

§9.13

between NCRR and the Sanctuary Contractor. A designated representative of the Secretary will monitor compliance. The responsibility to monitor compliance with the standards is delegated to NCRR/NIH/HHS. The NIH/NCRR Project Officer for this contract will conduct scheduled site visits at least one time annually (or more often if necessary) and review monthly and quarterly reports submitted to the Project and Contract Officer. Subcontractors are subjected to the same provisions. Failure to comply with the standards set forth in this part, or to correct deficiencies noted within the allowable time period, could result in termination of the contract by the Federal Government (HHS/NIH), or allow the Secretary to correct the deficiencies according to the terms and conditions outlined in the contract. The Secretary may impose additional sanctions on the contractor up to, and including, authorizing assumption or reassignment of the management of the sanctuary contract.

(b) *To what type of outside review or inspection will the federally supported sanctuary be subjected?* As noted in paragraph (a) of this section, the contractor for the sanctuary will be monitored on a regularly scheduled basis by representatives of NCRR/NIH/HHS. The NCRR representative will use facility site visits, reports, personal contact, and any other means as appropriate to ensure compliance with these standards. The contractor and subcontractors are required to obtain and maintain an Animal Welfare Assurance from NIH's Office of Laboratory Animal Welfare (OLAW) when chimpanzees are used for noninvasive studies as authorized in the CHIMP Act. In addition, the sanctuary must achieve accreditation by a nationally recognized animal program accrediting body (such as the AAALAC, the AZA, or similar recognized body) within a time frame to be determined by NCRR/NIH. The federally supported sanctuary must comply with the requirements set forth in the Animal Welfare Regulations (9 CFR parts 1 through 3).

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§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