L. 91–513, title I, § 2(a)(4), Oct. 27, 1970, 84 Stat. 1240, related to release of patients and determination by Surgeon General.

PART F—LICENSING OF BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES

SUBPART 1—BIOLOGICAL PRODUCTS

§ 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) of this section.

(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].

(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 (except any chemically synthesized polypeptide), 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) animal studies (including the assessment of toxicity); 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; and

(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.

(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

Upon review of an application submitted under this subsection relying on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable 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.

(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.

(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.

***(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)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(3)]—

(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

[1] See References in Text note below.

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)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355a(d)(3)]—

(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)(3)[1] [21 U.S.C. 355a(d)(3)] 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.)

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.

Sections 526, 527(a), and 505A(d)(3), referred to in subsec. (m)(2)(B), (3)(B), (4), probably mean sections 526, 527(a), and 505A(d)(3) 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)(3), 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

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, anti-

toxin, 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.

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.

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. Secretary of Health, Education, and Welfare redesignated Secretary of Health and Human Services by section 509(b) of Pub. L. 96–88 which is classified to section 3508(b) of Title 20, Education.

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. Secretary and Department of Health, Education, and Welfare redesignated Secretary and Department of Health and Human Services by section 509(b) of Pub. L. 96–88 which is classified to section 3508(b) of Title 20.

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, 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.—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.

''(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.]''

§ 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 and appropriate skills to handle such agents and toxins; and

(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) of this section, in order to protect the public health and safety.

(d) Registration; identification; database

(1) Registration

Regulations under subsections (b) and (c) of this section 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) of this section.

(2) Identification; database

Regulations under subsections (b) and (c) of this section 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) of this section 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 the risk of 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) of this section 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) of this section 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) of this section 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) of this section 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 enforce-

ment 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) of this section 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) of this section to ensure their compliance with such regulations, including prohibitions on restricted persons and other provisions of subsection (e) of this section.

(g) Exemptions

(1) Clinical or diagnostic laboratories

Regulations under subsections (b) and (c) of this section 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) of this section 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) of this section 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) of this section 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) of this section to such product is not necessary to protect public health and safety.

(ii) Certain processes

Regulations under subsections (b) and (c) of this section 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

[1] So in original. Probably should be ''judicial''.

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) of this section 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) of this section, or any other compilation of the registration or transfer information submitted under subsections (b) and (c) of this section 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) of this section, 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) of this section 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) of this section; 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) of this section 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

[2] So in original. Probably should be ''section''.

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 6 of the Inspector General Act of 1978 (5 U.S.C. App.).

(j) Notification in event of release

Regulations under subsections (b) and (c) of this section 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*) of this section), the Secretary shall promptly notify the Secretary of Agriculture upon notification by the registered person.

(k) Reports

The Secretary shall report to the Congress annually on the number and nature of notifications received under subsection (e)(8) of this section (relating to theft or loss) and subsection (j) of this section (relating to releases).

(*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) of this section.

(3) The term ''listed agents or toxins'' means biological agents or toxins listed pursuant to subsection (a)(1) of this section.

(4) The term ''overlap agents and toxins'' means biological agents and toxins that—

(A) are listed pursuant to subsection (a)(1) of this section; 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) of this section; 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) of this section.

(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 2002 through 2007.

(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.)

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, as amended, 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, as amended, 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.

Section 6 of the Inspector General Act of 1978, referred to in subsec. (i)(2), is section 6 of Pub. L. 95–452, which is set out in the Appendix to Title 5, Government Organization and Employees.

AMENDMENTS

2002—Subsec. (e)(1). Pub. L. 107–296 substituted ''collaboration with the Secretary of Homeland Security and'' for ''consultation with''.

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].''

NATIONAL SCIENCE ADVISORY BOARD FOR BIOSECURITY

Pub. L. 109–417, title II, § 205, Dec. 19, 2006, 120 Stat. 2851, provided that: ''The National Science Advisory Board for Biosecurity shall, when requested by the Secretary of Health and Human Services, provide to relevant Federal departments and agencies, advice, guidance, or recommendations concerning—

''(1) a core curriculum and training requirements for workers in maximum containment biological laboratories; and

''(2) periodic evaluations of maximum containment biological laboratory capacity nationwide and assessments of the future need for increased laboratory capacity.''

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.''

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.]

§ 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.)

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. Secretary of Health, Education, and Welfare redesignated Secretary of Health and Human Services by section 509(b) of Pub. L. 96–88 which is classified to section 3508(b) of Title 20, Education.

SUBPART 2—CLINICAL LABORATORIES

§ 263a. Certification of laboratories

(a) "Laboratory" or "clinical laboratory" defined

As used in this section, the term ''laboratory'' or ''clinical laboratory'' means a facility for the

biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

(b) Certificate requirement

No person may solicit or accept materials derived from the human body for laboratory examination or other procedure unless there is in effect for the laboratory a certificate issued by the Secretary under this section applicable to the category of examinations or procedures which includes such examination or procedure.

(c) Issuance and renewal of certificates

(1) In general

The Secretary may issue or renew a certificate for a laboratory only if the laboratory meets the requirements of subsection (d) of this section.

(2) Term

A certificate issued under this section shall be valid for a period of 2 years or such shorter period as the Secretary may establish.

(d) Requirements for certificates

(1) In general

A laboratory may be issued a certificate or have its certificate renewed if—

(A) the laboratory submits (or if the laboratory is accredited under subsection (e) of this section, the accreditation body which accredited the laboratory submits), an application—

(i) in such form and manner as the Secretary shall prescribe,

(ii) that describes the characteristics of the laboratory examinations and other procedures performed by the laboratory including—

(I) the number and types of laboratory examinations and other procedures performed,

(II) the methodologies for laboratory examinations and other procedures employed, and

(III) the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and other procedures, and

(iii) that contains such other information as the Secretary may require to determine compliance with this section, and

the laboratory agrees to provide to the Secretary (or if the laboratory is accredited, to the accreditation body which accredited it) a description of any change in the information submitted under clause (ii) not later than 6 months after the change was put into effect,

(B) the laboratory provides the Secretary—

(i) with satisfactory assurances that the laboratory will be operated in accordance with standards issued by the Secretary under subsection (f) of this section, or

(ii) with proof of accreditation under subsection (e) of this section,

(C) the laboratory agrees to permit inspections by the Secretary under subsection (g) of this section,

(D) the laboratory agrees to make records available and submit reports to the Secretary as the Secretary may reasonably require, and

(E) the laboratory agrees to treat proficiency testing samples in the same manner as it treats materials derived from the human body referred to it for laboratory examinations or other procedures in the ordinary course of business, except that no proficiency testing sample shall be referred to another laboratory for analysis as prohibited under subsection (i)(4).

(2) Requirements for certificates of waiver

(A) In general

A laboratory which only performs laboratory examinations and procedures described in paragraph (3) shall be issued a certificate of waiver or have its certificate of waiver renewed if—

(i) the laboratory submits an application—

(I) in such form and manner as the Secretary shall prescribe,

(II) that describes the characteristics of the laboratory examinations and other procedures performed by the laboratory, including the number and types of laboratory examinations and other procedures performed, the methodologies for laboratory examinations and other procedures employed, and the qualifications (educational background, training, and experience) of the personnel directing and supervising the laboratory and performing the laboratory examinations and other procedures, and

(III) that contains such other information as the Secretary may reasonably require to determine compliance with this section, and

(ii) the laboratory agrees to make records available and submit reports to the Secretary as the Secretary may require.

(B) Changes

If a laboratory makes changes in the examinations and other procedures performed by it only with respect to examinations and procedures which are described in paragraph (3), the laboratory shall report such changes to the Secretary not later than 6 months after the change has been put into effect. If a laboratory proposes to make changes in the examinations and procedures performed by it such that the laboratory will perform an examination or procedure not described in paragraph (3), the laboratory shall report such change to the Secretary before the change takes effect.

(C) Effect

Subsections (f) and (g) of this section shall not apply to a laboratory to which has been issued a certificate of waiver.

(3) Examinations and procedures

The examinations and procedures identified in paragraph (2) are laboratory examinations and procedures that have been approved by the Food and Drug Administration for home use or that, as determined by the Secretary, are simple laboratory examinations and procedures that have an insignificant risk of an erroneous result, including those that—

(A) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results by the user negligible, or

(B) the Secretary has determined pose no unreasonable risk of harm to the patient if performed incorrectly.

(4) "Certificate" defined

As used in this section, the term ''certificate'' includes a certificate of waiver issued under paragraph (2).

(e) Accreditation

(1) In general

A laboratory may be accredited for purposes of obtaining a certificate if the laboratory—

(A) meets the standards of an approved accreditation body, and

(B) authorizes the accreditation body to submit to the Secretary (or such State agency as the Secretary may designate) such records or other information as the Secretary may require.

(2) Approval of accreditation bodies

(A) In general

The Secretary may approve a private nonprofit organization to be an accreditation body for the accreditation of laboratories if—

(i) using inspectors qualified to evaluate the methodologies used by the laboratories in performing laboratory examinations and other procedures, the accreditation body agrees to inspect a laboratory for purposes of accreditation with such frequency as determined by[1] Secretary,

(ii) the standards applied by the body in determining whether or not to accredit a laboratory are equal to or more stringent than the standards issued by the Secretary under subsection (f) of this section,

(iii) there is adequate provision for assuring that the standards of the accreditation body continue to be met by the laboratory,

(iv) in the case of any laboratory accredited by the body which has had its accreditation denied, suspended, withdrawn, or revoked or which has had any other action taken against it by the accrediting body, the accrediting body agrees to submit to the Secretary the name of such laboratory within 30 days of the action taken,

(v) the accreditation body agrees to notify the Secretary at least 30 days before it changes its standards, and

(vi) if the accreditation body has its approval withdrawn by the Secretary, the body agrees to notify each laboratory accredited by the body of the withdrawal within 10 days of the withdrawal.

(B) Criteria and procedures

The Secretary shall promulgate criteria and procedures for approving an accreditation body and for withdrawing such approval if the Secretary determines that the accreditation body does not meet the requirements of subparagraph (A).

(C) Effect of withdrawal of approval

If the Secretary withdraws the approval of an accreditation body under subparagraph (B), the certificate of any laboratory accredited by the body shall continue in effect for 60 days after the laboratory receives notification of the withdrawal of the approval, except that the Secretary may extend such period for a laboratory if it determines that the laboratory submitted an application for accreditation or a certificate in a timely manner after receipt of the notification of the withdrawal of approval. If an accreditation body withdraws or revokes the accreditation of a laboratory, the certificate of the laboratory shall continue in effect—

(i) for 45 days after the laboratory receives notice of the withdrawal or revocation of the accreditation, or

(ii) until the effective date of any action taken by the Secretary under subsection (i) of this section.

(D) Evaluations

The Secretary shall evaluate annually the performance of each approved accreditation body by—

(i) inspecting under subsection (g) of this section a sufficient number of the laboratories accredited by such body to allow a reasonable estimate of the performance of such body, and

(ii) such other means as the Secretary determines appropriate.

