).

(b) Entities with Tier 1 select agents and toxins must conduct annual insider threat awareness briefings on how to identify and report suspicious behaviors.

(c) Refresher training must be provided annually for individuals with access approval from the HHS Secretary or Administrator or at such time as the registered individual or entity significantly amends its security, incident response, or biosafety plans.

(d) The Responsible Official must ensure a record of the training provided to each individual with access to select agents and toxins and each escorted individual (*e.g.,* laboratory workers, visitors, etc.) is maintained. The record must include the name of the individual, the date of the training, a description of the training provided, and the means used to verify that the employee understood the training.

(e) The Responsible Official must ensure and document that individuals are provided the contact information of the HHS Office of Inspector General Hotline and the USDA Office of Inspector General Hotline so that they may anonymously report any safety or security concerns related to select agents and toxins.

[77 FR 61114, Oct. 5, 2012, as amended at 82 FR 6293, Jan. 19, 2017]

§ 73.16 Transfers.

(a) Except as provided in paragraphs (c) and (d) of this section, a select agent or toxin may only be transferred to individuals or entities registered to possess, use, or transfer that agent or toxin. A select agent or toxin may only be transferred under the conditions of this section and must be authorized by CDC or APHIS prior to the transfer.[4]

(b) A transfer may be authorized if:

(1) The sender:

[4] This section does not cover transfers within an entity when the sender and the recipient are covered by the same certificate of registration.

(i) Has at the time of transfer a certificate of registration that covers the particular select agent or toxin to be transferred and meets all requirements in this part,

(ii) Meets the exemption requirements for the particular select agent or toxin to be transferred, or

(iii) Is transferring the select agent or toxin from outside the United States and meets all import requirements.

(2) At the time of transfer, the recipient has a certificate of registration that includes the particular select agent or toxin to be transferred and meets all of the requirements of this part.

(c) A select agent or toxin that is contained in a specimen for proficiency testing may be transferred without prior authorization from CDC or APHIS provided that, at least seven calendar days prior to the transfer, the sender reports to CDC or APHIS the select agent or toxin to be transferred and the name and address of the recipient.

(d) On a case-by-case basis, the HHS Secretary may authorize a transfer of a select agent or toxin, not otherwise eligible for transfer under this part under conditions prescribed by the HHS Secretary.

(e) To obtain authorization for transfer, APHIS/CDC Form 2 must be submitted.

(f) After authorization is provided by APHIS or CDC, the packaging of the select agent(s) and toxin(s) is performed by an individual approved by the HHS Secretary or Administrator to have access to select agents and toxins and is in compliance with all applicable laws concerning packaging.

(g) The sender must comply with all applicable laws governing packaging and shipping.

(h) Transportation in commerce starts when the select agent(s) or toxin(s) are packaged for shipment and ready for receipt by a courier transporting select agent(s) or toxin(s) and ends when the package is received by the intended recipient who is an individual approved by the HHS Secretary or Administrator to have access to select agents and toxins, following a security risk assessment by the Attorney General.

(i) The recipient must submit a completed APHIS/CDC Form 2 within two business days of receipt of a select agent or toxin.

(j) The recipient must immediately notify CDC or APHIS if the select agent or toxin has not been received within 48 hours after the expected delivery time, or if the package containing select agents or toxins has been damaged to the extent that a release of the select agent or toxin may have occurred.

(k) An authorization for a transfer shall be valid only for 30 calendar days after issuance, except that such an authorization becomes immediately null and void if any facts supporting the authorization change (e.g., change in the certificate of registration for the sender or recipient, change in the application for transfer).

(l) A registered individual or entity transferring an amount of a HHS toxin otherwise excluded under the provisions of § 73.3(d) must:

(1) Transfer the amounts only after the transferor uses due diligence and documents that the recipient has a legitimate need (*e.g.,* prophylactic, protective, bona fide research, or other peaceful purpose) to handle or use such toxins. Information to be documented includes, but is not limited, to the recipient information, toxin and amount transferred, and declaration that the recipient has legitimate purpose to store and use such toxins.

