(A) A hospital that meets the criteria in section 1396r–4(b)(1) of this title; and

(B) All Federally qualified health centers (as defined in section 1395x(aa) of this title[1] located in the community.

(3) Priority

In awarding grants, the Secretary shall give priority to networks that include—

(A) the capability to provide the broadest range of services to low-income individuals;

(B) the broadest range of providers that currently serve a high volume of low-income individuals; and

(C) a county or municipal department of health.

(c) Application

(1) Application

A network described in subsection (b) shall submit an application to the Secretary.

(2) Renewal

In subsequent years, based on the performance of grantees, the Secretary may provide renewal grants to prior year grant recipients.

(d) Use of funds

(1) Use by grantees

Grant funds may be used for the following activities:

(A) Assist low-income individuals to—

(i) access and appropriately use health services;

(ii) enroll in health coverage programs; and

(iii) obtain a regular primary care provider or a medical home.

(B) Provide case management and care management.

(C) Perform health outreach using neighborhood health workers or through other means.

(D) Provide transportation.

(E) Expand capacity, including through telehealth, after-hours services or urgent care.

(F) Provide direct patient care services.

(2) Grant funds to HRSA grantees

The Secretary may limit the percent of grant funding that may be spent on direct care services provided by grantees of programs administered by the Health Resources and Services Administration or impose other requirements on such grantees deemed necessary.

(e) Authorization of appropriations

There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2011 through 2015.

(July 1, 1944, ch. 373, title III, §340H, as added Pub. L. 111–148, title X, §10333, Mar. 23, 2010, 124 Stat. 970.)

CODIFICATION

Another section 340H of act July 1, 1944, ch. 373, as added by Pub. L. 111–148, title V, §5508(c), March 23, 2010, 124 Stat. 670, is classified to section 256h of this title.

[1] So in original. A closing parenthesis probably should appear.

PART E—NARCOTIC ADDICTS AND OTHER DRUG ABUSERS

§ 257. Repealed. Pub. L. 106–310, div. B, title XXXIV, § 3405(a), Oct. 17, 2000, 114 Stat. 1221

Section, acts July 1, 1944, ch. 373, title III, §341, 58 Stat. 698; May 8, 1954, ch. 195, §3, 68 Stat. 80; July 24, 1956, ch. 676, title III, §302(a), 70 Stat. 622; Pub. L. 89–793, title VI, §601, Nov. 8, 1966, 80 Stat. 1449; 1967 Reorg. Plan No. 3, §401, eff. Nov. 3, 1967 (in part), 32 F.R. 11669, 81 Stat. 951; Pub. L. 91–513, title I, §2(a)(1), Oct. 27, 1970, 84 Stat. 1240; Pub. L. 92–255, title IV, §402, Mar. 21, 1972, 86 Stat. 77; Pub. L. 93–198, title IV, §421, Dec. 24, 1973, 87 Stat. 789; Pub. L. 98–473, title II, §232(a), Oct. 12, 1984, 98 Stat. 2031; Pub. L. 99–646, §22(a), Nov. 10, 1986, 100 Stat. 3597; Pub. L. 102–54, §13(q)(1)(B)(i), June 13, 1991, 105 Stat. 278, related to care and treatment of narcotic addicts.

§ 257a. Transferred

CODIFICATION

Section, Pub. L. 91–513, title I, §4, Oct. 27, 1970, 84 Stat. 1241; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695, which related to medical treatment of narcotics addiction, was transferred to section 290bb–2a of this title.

§ 258. Repealed. Pub. L. 106–310, div. B, title XXXIV, § 3405(a), Oct. 17, 2000, 114 Stat. 1221

Section, acts July 1, 1944, ch. 373, title III, §342, 58 Stat. 699; 1953 Reorg. Plan No. 1, §§5, 8, eff. Apr. 11, 1953, 18 F.R. 2053, 67 Stat. 631; Pub. L. 91–513, title I, §2(a)(2)(A), Oct. 27, 1970, 84 Stat. 1240; Pub. L. 96–88, title V, §509(b), Oct. 17, 1979, 93 Stat. 695, related to employment, establishment of industries, plants, etc., sale of commodities, and disposition of proceeds.

§ 258a. Transferred

CODIFICATION

Section, act July 8, 1947, ch. 210, title II, §201, 61 Stat. 269, which related to transfer of balances in working capital fund, narcotic hospitals, to surplus fund, was transferred and is set out as a note under section 290aa of this title.

§§ 259 to 261a. Repealed. Pub. L. 106–310, div. B, title XXXIV, § 3405(a), Oct. 17, 2000, 114 Stat. 1221

Section 259, acts July 1, 1944, ch. 373, title III, §343, 58 Stat. 699; Pub. L. 91–513, title I, §2(a)(2)(A), (3), (4), Oct. 27, 1970, 84 Stat. 1240; Pub. L. 92–293, §3, May 11, 1972, 86 Stat. 136; Pub. L. 98–473, title II, §232(b), Oct. 12, 1984, 98 Stat. 2031, related to convict addicts or other persons with drug abuse or drug dependence problems.

Section 260, acts July 1, 1944, ch. 373, title III, §344, 58 Stat. 701; June 25, 1948, ch. 654, §5, 62 Stat. 1018; July 24, 1956, ch. 676, title III, §302(b), 70 Stat. 622; Pub. L. 91–513, title I, §2(a)(2)(A), (3), (4), Oct. 27, 1970, 84 Stat. 1240, related to addicts and persons with drug abuse or drug dependence problems.

Section 260a, act July 1, 1944, ch. 373, title III, §345, as added May 8, 1954, ch. 195, §2, 68 Stat. 79; amended July 24, 1956, ch. 676, title III, §302(c), 70 Stat. 622; Pub. L. 91–358, title I, §155(c)(32), July 29, 1970, 84 Stat. 572, related to admission of addicts committed from District of Columbia.

Section 261, acts July 1, 1944, ch. 373, title III, §346, formerly §345, 58 Stat. 701; renumbered §346, May 8, 1954, ch. 195, §2, 68 Stat. 79; amended Pub. L. 91–513, title I, §2(a)(2)(A), (5), Oct. 27, 1970, 84 Stat. 1240, related to penalties for introducing prohibited articles and substances into hospitals and escaping from, or aiding and abetting escape from hospitals.

Section 261a, act July 1, 1944, ch. 373, title III, §347, as added May 8, 1954, ch. 195, §4, 68 Stat. 80; amended Pub.

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