(3) Omitted

(f) Standards

(1) In general

The Secretary shall issue standards to assure consistent performance by laboratories issued a certificate under this section of valid and reliable laboratory examinations and other procedures. Such standards shall require each laboratory issued a certificate under this section—

(A) to maintain a quality assurance and quality control program adequate and appropriate for the validity and reliability of the laboratory examinations and other procedures of the laboratory and to meet requirements relating to the proper collection, transportation, and storage of specimens and the reporting of results,

(B) to maintain records, equipment, and facilities necessary for the proper and effective operation of the laboratory,

(C) in performing and carrying out its laboratory examinations and other procedures, to use only personnel meeting such qualifications as the Secretary may establish for

[1] So in original. Probably should be ''by the''.

the direction, supervision, and performance of examinations and procedures within the laboratory, which qualifications shall take into consideration competency, training, experience, job performance, and education and which qualifications shall, as appropriate, be different on the basis of the type of examinations and procedures being performed by the laboratory and the risks and consequences of erroneous results associated with such examinations and procedures,

(D) to qualify under a proficiency testing program meeting the standards established by the Secretary under paragraph (3), and

(E) to meet such other requirements as the Secretary determines necessary to assure consistent performance by such laboratories of accurate and reliable laboratory examinations and procedures.

(2) Considerations

In developing the standards to be issued under paragraph (1), the Secretary shall, within the flexibility provided under subparagraphs (A) through (E) of paragraph (1), take into consideration—

(A) the examinations and procedures performed and the methodologies employed,

(B) the degree of independent judgment involved,

(C) the amount of interpretation involved,

(D) the difficulty of the calculations involved,

(E) the calibration and quality control requirements of the instruments used,

(F) the type of training required to operate the instruments used in the methodology, and

(G) such other factors as the Secretary considers relevant.

(3) Proficiency testing program

(A) In general

The Secretary shall establish standards for the proficiency testing programs for laboratories issued a certificate under this section which are conducted by the Secretary, conducted by an organization approved under subparagraph (C), or conducted by an approved accrediting body. The standards shall require that a laboratory issued a certificate under this section be tested for each examination and procedure conducted within a category of examinations or procedures for which it has received a certificate, except for examinations and procedures for which the Secretary has determined that a proficiency test cannot reasonably be developed. The testing shall be conducted on a quarterly basis, except where the Secretary determines for technical and scientific reasons that a particular examination or procedure may be tested less frequently (but not less often than twice per year).

(B) Criteria

The standards established under subparagraph (A) shall include uniform criteria for acceptable performance under a proficiency testing program, based on the available technology and the clinical relevance of the laboratory examination or other procedure subject to such program. The criteria shall be established for all examinations and procedures and shall be uniform for each examination and procedure. The standards shall also include a system for grading proficiency testing performance to determine whether a laboratory has performed acceptably for a particular quarter and acceptably for a particular examination or procedure or category of examination or procedure over a period of successive quarters.

(C) Approved proficiency testing programs

For the purpose of administering proficiency testing programs which meet the standards established under subparagraph (A), the Secretary shall approve a proficiency testing program offered by a private nonprofit organization or a State if the program meets the standards established under subparagraph (A) and the organization or State provides technical assistance to laboratories seeking to qualify under the program. The Secretary shall evaluate each program approved under this subparagraph annually to determine if the program continues to meet the standards established under subparagraph (A) and shall withdraw the approval of any program that no longer meets such standards.

(D) Onsite testing

The Secretary shall perform, or shall direct a program approved under subparagraph (C) to perform, onsite proficiency testing to assure compliance with the requirements of subsection (d)(5) of this section. The Secretary shall perform, on an onsite or other basis, proficiency testing to evaluate the performance of a proficiency testing program approved under subparagraph (C) and to assure quality performance by a laboratory.

(E) Training, technical assistance, and enhanced proficiency testing

The Secretary may, in lieu of or in addition to actions authorized under subsection (h), (i), or (j) of this section, require any laboratory which fails to perform acceptably on an individual examination and procedure or a category of examination and procedures—

(i) to undertake training and to obtain the necessary technical assistance to meet the requirements of the proficency[2] testing program,

(ii) to enroll in a program of enhanced proficiency testing, or

(iii) to undertake any combination of the training, technical assistance, or testing described in clauses (i) and (ii).

(F) Testing results

The Secretary shall establish a system to make the results of the proficiency testing programs subject to the standards established by the Secretary under subparagraph (A) available, on a reasonable basis, upon request of any person. The Secretary shall include with results made available under this

[2] So in original. Probably should be ''proficiency''.

subparagraph such explanatory information as may be appropriate to assist in the interpretation of such results.

(4) National standards for quality assurance in cytology services

(A) Establishment

The Secretary shall establish national standards for quality assurance in cytology services designed to assure consistent performance by laboratories of valid and reliable cytological services.

(B) Standards

The standards established under subparagraph (A) shall include—

(i) the maximum number of cytology slides that any individual may screen in a 24-hour period,

(ii) requirements that a clinical laboratory maintain a record of (I) the number of cytology slides screened during each 24-hour period by each individual who examines cytology slides for the laboratory, and (II) the number of hours devoted during each 24-hour period to screening cytology slides by such individual,

(iii) criteria for requiring rescreening of cytological preparations, such as (I) random rescreening of cytology specimens determined to be in the benign category, (II) focused rescreening of such preparations in high risk groups, and (III) for each abnormal cytological result, rescreening of all prior cytological specimens for the patient, if available,

(iv) periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced and unannounced on-site proficiency testing of such individuals, with such testing to take place, to the extent practicable, under normal working conditions,

(v) procedures for detecting inadequately prepared slides, for assuring that no cytological diagnosis is rendered on such slides, and for notifying referring physicians of such slides,

(vi) requirements that all cytological screening be done on the premises of a laboratory that is certified under this section,

(vii) requirements for the retention of cytology slides by laboratories for such periods of time as the Secretary considers appropriate, and

(viii) standards requiring periodic inspection of cytology services by persons capable of evaluating the quality of cytology services.

(g) Inspections

(1) In general

The Secretary may, on an announced or unannounced basis, enter and inspect, during regular hours of operation, laboratories which have been issued a certificate under this section. In conducting such inspections the Secretary shall have access to all facilities, equipment, materials, records, and information that the Secretary determines have a bearing on whether the laboratory is being operated in accordance with this section. As part of such an inspection the Secretary may copy any such material or require to it[3] be submitted to the Secretary. An inspection under this paragraph may be made only upon presenting identification to the owner, operator, or agent in charge of the laboratory being inspected.

(2) Compliance with requirements and standards

The Secretary shall conduct inspections of laboratories under paragraph (1) to determine their compliance with the requirements of subsection (d) of this section and the standards issued under subsection (f) of this section. Inspections of laboratories not accredited under subsection (e) of this section shall be conducted on a biennial basis or with such other frequency as the Secretary determines to be necessary to assure compliance with such requirements and standards. Inspections of laboratories accredited under subsection (e) of this section shall be conducted on such basis as the Secretary determines is necessary to assure compliance with such requirements and standards.

(h) Intermediate sanctions

(1) In general

If the Secretary determines that a laboratory which has been issued a certificate under this section no longer substantially meets the requirements for the issuance of a certificate, the Secretary may impose intermediate sanctions in lieu of the actions authorized by subsection (i) of this section.

(2) Types of sanctions

The intermediate sanctions which may be imposed under paragraph (1) shall consist of—

(A) directed plans of correction,

(B) civil money penalties in an amount not to exceed $10,000 for each violation listed in subsection (i)(1) of this section or for each day of substantial noncompliance with the requirements of this section,

(C) payment for the costs of onsite monitoring, or

(D) any combination of the actions described in subparagraphs (A), (B), and (C).

(3) Procedures

The Secretary shall develop and implement procedures with respect to when and how each of the intermediate sanctions is to be imposed under paragraph (1). Such procedures shall provide for notice to the laboratory and a reasonable opportunity to respond to the proposed sanction and appropriate procedures for appealing determinations relating to the imposition of intermediate sanctions[4]

(i) Suspension, revocation, and limitation

(1) In general

Except as provided in paragraph (2), the certificate of a laboratory issued under this section may be suspended, revoked, or limited if the Secretary finds, after reasonable notice

[3] So in original. Probably should be ''require it to''.

[4] So in original. Probably should be followed by a period.

and opportunity for hearing to the owner or operator of the laboratory, that such owner or operator or any employee of the laboratory—

(A) has been guilty of misrepresentation in obtaining the certificate,

(B) has performed or represented the laboratory as entitled to perform a laboratory examination or other procedure which is not within a category of laboratory examinations or other procedures authorized in the certificate,

(C) has failed to comply with the requirements of subsection (d) of this section or the standards prescribed by the Secretary under subsection (f) of this section,

(D) has failed to comply with reasonable requests of the Secretary for—

(i) any information or materials, or

(ii) work on materials,

that the Secretary concludes is necessary to determine the laboratory's continued eligibility for its certificate or continued compliance with the Secretary's standards under subsection (f) of this section,

(E) has refused a reasonable request of the Secretary, or any Federal officer or employee duly designated by the Secretary, for permission to inspect the laboratory and its operations and pertinent records during the hours the laboratory is in operation,

(F) has violated or aided and abetted in the violation of any provisions of this section or of any regulation promulgated thereunder, or

(G) has not complied with an intermediate sanction imposed under subsection (h) of this section.

(2) Action before a hearing

If the Secretary determines that—

(A) the failure of a laboratory to comply with the standards of the Secretary under subsection (f) of this section presents an imminent and serious risk to human health, or

(B) a laboratory has engaged in an action described in subparagraph (D) or (E) of paragraph (1),

the Secretary may suspend or limit the certificate of the laboratory before holding a hearing under paragraph (1) regarding such failure or refusal. The opportunity for a hearing shall be provided no later than 60 days from the effective date of the suspension or limitation. A suspension or limitation under this paragraph shall stay in effect until the decision of the Secretary made after the hearing under paragraph (1).

(3) Ineligibility to own or operate laboratories after revocation

No person who has owned or operated a laboratory which has had its certificate revoked may, within 2 years of the revocation of the certificate, own or operate a laboratory for which a certificate has been issued under this section, except that if the revocation occurs pursuant to paragraph (4) the Secretary may substitute intermediate sanctions under subsection (h) instead of the 2-year prohibition against ownership or operation which would otherwise apply under this paragraph. The certificate of a laboratory which has been excluded from participation under the medicare program under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] because of actions relating to the quality of the laboratory shall be suspended for the period the laboratory is so excluded.

(4) Improper referrals

Any laboratory that the Secretary determines intentionally refers its proficiency testing samples to another laboratory for analysis may have its certificate revoked for at least one year and shall be subject to appropriate fines and penalties as provided for in subsection (h) of this section.

(j) Injunctions

Whenever the Secretary has reason to believe that continuation of any activity by a laboratory would constitute a significant hazard to the public health the Secretary may bring suit in the district court of the United States for the district in which such laboratory is situated to enjoin continuation of such activity. Upon proper showing, a temporary injunction or restraining order against continuation of such activity pending issuance of a final order under this subsection shall be granted without bond by such court.

(k) Judicial review

(1) Petition

Any laboratory which has had an intermediate sanction imposed under subsection (h) of this section or has had its certificate suspended, revoked, or limited under subsection (i) of this section may, at any time within 60 days after the date the action of the Secretary under subsection (i) or (h) of this section becomes final, file a petition with the United States court of appeals for the circuit wherein the laboratory has its principal place of business for judicial review of such action. As soon as practicable after receipt of the petition, the clerk of the court shall transmit a copy of the petition to the Secretary or other officer designated by the Secretary for that purpose. As soon as practicable after receipt of the copy, the Secretary shall file in the court the record on which the action of the Secretary is based, as provided in section 2112 of title 28.