(2) Report to CDC if they detect a known or suspected violation of Federal law or become aware of suspicious activity related to a toxin listed in § 73.3(d) of this part.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61115, Oct. 5, 2012; 79 FR 26862, May 12, 2014; 82 FR 6294, Jan. 19, 2017]

§ 73.17 Records.

(a) An individual or entity required to register under this part must maintain complete records relating to the activities covered by this part. Such records must include:

(1) An accurate, current inventory for each select agent (including viral genetic elements, recombinant and/or synthetic nucleic acids, and organisms containing recombinant and/or synthetic nucleic acids) held in long-term storage (placement in a system designed to ensure viability for future use, such as in a freezer or lyophilized materials), including:

(i) The name and characteristics (e.g., strain designation, GenBank Accession number, etc.),

(ii) The quantity acquired from another individual or entity (e.g., containers, vials, tubes, etc.), date of acquisition, and the source,

(iii) Where stored (e.g., building, room, and freezer or other storage container),

(iv) When moved from storage and by whom and when returned to storage and by whom,

(v) The select agent used, purpose of use, and, when applicable, final disposition,

(vi) Records created under § 73.16 and 9 CFR 121.16 (Transfers),

(vii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the select agent, the quantity transferred, the date of transfer, the sender, and the recipient, and

(viii) Records created under § 73.19 and 9 CFR part 121.19 (Notification of theft, loss, or release),

(2) An accurate, current accounting of any animals or plants intentionally or accidentally exposed to or infected with a select agent (including number and species, location, and appropriate disposition);

(3) Accurate, current inventory for each toxin held, including:

(i) The name and characteristics,

(ii) The quantity acquired from another individual or entity (e.g., containers, vials, tubes, etc.), date of acquisition, and the source,

(iii) The initial and current quantity amount (e.g., milligrams, milliliters, grams, etc.),

(iv) The toxin used and purpose of use, quantity, date(s) of the use and by whom,

(v) Where stored (e.g., building, room, and freezer or other storage container),

(vi) When moved from storage and by whom and when returned to storage and by whom including quantity amount,

(vii) Records created under § 73.16 and 9 CFR part 121.16 (Transfers),

(viii) For intra-entity transfers (sender and the recipient are covered by the same certificate of registration), the toxin, the quantity transferred, the date of transfer, the sender, and the recipient,

(ix) Records created under § 73.19 and 9 CFR part 121.19 (Notification of theft, loss, or release), and

(x) If destroyed, the quantity of toxin destroyed, the date of such action, and by whom,

(4) A current list of all individuals that have been granted access approval from the HHS Secretary or Administrator,

(5) Information about all entries into areas containing select agents or toxins, including the name of the individual, name of the escort (if applicable), and date and time of entry,

(6) Accurate, current records created under § 73.9 and 9 CFR part 121.9 (Responsible Official), § 73.11 and 9 CFR part 121.11 (Security), § 73.12 and 9 CFR part 121.12 (Biosafety), § 73.14 and 9 CFR part 121. 14 (Incident response), and § 73.15 and 9 CFR part 121.15 (Training), and

(7) A written explanation of any discrepancies.

(8) For select agents or material containing select agents or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a validated inactivation procedure or a procedure for removal of viable select agent:

(i) A written description of the validated inactivation procedure or viable select agent removal method used, including validation data;

(ii) A written description of the viability testing protocol used;

(iii) A written description of the investigation conducted by the entity Responsible Official involving an inactivation or viable select agent removal failure and the corrective actions taken;

(iv) The name of each individual performing the validated inactivation or viable select agent removal method;

(v) The date(s) the validated inactivation or viable select agent removal method was completed;

(vi) The location where the validated inactivation or viable select agent removal method was performed; and

(vii) A certificate, signed by the Principal Investigator, that includes the date of inactivation or viable select agent removal, the validated inactivation or viable select agent removal method used, and the name of the Principal Investigator. A copy of the certificate must accompany any transfer of inactivated or select agent removed material.

(b) The individual or entity must implement a system to ensure that all records and data bases created under this part are accurate and legible, have controlled access, and authenticity may be verified.

