

*qualifications and training must the staff possess?* (a) The professional, managerial, and support staff must be sufficient to support the scope and diversity of the activities and chimpanzee population of the sanctuary. The level of staffing shall be adequate to ensure that the chimpanzees receive appropriate health care, are well cared for, and the administrative and fiscal operations are sound and in keeping with current practices required by NCCR/NIH;

(b) There must be a sufficient number of appropriately trained animal care and technical personnel to provide appropriate care to the chimpanzees at all times, including evenings, weekends, and holidays. The number of animal care staff to chimpanzee ratio shall be adjusted as experience is gained during the operation of the sanctuary. Sufficiently trained staff also must be available to maintain adequate behavioral enrichment;

(c) The Facility Director must be a person with experience in chimpanzee care and socialization techniques. In addition, the Director must have management and administrative experience;

(d) The Biosafety Officer must have experience in developing and monitoring biohazards and dealing with biosafety issues related to captive nonhuman primates. Experience in these areas dealing specifically with chimpanzees is desirable;

(e) The remaining staff, which may include part-time, full-time, or contractor Facility Veterinarian(s) and Behaviorist(s), must possess the skills, knowledge, and/or experience required to perform their duties, as elaborated within the regulation.

**§9.10 Occupational Health and Safety Program (OHSP) and biosafety requirements.**

(a) *How are employee Occupational Health and Safety Program risks and concerns addressed?* The sanctuary shall assure that an Occupational Health and Safety Program (OHSP) is developed and implemented in accordance with current veterinary medical practices and the guidelines and standards found in the *Guide* (incorporated by reference, see paragraph (a) of section 9.4);

(b) *How are biosafety concerns addressed?* The sanctuary shall institute and administer an effective biosafety program that addresses the biosafety hazards at that particular site. The program shall include identifying biohazards, outlining practices and procedures to be followed, providing personal safety equipment or protective clothing and equipment, and establishing a description of the facility requirements for working with hazardous agents or materials. Policies and procedures must be implemented to avoid exposure to environmental and animal hazards. Biosafety must be included in the training program for all Sanctuary employees. In establishing a program, the Sanctuary must use current accepted practices and publications prepared by the CDC, NIH, and professional societies specializing in biosafety. The input and guidance of personnel trained or experienced in biosafety are essential. Complete records of both clinical and experimental agent exposure must accompany each chimpanzee sent to the sanctuary. The donating facility must also provide recent testing (for example, serology, virus culture, histology) so that the sanctuary staff is fully aware of the health condition of the arriving chimpanzee. The records may be created and retained in electronic form.

**§9.11 Animal transport.**

The transportation of chimpanzees by surface or air must be in accordance with the requirements set forth in the Animal Welfare Act and Regulations and the International Air Transport Association (IATA) Live Animal Regulations and guidelines, as applicable.

**§9.12 Compliance with the Standards of Care, and USDA and PHS policies and regulations.**

(a) *How will compliance with the standards set forth in this part be monitored and what are the consequences of non-compliance with the standards?* The federally supported chimpanzee sanctuary must comply with the standards of care set forth in this part and include a statement in the Annual Progress Report certifying compliance with these standards of care in accordance with the terms of the current contract

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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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- 10.21 Exclusion of orphan drugs for certain covered entities.

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