(2) Additional evidence

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 of 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 the court may deem proper. The Secretary may modify the findings of the Secretary as to the facts, or make new findings, by reason of the additional evidence so taken, and the Secretary shall file such modified or new findings, and the recommendations of the Secretary, if any, for the modification

or setting aside of his original action, with the return of such additional evidence.

(3) Judgment of court

Upon the filing of the petition referred to in paragraph (1), the court shall have jurisdiction to affirm the action, or to set it aside in whole or in part, temporarily or permanently. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) Finality of judgment

The judgment of the court affirming or setting aside, in whole or in part, any such action of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28.

(*l*) Sanctions

Any person who intentionally violates any requirement of this section or any regulation promulgated thereunder shall be imprisoned for not more than one year or fined under title 18, or both, except that if the conviction is for a second or subsequent violation of such a requirement such person shall be imprisoned for not more than 3 years or fined in accordance with title 18, or both.

(m) Fees

(1) Certificate fees

The Secretary shall require payment of fees for the issuance and renewal of certificates, except that the Secretary shall only require a nominal fee for the issuance and renewal of certificates of waiver.

(2) Additional fees

The Secretary shall require the payment of fees for inspections of laboratories which are not accredited and for the cost of performing proficiency testing on laboratories which do not participate in proficiency testing programs approved under subsection (f)(3)(C) of this section.

(3) Criteria

(A) Fees under paragraph (1)

Fees imposed under paragraph (1) shall be sufficient to cover the general costs of administering this section, including evaluating and monitoring proficiency testing programs approved under subsection (f) of this section and accrediting bodies and implementing and monitoring compliance with the requirements of this section.

(B) Fees under paragraph (2)

Fees imposed under paragraph (2) shall be sufficient to cover the cost of the Secretary in carrying out the inspections and proficiency testing described in paragraph (2).

(C) Fees imposed under paragraphs (1) and (2)

Fees imposed under paragraphs (1) and (2) shall vary by group or classification of laboratory, based on such considerations as the Secretary determines are relevant, which may include the dollar volume and scope of the testing being performed by the laboratories.

(n) Information

On April 1, 1990 and annually thereafter, the Secretary shall compile and make available to physicians and the general public information, based on the previous calendar year, which the Secretary determines is useful in evaluating the performance of a laboratory, including—

(1) a list of laboratories which have been convicted under Federal or State laws relating to fraud and abuse, false billings, or kickbacks,

(2) a list of laboratories—

(A) which have had their certificates revoked, suspended, or limited under subsection (i) of this section, or

(B) which have been the subject of a sanction under subsection (*l*) of this section,

together with a statement of the reasons for the revocation, suspension, limitation, or sanction,

(3) a list of laboratories subject to intermediate sanctions under subsection (h) of this section together with a statement of the reasons for the sanctions,

(4) a list of laboratories whose accreditation has been withdrawn or revoked together with a statement of the reasons for the withdrawal or revocation,

(5) a list of laboratories against which the Secretary has taken action under subsection (j) of this section together with a statement of the reasons for such action, and

(6) a list of laboratories which have been excluded from participation under title XVIII or XIX of the Social Security Act [42 U.S.C. 1395 et seq., 1396 et seq.].

The information to be compiled under paragraphs (1) through (6) shall be information for the calendar year preceding the date the information is to be made available to the public and shall be accompanied by such explanatory information as may be appropriate to assist in the interpretation of the information compiled under such paragraphs.

(*o*) Delegation

In carrying out this section, the Secretary may, pursuant to agreement, use the services or facilities of any Federal or State or local public agency or nonprofit private organization, and may pay therefor in advance or by way of reimbursement, and in such installments, as the Secretary may determine.

(p) State laws

(1) Except as provided in paragraph (2), nothing in this section shall be construed as affecting the power of any State to enact and enforce laws relating to the matters covered by this section to the extent that such laws are not inconsistent with this section or with the regulations issued under this section.

(2) If a State enacts laws relating to matters covered by this section which provide for requirements equal to or more stringent than the requirements of this section or than the regulations issued under this section, the Secretary may exempt clinical laboratories in that State from compliance with this section.

(q) Consultations

In carrying out this section, the Secretary shall consult with appropriate private organizations and public agencies.

(July 1, 1944, ch. 373, title III, § 353, as added Pub. L. 90–174, § 5(a), Dec. 5, 1967, 81 Stat. 536; amended Pub. L. 100–578, § 2, Oct. 31, 1988, 102 Stat. 2903; Pub. L. 105–115, title I, § 123(h), Nov. 21, 1997, 111 Stat. 2324; Pub. L. 112–202, § 2, Dec. 4, 2012, 126 Stat. 1483.)

REFERENCES IN TEXT

The Social Security Act, referred to in subsecs. (i)(3) and (n)(6), is act Aug. 14, 1935, ch. 531, 49 Stat. 620, as amended. Titles XVIII and XIX of the Social Security Act are classified generally to subchapters XVIII (§ 1395 et seq.) and XIX (§ 1396 et seq.), respectively, of chapter 7 of this title. For complete classification of this Act to the Code, see section 1305 of this title and Tables.

CODIFICATION

Subsec. (e)(3) of this section, which required the Secretary to annually prepare and submit to certain committees of Congress a report describing the results of the evaluation conducted under subsec. (e)(2)(D) of this section, terminated, effective May 15, 2000, pursuant to section 3003 of Pub. L. 104–66, as amended, set out as a note under section 1113 of Title 31, Money and Finance. See, also, page 96 of House Document No. 103–7.

AMENDMENTS

2012—Subsec. (d)(1)(E). Pub. L. 112–202, § 2(1), inserted '', except that no proficiency testing sample shall be referred to another laboratory for analysis as prohibited under subsection (i)(4)'' before period at end.

Subsec. (i)(3). Pub. L. 112–202, § 2(2)(A), inserted '', except that if the revocation occurs pursuant to paragraph (4) the Secretary may substitute intermediate sanctions under subsection (h) instead of the 2-year prohibition against ownership or operation which would otherwise apply under this paragraph'' after ''issued under this section''.

Subsec. (i)(4). Pub. L. 112–202, § 2(2)(B), substituted ''may have its certificate revoked'' for ''shall have its certificate revoked''.

1997—Subsec. (d)(3). Pub. L. 105–115 amended heading and text of par. (3) generally. Prior to amendment, text read as follows: ''The examinations and procedures identified in paragraph (2) are simple laboratory examinations and procedures which, as determined by the Secretary, have an insignificant risk of an erroneous result, including those which—

''(A) have been approved by the Food and Drug Administration for home use,

''(B) employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible, or

''(C) the Secretary has determined pose no reasonable risk of harm to the patient if performed incorrectly.''

1988—Pub. L. 100–578 substituted ''Certification of laboratories'' for ''Licensing of laboratories'' in section catchline, and amended text generally, revising and restating as subsecs. (a) to (q) provisions of former subsecs. (a) to (*l*).

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 1988 AMENDMENT; EXCEPTIONS; CONTINUING APPLICABILITY

Pub. L. 100–578, § 3, Oct. 31, 1988, 102 Stat. 2914, provided that: ''Subsections (g)(1), (h), (i), (j), (k), (*l*), and (m) of section 353 of the Public Health Service Act [42 U.S.C. 263a], as amended by section 101 [probably means section 2 of Pub. L. 100–578], shall take effect January 1, 1989, except that any reference in such subsections to the standards established under subsection (f) shall be considered a reference to the standards established under subsection (d) of such section 353, as in effect on December 31, 1988. During the period beginning January 1, 1989, and ending December 31, 1989, subsections (a) through (d) and subsection (i) through (*l*) of such section 353 as in effect on December 31, 1988, shall continue to apply to clinical laboratories. The remaining subsections of such section 353, as so amended, shall take effect January 1, 1990, except that subsections (f)(1)(C) and (g)(2) shall take effect July 1, 1991, with respect to laboratories which were not subject to the requirements of such section 353 as in effect on December 31, 1988.''

EFFECTIVE DATE

Pub. L. 90–174, § 5(b), Dec. 5, 1967, 81 Stat. 539, provided that: ''The amendment made by subsection (a) [enacting this section] shall become effective on the first day of the thirteenth month after the month [December 1967] in which it is enacted, except that the Secretary of Health, Education, and Welfare may postpone such effective date for such additional period as he finds necessary, but not beyond the first day of the 19th month after such month [December 1967] in which the amendment is enacted.''

STUDIES

Pub. L. 100–578, § 4, Oct. 31, 1988, 102 Stat. 2914, directed Secretary to conduct studies and submit report to Congress, not later than May 1, 1990, relating to the reliability and quality control procedures of clinical laboratory testing programs and the effect of errors in the testing procedures and results on the diagnosis and treatment of patients.

§ 263a–1. Assisted reproductive technology programs

(a) In general

Effective 2 years after October 24, 1992, each assisted reproductive technology (as defined in section 263a–7[1] of this title) program shall annually report to the Secretary through the Centers for Disease Control—

(1) pregnancy success rates achieved by such program through each assisted reproductive technology, and

(2) the identity of each embryo laboratory (as defined in section 263a–7[1] of this title) used by such program and whether the laboratory is certified under section 263a–2 of this title or has applied for such certification.

(b) Pregnancy success rates

(1) In general

For purposes of subsection (a)(1) of this section, the Secretary shall, in consultation with the organizations referenced in subsection (c) of this section, define pregnancy success rates and shall make public any proposed definition in such manner as to facilitate comment from any person (including any Federal or other public agency) during its development.

(2) Definition

In developing the definition of pregnancy success rates, the Secretary shall take into account the effect on success rates of age, diag-

[1] See References in Text note below.

nosis, and other significant factors and shall include in such rates—

(A) the basic live birth rate calculated for each assisted reproductive technology performed by an assisted reproductive technology program by dividing the number of pregnancies which result in live births by the number of ovarian stimulation procedures attempted by such program, and

(B) the live birth rate per successful oocyte retrieval procedure calculated for each assisted reproductive technology performed by an assisted reproductive technology program by dividing the number of pregnancies which result in live births by the number of successful oocyte retrieval procedures performed by such program.

(c) Consultation

In developing the definition under subsection (b) of this section, the Secretary shall consult with appropriate consumer and professional organizations with expertise in using, providing, and evaluating professional services and embryo laboratories associated with assisted reproductive technologies.

(Pub. L. 102–493, § 2, Oct. 24, 1992, 106 Stat. 3146.)

REFERENCES IN TEXT

Section 263a–7 of this title, referred to in subsec. (a), was in the original ''section 7'' meaning section 7 of Pub. L. 102–493, which was translated as reading section 8 to reflect the probable intent of Congress, because definitions are contained in section 8 instead of section 7.

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as part of the Public Health Service Act which comprises this chapter.

CHANGE OF NAME

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, § 312, Oct. 27, 1992, 106 Stat. 3504.

EFFECTIVE DATE

Pub. L. 102–493, § 9, Oct. 24, 1992, 106 Stat. 3152, provided that: ''This Act [enacting this section, sections 263a–2 to 263a–7 of this title, and provisions set out as a note under section 201 of this title] shall take effect upon the expiration of 2 years after the date of the enactment of this Act [Oct. 24, 1992].''

§ 263a–2. Certification of embryo laboratories

(a) In general

(1) Development

Not later than 2 years after October 24, 1992, the Secretary, through the Centers for Disease Control, shall develop a model program for the certification of embryo laboratories (referred to in this section as a ''certification program'') to be carried out by the States.

