

work”) shall be a consortium of health care providers with a joint governance structure (including providers within a single entity) that provides comprehensive coordinated and integrated health care services (as defined by the Secretary) for low-income populations.

(2) Required inclusion

A network shall include the following providers (unless such provider does not exist within the community, declines or refuses to participate, or places unreasonable conditions on their participation):

(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 title¹ 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, §340I, formerly §340H, as added Pub. L. 111-148, title X, §10333, Mar. 23, 2010, 124 Stat. 970; renumbered §340I, Pub. L. 115-63, title III, §301(c)(2), Sept. 29, 2017, 131 Stat. 1172.)

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, as amended by Pub. L. 114-198, title I, § 110(b), July 22, 2016, 130 Stat. 710

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.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2016 AMENDMENT

Pub. L. 114-198, title I, §110(b), July 22, 2016, 130 Stat. 710, provided that the amendment made by section 110(b) (amending directory language of section 3405(a) of Pub. L. 106-310, which repealed this section) is effective as if included in the enactment of Pub. L. 106-310.

§ 257a. Transferred

Editorial Notes

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, as amended by Pub. L. 114-198, title I, § 110(b), July 22, 2016, 130 Stat. 710

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.

Statutory Notes and Related Subsidiaries

EFFECTIVE DATE OF 2016 AMENDMENT

Pub. L. 114-198, title I, §110(b), July 22, 2016, 130 Stat. 710, provided that the amendment made by section 110(b) (amending directory language of section 3405(a) of Pub. L. 106-310, which repealed this section) is effective as if included in the enactment of Pub. L. 106-310.

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

§ 258a. Transferred**Editorial Notes****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, as amended by Pub. L. 114-198, title I, § 110(b), July 22, 2016, 130 Stat. 710

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.

Statutory Notes and Related Subsidiaries**EFFECTIVE DATE OF 2016 AMENDMENT**

Pub. L. 114-198, title I, § 110(b), July 22, 2016, 130 Stat. 710, provided that the amendment made by section 110(b) (amending directory language of section 3405(a) of Pub. L. 106-310, which repealed sections 259 to 261a of this title) is effective as if included in the enactment of Pub. L. 106-310.

**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).

(D) POSTMARKET STUDIES AND CLINICAL TRIALS; LABELING; RISK EVALUATION AND MITIGATION STRATEGY.—A person that submits an application for a license under this paragraph is subject to sections 505(o), 505(p), and 505-1 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(o), (p), 355-1].

(E)(i) The Secretary may rely upon qualified data summaries to support the approval of a supplemental application, with respect to a qualified indication for a drug, submitted under this subsection, if such supplemental application complies with the requirements of subparagraph (B) of section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 355(c)(5)].

(ii) In this subparagraph, the terms “qualified indication” and “qualified data summary” have the meanings given such terms in section 505(c)(5) of the Federal Food, Drug, and Cosmetic Act.

(3) The Secretary shall prescribe requirements under which a biological product undergoing investigation shall be exempt from the requirements of paragraph (1).

(b) Falsely labeling or marking package or container; altering label or mark

No person shall falsely label or mark any package or container of any biological product or alter any label or mark on the package or container of the biological product so as to falsify the label or mark.

(c) Inspection of establishment for propagation and preparation

Any officer, agent, or employee of the Department of Health and Human Services, authorized by the Secretary for the purpose, may during all reasonable hours enter and inspect any establishment for the propagation or manufacture and preparation of any biological product.

(d) Recall of product presenting imminent hazard; violations

(1) Upon a determination that a batch, lot, or other quantity of a product licensed under this