(c) The individual or entity must promptly produce upon request any information that is related to the requirements of this part but is not otherwise contained in a record required to be kept by this section. The location of such information may include, but is not limited to, biocontainment certifications, laboratory notebooks, institutional biosafety and/or animal use committee minutes and approved protocols, and records associated with occupational health and suitability programs. All records created under this part must be maintained for 3 years.

[70 FR 13316, Mar. 18, 2005, as amended at 77 FR 61115, Oct. 5, 2012; 82 FR 6294, Jan. 19, 2017]

§ 73.18 Inspections.

(a) Without prior notification, the HHS Secretary, shall be allowed to inspect any site at which activities regulated by this part are conducted and shall be allowed to inspect and copy any records relating to the activities covered by this part.

(b) Prior to issuing a certificate of registration to an individual or entity, the HHS Secretary may inspect and evaluate the premises and records to ensure compliance with this part.

§ 73.19 Notification of theft, loss, or release.

(a) Upon discovery of the theft or loss of a select agent or toxin, an individual or entity must immediately notify CDC or APHIS and appropriate Federal, State, or local law enforcement agencies. Thefts or losses must be reported even if the select agent or toxin is subsequently recovered or the responsible parties are identified.

(1) The theft or loss of a select agent or toxin must be reported immediately by telephone, facsimile, or e-mail. The following information must be provided:

(i) The name of the select agent or toxin and any identifying information (e.g., strain or other characterization information),

(ii) An estimate of the quantity lost or stolen,

(iii) An estimate of the time during which the theft or loss occurred,

(iv) The location (building, room) from which the theft or loss occurred, and

(v) The list of Federal, State, or local law enforcement agencies to which the individual or entity reported, or intends to report the theft or loss.

(2) A completed APHIS/CDC Form 3 must submitted within seven calendar days.

(b) Upon discovery of a release of an agent or toxin causing occupational exposure or release of a select agent or toxin outside of the primary barriers of the biocontainment area, an individual or entity must immediately notify CDC or APHIS.

(1) The release of a select agent or toxin must be reported by telephone, facsimile, or e-mail. The following information must be provided:

(i) The name of the select agent or toxin and any identifying information (e.g., strain or other characterization information),

(ii) An estimate of the quantity released,

(iii) The time and duration of the release,

(iv) The environment into which the release occurred (e.g., in building or outside of building, waste system),

(v) The location (building, room) from which the release occurred,

(vi) The number of individuals potentially exposed at the entity,

(vii) Actions taken to respond to the release, and

(viii) Hazards posed by the release.

(2) A completed APHIS/CDC Form 3 must be submitted within seven calendar days.

§ 73.20 Administrative review.

(a) An individual or entity may appeal a denial, revocation, or suspension of registration under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the HHS Secretary within 30 calendar days of the decision.

(b) An individual may appeal a denial, limitation, or revocation of access approval under this part. The appeal must be in writing, state the factual basis for the appeal, and be submitted to the HHS Secretary within 180 calendar days of the decision.

(c) The HHS Secretary's decision constitutes final agency action.

[77 FR 61115, Oct. 5, 2012]

§ 73.21 Civil money penalties.

(a) The Inspector General of the Department of Health and Human Services is delegated authority to conduct investigations and to impose civil money penalties against any individual or entity in accordance with regulations in 42 CFR part 1003 for violations of the regulations in this part, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188). The delegation of authority includes all powers contained in section 6 of the Inspector General Act of 1978 (5 U.S.C. App.).

(b) The administrative law judges in, assigned to, or detailed to the Departmental Appeals Board have been delegated authority to conduct hearings and to render decisions in accordance with 42 CFR part 1005 with respect to the imposition of civil money penalties, as authorized by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188). This delegation includes, but is not limited to, the authority to administer oaths and affirmations, to subpoena witnesses and documents, to examine witnesses, to exclude or receive and give appropriate weight to materials and testimony offered as evidence, to make findings of fact and conclusions of law, and to determine the civil money penalties to be imposed.

(c) The Departmental Appeals Board of the Department of Health and Human Services is delegated authority to make final determinations with respect to the imposition of civil money penalties for violations of the regulations of this part.