(2) Consultation

In developing the certification program under paragraph (1), the Secretary shall consult with appropriate consumer and professional organizations with expertise in using, providing, and evaluating professional services and embryo laboratories associated with the assisted reproductive technology programs.

(b) Distribution

The Secretary shall distribute a description of the certification program to—

(1) the Governor of each State,

(2) the presiding officers of each State legislature,

(3) the public health official of each State, and

(4) the official responsible in each State for the operation of the State's contract with the Secretary under section 1395aa of this title,

and shall encourage such officials to assist in the State adopting such program.

(c) Requirements

The certification program shall include the following requirements:

(1) Administration

The certification program shall be administered by the State and shall provide for the inspection and certification of embryo laboratories in the State by the State or by approved accreditation organizations.

(2) Application requirements

The certification program shall provide for the submission of an application to a State by an embryo laboratory for certification, in such form as may be specified by the State. Such an application shall include—

(A) assurances satisfactory to the State that the embryo laboratory will be operated in accordance with the standards under subsection (d) of this section,

(B) a report to the State identifying the assisted reproductive technology programs with which the laboratory is associated, and

(C) such other information as the State finds necessary.

An embryo laboratory which meets the requirements of section 263a of this title shall, for the purposes of subparagraph (A) be considered in compliance with the standards referred to in such subparagraph which are the same as the standards in effect under section 263a of this title.

(d) Standards

The certification program shall include the following standards developed by the Secretary:

(1) A standard to assure consistent performance of procedures by each embryo laboratory certified under the certification program or by an approved accreditation organization in a State which has not adopted the certification program.

(2) A standard for a quality assurance and a quality control program to assure valid, reliable, and reproduceable [1] procedures in the laboratory.

(3) A standard for the maintenance of records (on a program by program basis) on laboratory tests and procedures performed, including the scientific basis of, and the methodology used for, the tests, procedures, and preparation of any standards or controls, criteria for acceptable and unacceptable outcomes, criteria for sample rejection, and procedures for safe sample disposal.

[1] So in original. Probably should be ''reproducible''.

(4) A standard for the maintenance of written records on personnel and facilities necessary for proper and effective operation of the laboratory, schedules of preventive maintenance, function verification for equipment, and the release of such records to the State upon demand.

(5) A standard for the use of such personnel who meet such qualifications as the Secretary may develop.

(e) Certification under State programs

A State may qualify to adopt the certification program if the State has submitted an application to the Secretary to adopt such program and the Secretary has approved the application. Such an application shall include—

(1) assurances by the State satisfactory to the Secretary that the certification program within the State meets the requirements of this section,

(2) an agreement to make such reports as the Secretary may require, and

(3) information about any proposed use of accreditation organizations under subsection (g)[2] of this section.

(f) Use of accreditation organizations

A State which has adopted the certification program may use accreditation organizations approved under section 263a–3 of this title to inspect and certify embryo laboratories.

(g) Inspections

(1) In general

A State which qualifies to adopt the certification program within the State shall conduct inspections in accordance with paragraph (2) to determine if laboratories in the State meet the requirements of such program. Such inspections shall be carried out by the State or by accreditation organizations used by the State under subsection (g)[2] of this section.

(2) Requirements

Inspections carried out under paragraph (1) shall—

(A) be periodic and unannounced, or

(B) be announced in such circumstances as the Secretary determines will not diminish the likelihood of discovering deficiencies in the operations of a laboratory.

Before making a determination under subparagraph (B), the Secretary shall make public, in such manner as to facilitate comment from any person (including any Federal or other public agency), a proposal indicating the circumstances under which announced inspections would be permitted.

(3) Results

The specific findings, including deficiencies, identified in an inspection carried out under paragraph (1) and any subsequent corrections to those deficiencies shall be announced and made available to the public upon request beginning no later than 60 days after the date of the inspection.

(h) Validation inspections

(1) In general

The Secretary may enter and inspect, during regular hours of operation, embryo laboratories—

(A) which have been certified by a State under the certification program, or

(B) which have been certified by an accreditation organization approved by the Secretary under section 263a–3 of this title,

for the purpose of determining whether the laboratory is being operated in accordance with the standards in subsection (d) of this section.

(2) Access to facilities and records

In conducting an inspection of an embryo laboratory under paragraph (1), the Secretary shall have access to all facilities, equipment, materials, records, and information which the Secretary determines is necessary to determine if such laboratory is being operated in accordance with the standards in subsection (d) of this section. As part of such an inspection, the Secretary may copy any material, record, or information inspected or require it to be submitted to the Secretary. Such an inspection may be made only upon the presentation of identification to the owner, operator, or agent in charge of the laboratory being inspected.

(3) Failure to comply

If the Secretary determines as a result of an inspection under paragraph (1) that the embryo laboratory is not in compliance with the standards in subsection (d) of this section, the Secretary shall—

(A) notify the State in which the laboratory is located and, if appropriate, the accreditation organization which certified the laboratory,

(B) make available to the public the results of the inspection,

(C) conduct additional inspections of other embryo laboratories under paragraph (1) to determine if—

(i) such State in carrying out the certification program is reliably identifying the deficiencies of such laboratory, or

(ii) the accreditation organization which certified such laboratories is reliably identifying such deficencies,[3] and

(D) if the Secretary determines—

(i) that such State in carrying out the certification program has not met the requirements applicable to such program, or

(ii) the accreditation organization which certified such laboratory has not met the requirements of section 263a–3 of this title,

the Secretary may revoke the approval of the State certification program or revoke the approval of such accreditation organization.

(i) Limitation

(1) Secretary

In developing the certification program, the Secretary may not establish any regulation,

[2] So in original. Probably should be subsection ''(f)''.

[3] So in original. Probably should be ''deficiencies,''.

standard, or requirement which has the effect of exercising supervision or control over the practice of medicine in assisted reproductive technology programs.

(2) State

In adopting the certification program, a State may not establish any regulation, standard, or requirement which has the effect of exercising supervision or control over the practice of medicine in assisted reproductive technology programs.

(j) Term

The term of a certification issued by a State or an accreditation organization in a State shall be prescribed by the Secretary in the certification program and shall be valid for a period of time to be defined by the Secretary through the public comment process described in subsection (h)(2)[4] of this section. The Secretary shall provide an application for recertification to be submitted at the time of changes in the ownership of a certified laboratory or changes in the administration of such a laboratory.

(Pub. L. 102–493, §3, Oct. 24, 1992, 106 Stat. 3146.)

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as part of the Public Health Service Act which comprises this chapter.

CHANGE OF NAME

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.

EFFECTIVE DATE

Section effective upon expiration of 2 years after Oct. 24, 1992, see section 9 of Pub. L. 102–493, set out as a note under section 263a–1 of this title.

§ 263a–3. Accreditation organizations

(a) Approval of accreditation organizations

Not later than 2 years after October 24, 1992, the Secretary, through the Centers for Disease Control, shall promulgate criteria and procedures for the approval of accreditation organizations to inspect and certify embryo laboratories. The procedures shall require an application to the Secretary by an accreditation organization for approval. An accreditation organization which has received such an approval—

(1) may be used by States in the certification program under section 263a–2 of this title to inspect and certify embryo laboratories, or

(2) may certify embryo laboratories in States which have not adopted such a certification program.

(b) Criteria and procedures

The criteria and procedures promulgated under subsection (a) of this section shall include—

(1) requirements for submission of such reports and the maintenance of such records as the Secretary or a State may require, and

(2) requirements for the conduct of inspections under section 263a–2(h)[1] of this title.

(c) Evaluations

The Secretary shall evaluate annually the performance of each accreditation organization approved by the Secretary by—

(1) inspecting under section 263a–2(i)[2] of this title a sufficient number of embryo laboratories accredited by such an organization to allow a reasonable estimate of the performance of such organization, and

(2) such other means as the Secretary determines to be appropriate.

(d) Transition

If the Secretary revokes approval under section 263a–2(i)(3)(D)[3] of this title of an accreditation organization after an evaluation under subsection (c) of this section, the certification of any embryo laboratory accredited by the organization shall continue in effect for 60 days after the laboratory is notified by the Secretary of the withdrawal of approval, except that the Secretary may extend the period during which the certification shall remain in effect if the Secretary determines that the laboratory submitted an application to another approved accreditation organization for certification after receipt of such notice in a timely manner.

(Pub. L. 102–493, §4, Oct. 24, 1992, 106 Stat. 3150.)

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as part of the Public Health Service Act which comprises this chapter.

CHANGE OF NAME

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, §312, Oct. 27, 1992, 106 Stat. 3504.

EFFECTIVE DATE

Section effective upon expiration of 2 years after Oct. 24, 1992, see section 9 of Pub. L. 102–493, set out as a note under section 263a–1 of this title.

§ 263a–4. Certification revocation and suspension

(a) In general

A certification issued by a State or an accreditation organization for an embryo laboratory shall be revoked or suspended if the State or organization finds, on the basis of inspections and after reasonable notice and opportunity for hearing to the owner or operator of the laboratory, that the owner or operator or any employee of the laboratory—

(1) has been guilty of misrepresentation in obtaining the certification,

(2) has failed to comply with any standards under section 263a–2 of this title applicable to the certification, or

(3) has refused a request of the State or accreditation organization for permission to inspect the laboratory, its operations, and records.

(b) Effect

If the certification of an embryo laboratory is revoked or suspended, the certification of the

[4] So in original. Probably should be subsection ''(g)(2)''.

[1] So in original. Probably should be section ''263a–2(g)''.

[2] So in original. Probably should be section ''263a–2(h)''.

[3] So in original. Probably should be section ''263a–2(h)(3)(D)''.

laboratory shall continue in effect for 60 days after the laboratory receives notice of the revocation or suspension. If the certification of an embryo laboratory is revoked or suspended, the laboratory may apply for recertification after one year after the date of the revocation or suspension.

(Pub. L. 102–493, § 5, Oct. 24, 1992, 106 Stat. 3150.)

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as part of the Public Health Service Act which comprises this chapter.

EFFECTIVE DATE

Section effective upon expiration of 2 years after Oct. 24, 1992, see section 9 of Pub. L. 102–493, set out as a note under section 263a–1 of this title.

§ 263a–5. Publication

The Secretary, through the Centers for Disease Control, shall not later than 3 years after October 24, 1992, and annually thereafter publish and distribute to the States and the public—

(1)(A)[1] pregnancy success rates reported to the Secretary under section 263a–1(a)(1) of this title and, in the case of an assisted reproductive technology program which failed to report one or more success rates as required under such section, the name of each such program and each pregnancy success rate which the program failed to report, and

(B) from information reported under section 263a–1(a)(2) of this title—

(i) the identity of each embryo laboratory in a State which has adopted the certification program under such program and whether such laboratory is certified under section 263a–2 of this title,

(ii) the identity of each embryo laboratory in a State which has not adopted such certification program and which has been certified by an accreditation organization approved by the Secretary under section 263a–3 of this title, and

(iii) in the case of an embryo laboratory which is not certified under section 263a–2 of this title or certified by an accreditation organization approved by the Secretary under section 263a–3 of this title, whether the laboratory applied for certification.

(Pub. L. 102–493, § 6, Oct. 24, 1992, 106 Stat. 3151.)

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as part of the Public Health Service Act which comprises this chapter.

