

§ 9.13 Other federal laws, regulations, and statutes that apply to the sanctuary.

(a) Animal Welfare Act (7 U.S.C. 2131–2159).

(b) Animal Welfare Regulations, 9 CFR, subchapter A, parts 1 and 2; part 3, subpart D—Specifications for the Humane Handling, Care, Treatment, and Transport of Nonhuman Primates.

PART 10—340B DRUG PRICING PROGRAM

Sec.

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AUTHORITY: Sec. 340B of the Public Health Service Act (42 U.S.C. 256b), as amended; Sec. 215 of the Public Health Service Act (42 U.S.C. 216), as amended; Sec. 526 of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 360bb); Sec. 701(a) of the Federal Food, Drug, and Cosmetic Act, as amended (21 U.S.C. 371(a)); Sec. 1927 of the Social Security Act, as amended (42 U.S.C. 1396r–8).

SOURCE: 78 FR 44027, July 23, 2013, unless otherwise noted.

Subpart A—General Provisions

§ 10.1 Purpose.

This part implements section 340B of the Public Health Service Act (PHSA) “Limitation on Prices of Drugs Purchased by Covered Entities.”

§ 10.2 Summary of 340B Drug Pricing Program.

Section 340B of the PHSA instructs the Secretary of Health and Human Services to enter into agreements with

manufacturers of covered drugs under which the amount required to be paid to these manufacturers by certain statutorily-defined entities does not exceed the average manufacturer price for the drug under title XIX of the Social Security Act (SSA) reduced by a rebate percentage which is calculated as indicated in 340B(a)(1) and 340B(a)(2)(A). Manufacturers participating in the 340B Drug Pricing Program (340B Program) are required to provide these discounts on all covered outpatient drugs sold to participating 340B covered entities.

§ 10.3 Definitions.

Ceiling price means the maximum statutory price established under section 340B(a)(1) of the PHSA.

Covered entity means an entity that meets the requirements under section 340B(a)(5) of the PHSA and is listed in section 340B(a)(4) of the PHSA.

Covered outpatient drug has the meaning set forth in section 1927(k) of the SSA.

Group purchasing organization (GPO) is an entity that contracts with purchasers, such as hospitals, nursing homes, and home health agencies, to aggregate purchasing volume and negotiate final prices with manufacturers, distributors, and other vendors.

Manufacturer has the same meaning as set forth in section 1927(k)(5) of the SSA.

Orphan drug means a drug designated by the Secretary under section 526 of the Federal Food, Drug, and Cosmetic Act (FFDCA).

Participating drug manufacturer means a manufacturer that has entered into a Pharmaceutical Pricing Agreement with the Secretary.

Pharmaceutical Pricing Agreement (PPA) means an agreement described in section 340B(a)(1) of the PHSA.

Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom the authority involved has been delegated.

Section 340B means section 340B of the PHSA.