

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 [subsec. (g) of this section], 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 [this section] 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 [this section], 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 [subsec. (i) of this section] (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 [subsec. (a)(1) of this section] and that were underway as of the effective date of such rule.”

§ 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,