CHANGE OF NAME

Centers for Disease Control changed to Centers for Disease Control and Prevention by Pub. L. 102–531, title III, § 312, Oct. 27, 1992, 106 Stat. 3504.

EFFECTIVE DATE

Section effective upon expiration of 2 years after Oct. 24, 1992, see section 9 of Pub. L. 102–493, set out as a note under section 263a–1 of this title.

[1] So in original. No par. (2) has been enacted.

§ 263a–6. Fees

The Secretary may require the payment of fees for the purpose of, and in an amount sufficient to cover the cost of, administering sections 263a–1 to 263a–7 of this title. A State operating a program under section 263a–2 of this title may require the payment of fees for the purpose of, and in an amount sufficient to cover the costs of, administering its program.

(Pub. L. 102–493, § 7, Oct. 24, 1992, 106 Stat. 3151.)

REFERENCES IN TEXT

Sections 263a–1 to 263a–7 of this title, referred to in text, was in the original ''this Act'', meaning Pub. L. 102–493, Oct. 24, 1992, 106 Stat. 3146, known as the Fertility Clinic Success Rate and Certification Act of 1992, which enacted sections 263a–1 to 263a–7 of this title and provisions set out as notes under sections 201 and 263a–1 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as part of the Public Health Service Act which comprises this chapter.

EFFECTIVE DATE

Section effective upon expiration of 2 years after Oct. 24, 1992, see section 9 of Pub. L. 102–493, set out as a note under section 263a–1 of this title.

§ 263a–7. Definitions

For purposes of sections 263a–1 to 263a–7 of this title:

(1) Assisted reproductive technology

The term ''assisted reproductive technology'' means all treatments or procedures which include the handling of human oocytes or embryos, including in vitro fertilization, gamete intrafallopian transfer, zygote intrafallopian transfer, and such other specific technologies as the Secretary may include in this definition, after making public any proposed definition in such manner as to facilitate comment from any person (including any Federal or other public agency).

(2) Embryo laboratory

The term ''embryo laboratory'' means a facility in which human oocytes are subject to assisted reproductive technology treatment or procedures based on manipulation of oocytes or embryos which are subject to implantation.

(3) Secretary

The term ''Secretary'' means the Secretary of Health and Human Services.

(Pub. L. 102–493, § 8, Oct. 24, 1992, 106 Stat. 3151.)

REFERENCES IN TEXT

Sections 263a–1 to 263a–7 of this title, referred to in text, was in the original ''this Act'', meaning Pub. L. 102–493, Oct. 24, 1992, 106 Stat. 3146, known as the Fertility Clinic Success Rate and Certification Act of 1992, which enacted sections 263a–1 to 263a–7 of this title and provisions set out as notes under sections 201 and 263a–1 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 201 of this title and Tables.

CODIFICATION

Section was enacted as part of the Fertility Clinic Success Rate and Certification Act of 1992, and not as

part of the Public Health Service Act which comprises this chapter.

EFFECTIVE DATE

Section effective upon expiration of 2 years after Oct. 24, 1992, see section 9 of Pub. L. 102–493, set out as a note under section 263a–1 of this title.

SUBPART 3—MAMMOGRAPHY FACILITIES

PRIOR PROVISIONS

A prior subpart 3 of part F of title III of the Public Health Service Act, comprising this subpart, was renumbered subchapter C of chapter V of the Federal Food, Drug, and Cosmetic Act, by Pub. L. 101–629, §19(a)(4), Nov. 28, 1990, 104 Stat. 4530, as amended by Pub. L. 103–80, §4(a)(2), Aug. 13, 1993, 107 Stat. 779, and is classified to part C (§360hh et seq.) of subchapter V of chapter 9 of Title 21, Food and Drugs.

§ 263b. Certification of mammography facilities

(a) Definitions

As used in this section:

(1) Accreditation body

The term ''accreditation body'' means a body that has been approved by the Secretary under subsection (e)(1)(A) of this section to accredit mammography facilities.

(2) Certificate

The term ''certificate'' means the certificate described in subsection (b)(1) of this section.

(3) Facility

(A) In general

The term ''facility'' means a hospital, outpatient department, clinic, radiology practice, or mobile unit, an office of a physician, or other facility as determined by the Secretary, that conducts breast cancer screening or diagnosis through mammography activities. Such term does not include a facility of the Department of Veterans Affairs.

(B) Activities

For the purposes of this section, the activities of a facility include the operation of equipment to produce the mammogram, the processing of the film, the initial interpretation of the mammogram and the viewing conditions for that interpretation. Where procedures such as the film processing, or the interpretation of the mammogram are performed in a location different from where the mammogram is performed, the facility performing the mammogram shall be responsible for meeting the quality standards described in subsection (f) of this section.

(4) Inspection

The term ''inspection'' means an onsite evaluation of the facility by the Secretary, or State or local agency on behalf of the Secretary.

(5) Mammogram

The term ''mammogram'' means a radiographic image produced through mammography.

(6) Mammography

The term ''mammography'' means radiography of the breast.

(7) Survey

The term ''survey'' means an onsite physics consultation and evaluation performed by a medical physicist as described in subsection (f)(1)(E) of this section.

(8) Review physician

The term ''review physician'' means a physician as prescribed by the Secretary under subsection (f)(1)(D) of this section who meets such additional requirements as may be established by an accreditation body under subsection (e) of this section and approved by the Secretary to review clinical images under subsection (e)(1)(B)(i) of this section on behalf of the accreditation body.

(b) Certificate requirement

(1) Certificate

No facility may conduct an examination or procedure described in paragraph (2) involving mammography after October 1, 1994, unless the facility obtains—

(A) a certificate or a temporary renewal certificate—

(i) that is issued, and, if applicable, renewed, by the Secretary in accordance with paragraphs[1] (1) or (2) of subsection (c) of this section;

(ii) that is applicable to the examination or procedure to be conducted; and

(iii) that is displayed prominently in such facility; or

(B) a provisional certificate or a limited provisional certificate—

(i) that is issued by the Secretary in accordance with paragraphs (3) and (4) of subsection (c) of this section;

(ii) that is applicable to the examination or procedure to be conducted; and

(iii) that is displayed prominently in such facility.

The reference to a certificate in this section includes a temporary renewal certificate, provisional certificate, or a limited provisional certificate.

(2) Examination or procedure

A facility shall obtain a certificate in order to—

(A) operate radiological equipment that is used to image the breast;

(B) provide for the interpretation of a mammogram produced by such equipment at the facility or under arrangements with a qualified individual at a facility different from where the mammography examination is performed; and

(C) provide for the processing of film produced by such equipment at the facility or under arrangements with a qualified individual at a facility different from where the mammography examination is performed.

(c) Issuance and renewal of certificates

(1) In general

The Secretary may issue or renew a certificate for a facility if the person or agent de-

[1] So in original. Probably should be ''paragraph''.

scribed in subsection (d)(1)(A) of this section meets the applicable requirements of subsection (d)(1) of this section with respect to the facility. The Secretary may issue or renew a certificate under this paragraph for not more than 3 years.

(2) Temporary renewal certificate

The Secretary may issue a temporary renewal certificate, for a period of not to exceed 45 days, to a facility seeking reaccreditation if the accreditation body has issued an accreditation extension, for a period of not to exceed 45 days, for any of the following:

(A) The facility has submitted the required materials to the accreditation body within the established time frames for the submission of such materials but the accreditation body is unable to complete the reaccreditation process before the certification expires.

(B) The facility has acquired additional or replacement equipment, or has had significant personnel changes or other unforeseen situations that have caused the facility to be unable to meet reaccreditation timeframes, but in the opinion of the accreditation body have not compromised the quality of mammography.

(3) Limited provisional certificate

The Secretary may, upon the request of an accreditation body, issue a limited provisional certificate to an entity to enable the entity to conduct examinations for educational purposes while an onsite visit from an accreditation body is in progress. Such certificate shall be valid only during the time the site visit team from the accreditation body is physically in the facility, and in no case shall be valid for longer than 72 hours. The issuance of a certificate under this paragraph, shall not preclude the entity from qualifying for a provisional certificate under paragraph (4).

(4) Provisional certificate

The Secretary may issue a provisional certificate for an entity to enable the entity to qualify as a facility. The applicant for a provisional certificate shall meet the requirements of subsection (d)(1) of this section, except providing information required by clauses (iii) and (iv) of subsection (d)(1)(A) of this section. A provisional certificate may be in effect no longer than 6 months from the date it is issued, except that it may be extended once for a period of not more than 90 days if the owner, lessor, or agent of the facility demonstrates to the Secretary that without such extension access to mammography in the geographic area served by the facility would be significantly reduced and if the owner, lessor, or agent of the facility will describe in a report to the Secretary steps that will be taken to qualify the facility for certification under subsection (b)(1) of this section.

(d) Application for certificate

(1) Submission

The Secretary may issue or renew a certificate for a facility if—

(A) the person who owns or leases the facility or an authorized agent of the person, submits to the Secretary, in such form and manner as the Secretary shall prescribe, an application that contains at a minimum—

(i) a description of the manufacturer, model, and type of each x-ray machine, image receptor, and processor operated in the performance of mammography by the facility;

(ii) a description of the procedures currently used to provide mammography at the facility, including—

(I) the types of procedures performed and the number of such procedures performed in the prior 12 months;

(II) the methodologies for mammography; and

(III) the names and qualifications (educational background, training, and experience) of the personnel performing mammography and the physicians reading and interpreting the results from the procedures;

(iii) proof of on-site survey by a qualified medical physicist as described in subsection (f)(1)(E) of this section; and

(iv) proof of accreditation in such manner as the Secretary shall prescribe; and

(B) the person or agent submits to the Secretary—

(i) a satisfactory assurance that the facility will be operated in accordance with standards established by the Secretary under subsection (f) of this section to assure the safety and accuracy of mammography;

(ii) a satisfactory assurance that the facility will—

(I) permit inspections under subsection (g) of this section;

(II) make such records and information available, and submit such reports, to the Secretary as the Secretary may require; and

(III) update the information submitted under subparagraph (A) or assurances submitted under this subparagraph on a timely basis as required by the Secretary; and

(iii) such other information as the Secretary may require.

An applicant shall not be required to provide in an application under subparagraph (A) any information which the applicant has supplied to the accreditation body which accredited the applicant, except as required by the Secretary.

(2) Appeal

If the Secretary denies an application for the certification of a facility submitted under paragraph (1)(A), the Secretary shall provide the owner or lessor of the facility or the agent of the owner or lessor who submitted such application—

(A) a statement of the grounds on which the denial is based, and

(B) an opportunity for an appeal in accordance with the procedures set forth in regulations of the Secretary published at part 498 of title 42, Code of Federal Regulations.

(3) Effect of denial

If the application for the certification of a facility is denied, the facility may not operate unless the denial of the application is overturned at the conclusion of the administrative appeals process provided in the regulations referred to in paragraph (2)(B).

(e) Accreditation

(1) Approval of accreditation bodies

(A) In general

The Secretary may approve a private nonprofit organization or State agency to accredit facilities for purposes of subsection (d)(1)(A)(iv) of this section if the accreditation body meets the standards for accreditation established by the Secretary as described in subparagraph (B) and provides the assurances required by subparagraph (C).

(B) Standards

The Secretary shall establish standards for accreditation bodies, including—

(i) standards that require an accreditation body to perform—

(I) a review of clinical images from each facility accredited by such body not less often than every 3 years which review will be made by qualified review physicians; and

(II) a review of a random sample of clinical images from such facilities in each 3-year period beginning October 1, 1994, which review will be made by qualified review physicians;

(ii) standards that prohibit individuals conducting the reviews described in clause (i) from maintaining any relationship to the facility undergoing review which would constitute a conflict of interest;

(iii) standards that limit the imposition of fees for accreditation to reasonable amounts;

(iv) standards that require as a condition of accreditation that each facility undergo a survey at least annually by a medical physicist as described in subsection (f)(1)(E) of this section to ensure that the facility meets the standards described in subparagraphs (A) and (B) of subsection (f)(1) of this section;

(v) standards that require monitoring and evaluation of such survey, as prescribed by the Secretary;

(vi) standards that are equal to standards established under subsection (f) of this section which are relevant to accreditation as determined by the Secretary; and

(vii) such additional standards as the Secretary may require.

(C) Assurances

The accrediting body shall provide the Secretary satisfactory assurances that the body will—

(i) comply with the standards as described in subparagraph (B);

(ii) comply with the requirements described in paragraph (4);

(iii) submit to the Secretary the name of any facility for which the accreditation body denies, suspends, or revokes accreditation;

(iv) notify the Secretary in a timely manner before the accreditation body changes the standards of the body;

(v) notify each facility accredited by the accreditation body if the Secretary withdraws approval of the accreditation body under paragraph (2) in a timely manner; and

(vi) provide such other additional information as the Secretary may require.

(D) Regulations

Not later than 9 months after October 27, 1992, the Secretary shall promulgate regulations under which the Secretary may approve an accreditation body.

(2) Withdrawal of approval

(A) In general

The Secretary shall promulgate regulations under which the Secretary may withdraw the approval of an accreditation body if the Secretary determines that the accreditation body does not meet the standards under subparagraph (B) of paragraph (1), the requirements of clauses (i) through (vi) of subparagraph (C) of paragraph (1), or the requirements of paragraph (4).

(B) Effect of withdrawal

If the Secretary withdraws the approval of an accreditation body under subparagraph (A), the certificate of any facility accredited by the body shall continue in effect until the expiration of a reasonable period, as determined by the Secretary, for such facility to obtain another accreditation.

(3) Accreditation

To be accredited by an approved accreditation body a facility shall meet—

(A) the standards described in paragraph (1)(B) which the Secretary determines are applicable to the facility, and

(B) such other standards which the accreditation body may require.

(4) Compliance

To ensure that facilities accredited by an accreditation body will continue to meet the standards of the accreditation body, the accreditation body shall—

(A) make onsite visits on an annual basis of a sufficient number of the facilities accredited by the body to allow a reasonable estimate of the performance of the body; and

(B) take such additional measures as the Secretary determines to be appropriate.

Visits made under subparagraph (A) shall be made after providing such notice as the Secretary may require.

(5) Revocation of accreditation

If an accreditation body revokes the accreditation of a facility, the certificate of the facility shall continue in effect until such time as may be determined by the Secretary.

(6) Evaluation and report

(A) Evaluation

The Secretary shall evaluate annually the performance of each approved accreditation body by—

(i) inspecting under subsection (g)(2) of this section a sufficient number of the facilities accredited by the body to allow a reasonable estimate of the performance of the body; and

(ii) such additional means as the Secretary determines to be appropriate.

(B) Report

The Secretary shall annually prepare and submit to the Committee on Labor and Human Resources of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that describes the results of the evaluation conducted in accordance with subparagraph (A).

(f) Quality standards

(1) In general

The standards referred to in subsection (d)(1)(B)(i) of this section are standards established by the Secretary which include—

(A) standards that require establishment and maintenance of a quality assurance and quality control program at each facility that is adequate and appropriate to ensure the reliability, clarity, and accuracy of interpretation of mammograms and standards for appropriate radiation dose;

(B) standards that require use of radiological equipment specifically designed for mammography, including radiologic standards and standards for other equipment and materials used in conjunction with such equipment;

(C) a requirement that personnel who perform mammography—

(i)(I) be licensed by a State to perform radiological procedures; or

(II) be certified as qualified to perform radiological procedures by an organization described in paragraph (2)(A); and

(ii) during the 2-year period beginning October 1, 1994, meet training standards for personnel who perform mammography or meet experience requirements which shall at a minimum include 1 year of experience in the performance of mammography; and

(iii) upon the expiration of such 2-year period meet minimum training standards for personnel who perform mammograms;

(D) a requirement that mammograms be interpreted by a physician who is certified as qualified to interpret radiological procedures, including mammography—

(i)(I) by a board described in paragraph (2)(B); or

(II) by a program that complies with the standards described in paragraph (2)(C); and

(ii) who meets training and continuing medical education requirements as established by the Secretary;

(E) a requirement that individuals who survey mammography facilities be medical physicists—

(i) licensed or approved by a State to perform such surveys, reviews, or inspections for mammography facilities;

(ii) certified in diagnostic radiological physics or certified as qualified to perform such surveys by a board as described in paragraph (2)(D); or

(iii) in the first 5 years after October 27, 1992, who meet other criteria established by the Secretary which are comparable to the criteria described in clause (i) or (ii);

(F) a requirement that a medical physicist who is qualified in mammography as described in subparagraph (E) survey mammography equipment and oversee quality assurance practices at each facility;

(G) a requirement that—

(i) a facility that performs any mammogram—

(I) except as provided in subclause (II), maintain the mammogram in the permanent medical records of the patient for a period of not less than 5 years, or not less than 10 years if no subsequent mammograms of such patient are performed at the facility, or longer if mandated by State law; and

(II) upon the request of or on behalf of the patient, transfer the mammogram to a medical institution, to a physician of the patient, or to the patient directly; and

(ii)(I) a facility must assure the preparation of a written report of the results of any mammography examination signed by the interpreting physician;

(II) such written report shall be provided to the patient's physicians (if any);

(III) if such a physician is not available or if there is no such physician, the written report shall be sent directly to the patient; and

(IV) whether or not such a physician is available or there is no such physician, a summary of the written report shall be sent directly to the patient in terms easily understood by a lay person; and

(H) standards relating to special techniques for mammography of patients with breast implants.

Subparagraph (G) shall not be construed to limit a patient's access to the patient's medical records.

(2) Certification of personnel

The Secretary shall by regulation—

(A) specify organizations eligible to certify individuals to perform radiological procedures as required by paragraph (1)(C);

(B) specify boards eligible to certify physicians to interpret radiological procedures, including mammography, as required by paragraph (1)(D);

(C) establish standards for a program to certify physicians described in paragraph (1)(D); and

(D) specify boards eligible to certify medical physicists who are qualified to survey mammography equipment and to oversee quality assurance practices at mammography facilities.

(g) Inspections

(1) Annual inspections

(A) In general

The Secretary may enter and inspect facilities to determine compliance with the certification requirements under subsection (b) of this section and the standards established under subsection (f) of this section. The Secretary shall, if feasible, delegate to a State or local agency the authority to make such inspections.

(B) Identification

The Secretary, or State or local agency acting on behalf of the Secretary, may conduct inspections only on presenting identification to the owner, operator, or agent in charge of the facility to be inspected.

(C) Scope of inspection

In conducting inspections, the Secretary or State or local agency acting on behalf of the Secretary—

(i) shall have access to all equipment, materials, records, and information that the Secretary or State or local agency considers necessary to determine whether the facility is being operated in accordance with this section; and

(ii) may copy, or require the facility to submit to the Secretary or the State or local agency, any of the materials, records, or information.

(D) Qualifications of inspectors

Qualified individuals, as determined by the Secretary, shall conduct all inspections. The Secretary may request that a State or local agency acting on behalf of the Secretary designate a qualified officer or employee to conduct the inspections, or designate a qualified Federal officer or employee to conduct inspections. The Secretary shall establish minimum qualifications and appropriate training for inspectors and criteria for certification of inspectors in order to inspect facilities for compliance with subsection (f) of this section.

(E) Frequency

The Secretary or State or local agency acting on behalf of the Secretary shall conduct inspections under this paragraph of each facility not less often than annually, subject to paragraph (6).

(F) Records and annual reports

The Secretary or a State or local agency acting on behalf of the Secretary which is responsible for inspecting mammography facilities shall maintain records of annual inspections required under this paragraph for a period as prescribed by the Secretary. Such a State or local agency shall annually prepare and submit to the Secretary a report concerning the inspections carried out under this paragraph. Such reports shall include a description of the facilities inspected and the results of such inspections.

(2) Inspection of accredited facilities

The Secretary shall inspect annually a sufficient number of the facilities accredited by an accreditation body to provide the Secretary with a reasonable estimate of the performance of such body.

(3) Inspection of facilities inspected by State or local agencies

The Secretary shall inspect annually facilities inspected by State or local agencies acting on behalf of the Secretary to assure a reasonable performance by such State or local agencies.

(4) Timing

The Secretary, or State or local agency, may conduct inspections under paragraphs (1), (2), and (3), during regular business hours or at a mutually agreeable time and after providing such notice as the Secretary may prescribe, except that the Secretary may waive such requirements if the continued performance of mammography at such facility threatens the public health.

(5) Limited reinspection

Nothing in this section limits the authority of the Secretary to conduct limited reinspections of facilities found not to be in compliance with this section.

(6) Demonstration program

(A) In general

The Secretary may establish a demonstration program under which inspections under paragraph (1) of selected facilities are conducted less frequently by the Secretary (or as applicable, by State or local agencies acting on behalf of the Secretary) than the interval specified in subparagraph (E) of such paragraph.

(B) Requirements

Any demonstration program under subparagraph (A) shall be carried out in accordance with the following:

(i) The program may not be implemented before April 1, 2001. Preparations for the program may be carried out prior to such date.

(ii) In carrying out the program, the Secretary may not select a facility for inclusion in the program unless the facility is substantially free of incidents of noncompliance with the standards under subsection (f) of this section. The Secretary may at any time provide that a facility will no longer be included in the program.

(iii) The number of facilities selected for inclusion in the program shall be sufficient to provide a statistically significant sample, subject to compliance with clause (ii).

(iv) Facilities that are selected for inclusion in the program shall be inspected at such intervals as the Secretary determines will reasonably ensure that the facilities are maintaining compliance with such standards.

(h) Sanctions

(1) In general

In order to promote voluntary compliance with this section, the Secretary may, in lieu

of taking the actions authorized by subsection (i) of this section, impose one or more of the following sanctions:

(A) Directed plans of correction which afford a facility an opportunity to correct violations in a timely manner.

(B) Payment for the cost of onsite monitoring.

(2) Patient information

If the Secretary determines that the quality of mammography performed by a facility (whether or not certified pursuant to subsection (c) of this section) was so inconsistent with the quality standards established pursuant to subsection (f) of this section as to present a significant risk to individual or public health, the Secretary may require such facility to notify patients who received mammograms at such facility, and their referring physicians, of the deficiencies presenting such risk, the potential harm resulting, appropriate remedial measures, and such other relevant information as the Secretary may require.

(3) Civil money penalties

The Secretary may assess civil money penalties in an amount not to exceed $10,000 for—

(A) failure to obtain a certificate as required by subsection (b) of this section,

(B) each failure by a facility to substantially comply with, or each day on which a facility fails to substantially comply with, the standards established under subsection (f) of this section or the requirements described in subclauses (I) through (III) of subsection (d)(1)(B)(ii) of this section,

(C) each failure to notify a patient of risk as required by the Secretary pursuant to paragraph (2), and

(D) each violation, or for each aiding and abetting in a violation of, any provision of, or regulation promulgated under, this section by an owner, operator, or any employee of a facility required to have a certificate.

(4) Procedures

The Secretary shall develop and implement procedures with respect to when and how each of the sanctions is to be imposed under paragraphs (1) through (3). Such procedures shall provide for notice to the owner or operator of the facility and a reasonable opportunity for the owner or operator to respond to the proposed sanctions and appropriate procedures for appealing determinations relating to the imposition of sanctions.

(i) Suspension and revocation

(1) In general

The certificate of a facility issued under subsection (c) of this section may be suspended or revoked if the Secretary finds, after providing, except as provided in paragraph (2), reasonable notice and an opportunity for a hearing to the owner or operator of the facility, that the owner, operator, or any employee of the facility—

(A) has been guilty of misrepresentation in obtaining the certificate;

(B) has failed to comply with the requirements of subsection (d)(1)(B)(ii)(III) of this section or the standards established by the Secretary under subsection (f) of this section;

(C) has failed to comply with reasonable requests of the Secretary (or of an accreditation body approved pursuant to subsection (e) of this section) for any record, information, report, or material that the Secretary (or such accreditation body or State carrying out certification program requirements pursuant to subsection (q) of this section) concludes is necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards established under subsection (f) of this section;

(D) has refused a reasonable request of the Secretary, any Federal officer or employee duly designated by the Secretary, or any State or local officer or employee duly designated by the State or local agency, for permission to inspect the facility or the operations and pertinent records of the facility in accordance with subsection (g) of this section;

(E) has violated or aided and abetted in the violation of any provision of, or regulation promulgated under, this section; or

(F) has failed to comply with a sanction imposed under subsection (h) of this section.

(2) Action before a hearing

(A) In general

The Secretary may suspend the certificate of the facility before holding a hearing required by paragraph (1) if the Secretary has reason to believe that the circumstance of the case will support one or more of the findings described in paragraph (1) and that—

(i) the failure or violation was intentional; or

(ii) the failure or violation presents a serious risk to human health.

(B) Hearing

If the Secretary suspends a certificate under subparagraph (A), the Secretary shall provide an opportunity for a hearing to the owner or operator of the facility not later than 60 days from the effective date of the suspension. The suspension shall remain in effect until the decision of the Secretary made after the hearing.

(3) Ineligibility to own or operate facilities after revocation

If the Secretary revokes the certificate of a facility on the basis of an act described in paragraph (1), no person who owned or operated the facility at the time of the act may, within 2 years of the revocation of the certificate, own or operate a facility that requires a certificate under this section.

(j) Injunctions

If the Secretary determines that—

(1) continuation of any activity related to the provision of mammography by a facility would constitute a serious risk to human health, the Secretary may bring suit in the district court of the United States for the district in which the facility is situated to enjoin continuation of the activity; and

(2) a facility is operating without a certificate as required by subsection (b) of this section, the Secretary may bring suit in the district court of the United States for the district in which the facility is situated to enjoin the operation of the facility.

Upon a proper showing, the district court shall grant a temporary injunction or restraining order against continuation of the activity or against operation of a facility, as the case may be, without requiring the Secretary to post a bond, pending issuance of a final order under this subsection.

(k) Judicial review

(1) Petition

If the Secretary imposes a sanction on a facility under subsection (h) of this section or suspends or revokes the certificate of a facility under subsection (i) of this section, the owner or operator of the facility may, not later than 60 days after the date the action of the Secretary becomes final, file a petition with the United States court of appeals for the circuit in which the facility is situated for judicial review of the action. As soon as practicable after receipt of the petition, the clerk of the court shall transmit a copy of the petition to the Secretary or other officer designated by the Secretary. As soon as practicable after receipt of the copy, the Secretary shall file in the court the record on which the action of the Secretary is based, as provided in section 2112 of title 28.

(2) Additional evidence

If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that the 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 the additional evidence (and evidence in rebuttal of the 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 the court may determine to be proper. The Secretary may modify the findings of the Secretary as to the facts, or make new findings, by reason of the additional evidence so taken, and the Secretary shall file the modified or new findings, and the recommendations of the Secretary, if any, for the modification or setting aside of the original action of the Secretary with the return of the additional evidence.

(3) Judgment of court

Upon the filing of the petition referred to in paragraph (1), the court shall have jurisdiction to affirm the action, or to set the action aside in whole or in part, temporarily or permanently. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive.

(4) Finality of judgment

The judgment of the court affirming or setting aside, in whole or in part, any action of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28.

***(l)* Information**

(1) In general

Not later than October 1, 1996, and annually thereafter, the Secretary shall compile and make available to physicians and the general public information that the Secretary determines is useful in evaluating the performance of facilities, including a list of facilities—

(A) that have been convicted under Federal or State laws relating to fraud and abuse, false billings, or kickbacks;

(B) that have been subject to sanctions under subsection (h) of this section, together with a statement of the reasons for the sanctions;

(C) that have had certificates revoked or suspended under subsection (i) of this section, together with a statement of the reasons for the revocation or suspension;

(D) against which the Secretary has taken action under subsection (j) of this section, together with a statement of the reasons for the action;

(E) whose accreditation has been revoked, together with a statement of the reasons of the revocation;

(F) against which a State has taken adverse action; and

(G) that meets such other measures of performance as the Secretary may develop.

(2) Date

The information to be compiled under paragraph (1) shall be information for the calendar year preceding the date the information is to be made available to the public.

(3) Explanatory information

The information to be compiled under paragraph (1) shall be accompanied by such explanatory information as may be appropriate to assist in the interpretation of the information compiled under such paragraph.

(m) State laws

Nothing in this section shall be construed to limit the authority of any State to enact and enforce laws relating to the matters covered by this section that are at least as stringent as this section or the regulations issued under this section.

(n) National Advisory Committee

(1) Establishment

In carrying out this section, the Secretary shall establish an advisory committee to be known as the National Mammography Quality Assurance Advisory Committee (hereafter in this subsection referred to as the ''Advisory Committee'').

(2) Composition

The Advisory Committee shall be composed of not fewer than 13, nor more than 19 individuals, who are not officers or employees of the Federal Government. The Secretary shall make appointments to the Advisory Committee from among—

(A) physicians,

(B) practitioners, and
(C) other health professionals,

whose clinical practice, research specialization, or professional expertise include a significant focus on mammography. The Secretary shall appoint at least 4 individuals from among national breast cancer or consumer health organizations with expertise in mammography, at least 2 industry representatives with expertise in mammography equipment, and at least 2 practicing physicians who provide mammography services.

(3) Functions and duties

The Advisory Committee shall—

(A) advise the Secretary on appropriate quality standards and regulations for mammography facilities;

(B) advise the Secretary on appropriate standards and regulations for accreditation bodies;

(C) advise the Secretary in the development of regulations with respect to sanctions;

(D) assist in developing procedures for monitoring compliance with standards under subsection (f) of this section;

(E) make recommendations and assist in the establishment of a mechanism to investigate consumer complaints;

(F) report on new developments concerning breast imaging that should be considered in the oversight of mammography facilities;

(G) determine whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determine the effects of personnel or other requirements of subsection (f) of this section on access to the services of such facilities in such areas;

(H) determine whether there will exist a sufficient number of medical physicists after October 1, 1999, to assure compliance with the requirements of subsection (f)(1)(E) of this section;

(I) determine the costs and benefits of compliance with the requirements of this section (including the requirements of regulations promulgated under this section); and

(J) perform other activities that the Secretary may require.

The Advisory Committee shall report the findings made under subparagraphs (G) and (I) to the Secretary and the Congress no later than October 1, 1993.

(4) Meetings

The Advisory Committee shall meet not less than quarterly for the first 3 years of the program and thereafter, at least annually.

(5) Chairperson

The Secretary shall appoint a chairperson of the Advisory Committee.

(*o*) Consultations

In carrying out this section, the Secretary shall consult with appropriate Federal agencies within the Department of Health and Human Services for the purposes of developing standards, regulations, evaluations, and procedures for compliance and oversight.

(p) Breast cancer screening surveillance research grants

(1) Research

(A) Grants

The Secretary shall award grants to such entities as the Secretary may determine to be appropriate to establish surveillance systems in selected geographic areas to provide data to evaluate the functioning and effectiveness of breast cancer screening programs in the United States, including assessments of participation rates in screening mammography, diagnostic procedures, incidence of breast cancer, mode of detection (mammography screening or other methods), outcome and follow up information, and such related epidemiologic analyses that may improve early cancer detection and contribute to reduction in breast cancer mortality. Grants may be awarded for further research on breast cancer surveillance systems upon the Secretary's review of the evaluation of the program.

(B) Use of funds

Grants awarded under subparagraph (A) may be used—

(i) to study—

(I) methods to link mammography and clinical breast examination records with population-based cancer registry data;

(II) methods to provide diagnostic outcome data, or facilitate the communication of diagnostic outcome data, to radiology facilities for purposes of evaluating patterns of mammography interpretation; and

(III) mechanisms for limiting access and maintaining confidentiality of all stored data; and

(ii) to conduct pilot testing of the methods and mechanisms described in subclauses (I), (II), and (III) of clause (i) on a limited basis.

(C) Grant application

To be eligible to receive funds under this paragraph, an entity shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(D) Report

A recipient of a grant under this paragraph shall submit a report to the Secretary containing the results of the study and testing conducted under clauses (i) and (ii) of subparagraph (B), along with recommendations for methods of establishing a breast cancer screening surveillance system.

(2) Establishment

The Secretary shall establish a breast cancer screening surveillance system based on the recommendations contained in the report described in paragraph (1)(D).

(3) Standards and procedures

The Secretary shall establish standards and procedures for the operation of the breast cancer screening surveillance system, including

procedures to maintain confidentiality of patient records.

(4) Information

The Secretary shall recruit facilities to provide to the breast cancer screening surveillance system relevant data that could help in the research of the causes, characteristics, and prevalence of, and potential treatments for, breast cancer and benign breast conditions, if the information may be disclosed under section 552 of title 5.

(q) State program

(1) In general

The Secretary may, upon application, authorize a State—

(A) to carry out, subject to paragraph (2), the certification program requirements under subsections (b), (c), (d), (g)(1), (h), (i), and (j) of this section (including the requirements under regulations promulgated pursuant to such subsections), and

(B) to implement the standards established by the Secretary under subsection (f) of this section,

with respect to mammography facilities operating within the State.

(2) Approval

The Secretary may approve an application under paragraph (1) if the Secretary determines that—

(A) the State has enacted laws and issued regulations relating to mammography facilities which are the requirements of this section (including the requirements under regulations promulgated pursuant to such subsections), and

(B) the State has provided satisfactory assurances that the State—

(i) has the legal authority and qualified personnel necessary to enforce the requirements of and the regulations promulgated pursuant to this section (including the requirements under regulations promulgated pursuant to such subsections),

(ii) will devote adequate funds to the administration and enforcement of such requirements, and

(iii) will provide the Secretary with such information and reports as the Secretary may require.

(3) Authority of Secretary

In a State with an approved application—

(A) the Secretary shall carry out the Secretary's functions under subsections (e) and (f) of this section;

(B) the Secretary may take action under subsections (h), (i), and (j) of this section; and

(C) the Secretary shall conduct oversight functions under subsections (g)(2) and (g)(3) of this section.

(4) Withdrawal of approval

(A) In general

The Secretary may, after providing notice and opportunity for corrective action, withdraw the approval of a State's authority under paragraph (1) if the Secretary determines that the State does not meet the requirements of such paragraph. The Secretary shall promulgate regulations for the implementation of this subparagraph.

(B) Effect of withdrawal

If the Secretary withdraws the approval of a State under subparagraph (A), the certificate of any facility certified by the State shall continue in effect until the expiration of a reasonable period, as determined by the Secretary, for such facility to obtain certification by the Secretary.

(r) Funding

(1) Fees

(A) In general

The Secretary shall, in accordance with this paragraph assess and collect fees from persons described in subsection (d)(1)(A) of this section (other than persons who are governmental entities, as determined by the Secretary) to cover the costs of inspections conducted under subsection (g)(1) of this section by the Secretary or a State acting under a delegation under subparagraph (A) of such subsection. Fees may be assessed and collected under this paragraph only in such manner as would result in an aggregate amount of fees collected during any fiscal year which equals the aggregate amount of costs for such fiscal year for inspections of facilities of such persons under subsection (g)(1) of this section. A person's liability for fees shall be reasonably based on the proportion of the inspection costs which relate to such person.

(B) Deposit and appropriations

(i) Deposit and availability

Fees collected under subparagraph (A) shall be deposited as an offsetting collection to the appropriations for the Department of Health and Human Services as provided in appropriation Acts and shall remain available without fiscal year limitation.

(ii) Appropriations

Fees collected under subparagraph (A) shall be collected and available only to the extent provided in advance in appropriation Acts.

(2) Authorization of appropriations

There are authorized to be appropriated to carry out this section—

(A) to award research grants under subsection (p) of this section, such sums as may be necessary for each of the fiscal years 1993 through 2007; and

(B) for the Secretary to carry out other activities which are not supported by fees authorized and collected under paragraph (1), such sums as may be necessary for fiscal years 1993 through 2007.

(July 1, 1944, ch. 373, title III, § 354, as added Pub. L. 102–539, § 2, Oct. 27, 1992, 106 Stat. 3547; amended Pub. L. 105–248, §§ 2–13, Oct. 9, 1998, 112 Stat. 1864–1867; Pub. L. 108–365, §§ 2–4, Oct. 25, 2004, 118 Stat. 1738–1740.)

PRIOR PROVISIONS

A prior section 263b, act July 1, 1944, ch. 373, title III, § 354, as added Oct. 18, 1968, Pub. L. 90–602, § 2(3), 82 Stat. 1173; amended Nov. 28, 1990, Pub. L. 101–629, § 19(a)(1)(B), 104 Stat. 4529; Aug. 13, 1993, Pub. L. 103–80, § 4(a)(2), 107 Stat. 779, set forth Congressional declaration of purpose, prior to repeal by Pub. L. 101–629, § 19(a)(3), Nov. 28, 1990, 104 Stat. 4530.

Sections 263c to 263n, act July 1, 1944, ch. 373, title III, §§ 355–360F, as added Oct. 18, 1968, Pub. L. 90–602, § 2(3), 82 Stat. 1174, and amended, which related to electronic product radiation control, were renumbered sections 531 to 542, respectively, of the Federal Food, Drug, and Cosmetic Act by Pub. L. 101–629, § 19(a)(4), Nov. 28, 1990, 104 Stat. 4530, and are classified to sections 360hh to 360ss, respectively, of Title 21, Food and Drugs.

AMENDMENTS

2004—Subsec. (b)(1). Pub. L. 108–365, § 2(1)(C), substituted ''temporary renewal certificate, provisional certificate, or a limited provisional certificate'' for ''provisional certificate'' in concluding provisions.

Subsec. (b)(1)(A). Pub. L. 108–365, § 2(1)(A), inserted ''or a temporary renewal certificate'' after ''certificate'' in introductory provisions and substituted ''paragraphs (1) or (2) of subsection (c)'' for ''subsection (c)(1)'' in cl. (i).

Subsec. (b)(1)(B). Pub. L. 108–365, § 2(1)(B), inserted ''or a limited provisional certificate'' after ''certificate'' in introductory provisions and substituted ''paragraphs (3) and (4) of subsection (c)'' for ''subsection (c)(2)'' in cl. (i).

Subsec. (c)(2) to (4). Pub. L. 108–365, § 2(2), added pars. (2) and (3) and redesignated former par. (2) as (4).

Subsec. (n)(2). Pub. L. 108–365, § 3(1), reenacted subpar. (C) without change, added concluding provisions, and struck out former concluding provisions which read as follows: ''whose clinical practice, research specialization, or professional expertise include a significant focus on mammography. The Secretary shall appoint at least 4 individuals from among national breast cancer or consumer health organizations with expertise in mammography and at least 2 practicing physicians who provide mammography services.''

Subsec. (n)(4). Pub. L. 108–365, § 3(2), substituted ''annually'' for ''biannually''.

Subsec. (r)(2). Pub. L. 108–365, § 4, substituted ''2007'' for ''2002'' in subpars. (A) and (B).

1998—Subsec. (a)(4). Pub. L. 105–248, § 9(1), inserted ''or local'' after ''State''.

Subsec. (a)(8). Pub. L. 105–248, § 4(b), added par. (8).

Subsec. (d)(2)(B). Pub. L. 105–248, § 3, substituted ''part 498 of title 42, Code of Federal Regulations'' for ''42 C.F.R. 498 and in effect on October 27, 1992''.

Subsec. (e)(1)(B)(i)(I), (II). Pub. L. 105–248, § 4(a)(1), substituted ''review physicians'' for ''practicing physicians''.

Subsec. (e)(1)(B)(ii). Pub. L. 105–248, § 4(a)(2), substituted ''relationship'' for ''financial relationship''.

Subsec. (f)(1)(G)(i). Pub. L. 105–248, § 5, added cl. (i) and struck out former cl. (i) which read as follows: ''a facility that performs any mammogram maintain the mammogram in the permanent medical records of the patient—

''(I) for a period of not less than 5 years, or not less than 10 years if no additional mammograms of such patient are performed at the facility, or longer if mandated by State law; or

''(II) until such time as the patient should request that the patient's medical records be forwarded to a medical institution or a physician of the patient;

whichever is longer; and''.

Subsec. (f)(1)(G)(ii)(IV). Pub. L. 105–248, § 6, added subcl. (IV) and struck out former subcl. (IV) which read as follows: ''if such report is sent to the patient, the report shall include a summary written in terms easily understood by a lay person; and''.

Subsec. (g)(1). Pub. L. 105–248, § 9(1), inserted ''or local'' after ''State'' wherever appearing.

Subsec. (g)(1)(A). Pub. L. 105–248, § 7, in first sentence, struck out ''certified'' before ''facilities'' and inserted ''the certification requirements under subsection (b) of this section and'' after ''compliance with''.

Subsec. (g)(1)(E). Pub. L. 105–248, § 8(1), inserted '', subject to paragraph (6)'' before period at end.

Subsec. (g)(3). Pub. L. 105–248, § 9(1), (2), inserted ''or local'' after ''State'' in heading and in two places in text.

Subsec. (g)(4). Pub. L. 105–248, § 9(1), inserted ''or local'' after ''State''.

Subsec. (g)(6). Pub. L. 105–248, § 8(2), added par. (6).

Subsec. (h)(2). Pub. L. 105–248, § 10(a), added par. (2) and redesignated former par. (2) as (3).

Subsec. (h)(3). Pub. L. 105–248, § 10(a)(1), (b), redesignated par. (2) as (3), added subpar. (C), and redesignated former subpar. (C) as (D). Former par. (3) redesignated (4).

Subsec. (h)(4). Pub. L. 105–248, § 10(a)(1), (c), redesignated par. (3) as (4) and substituted ''paragraphs (1) through (3)'' for ''paragraphs (1) and (2)''.

Subsec. (i)(1)(C). Pub. L. 105–248, § 11, inserted ''(or of an accreditation body approved pursuant to subsection (e) of this section)'' after ''of the Secretary'' and inserted ''(or such accreditation body or State carrying out certification program requirements pursuant to subsection (q) of this section)'' after ''that the Secretary''.

Subsec. (i)(1)(D). Pub. L. 105–248, § 9(3), inserted ''or local'' after ''any State'' and ''or local agency'' after ''by the State''.

Subsec. (i)(2)(A). Pub. L. 105–248, § 12, substituted ''has reason to believe that the circumstance of the case will support one or more of the findings described in paragraph (1) and that—'' and cls. (i) and (ii) for ''makes the finding described in paragraph (1) and determines that—

''(i) the failure of a facility to comply with the standards established by the Secretary under subsection (f) of this section presents a serious risk to human health; or

''(ii) a facility has engaged in an action described in subparagraph (D) or (E) of paragraph (1).''

Subsec. (q)(4)(B). Pub. L. 105–248, § 13, substituted ''certified'' for ''accredited''.

Subsec. (r)(2)(A). Pub. L. 105–248, § 2, substituted ''subsection (p)'' for ''subsection (q)'' and ''2002'' for ''1997''.

Subsec. (r)(2)(B). Pub. L. 105–248, § 2, substituted ''fiscal years'' for ''fiscal year'' and ''2002'' for ''1997''.

CHANGE OF NAME

Committee on Labor and Human Resources of Senate changed to Committee on Health, Education, Labor, and Pensions of Senate by Senate Resolution No. 20, One Hundred Sixth Congress, Jan. 19, 1999.

Committee on Energy and Commerce of House of Representatives treated as referring to Committee on Commerce of House of Representatives by section 1(a) of Pub. L. 104–14, set out as a note preceding section 21 of Title 2, The Congress. 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.

TERMINATION OF ADVISORY COMMITTEES

Advisory committees established after Jan. 5, 1973, to terminate not later than the expiration of the 2-year period beginning on the date of their establishment, unless, in the case of a committee established by the President or an officer of the Federal Government, such committee is renewed by appropriate action prior to the expiration of such 2-year period, or in the case of a committee established by Congress, its duration is otherwise provided for by law. See section 14 of Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 776, set out in the Appendix to Title 5, Government Organization and Employees.

Pub. L. 93–641, § 6, Jan. 4, 1975, 88 Stat. 2275, set out as a note under section 217a of this title, provided that an advisory committee established pursuant to the Public Health Service Act shall terminate at such time as may be specifically prescribed by an Act of Congress enacted after Jan. 4, 1975.

REGULATIONS

Pub. L. 103–183, title VII, § 707, Dec. 14, 1993, 107 Stat. 2241, provided that: ''The Secretary of Health and Human Services is authorized to issue interim final regulations—

''(1) under which the Secretary may approve accreditation bodies under section 354(e) of the Public Health Service Act (42 U.S.C. 263b(e)); and

''(2) establishing quality standards under section 354(f) of the Public Health Service Act (42 U.S.C. 263b(f)).''

STUDY

Section 3 of Pub. L. 102–539 directed Comptroller General of United States to conduct a study of the certification program authorized by this section to determine if the program has resulted in improvement of quality and accessibility of mammography services, and if the program has reduced the frequency of poor quality mammography and improved early detection of breast cancer, with Comptroller General, not later than 3 years from Oct. 27, 1992, submit to Congress an interim report of results of study and, not later than 5 years from such date to submit a final report.

PART G—QUARANTINE AND INSPECTION

§ 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) of this section, 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.)

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.

[1] So in original. The comma probably should not appear.