

collection tubes at or near body temperature. A dish/plate/microscope stage warmer is a device used to maintain the temperature of the egg (oocyte) during manipulation.

(4) Embryo incubators, used to store and preserve gametes and/or embryos at or near body temperature.

(5) Cryopreservation instrumentation and devices, used to contain, freeze, and maintain gametes and/or embryos at an appropriate freezing temperature.

(b) *Classification.* Class II (special controls) (design specifications, labeling requirements, and clinical testing).

§ 884.6130 Assisted reproduction microtools.

(a) *Identification.* Assisted reproduction microtools are pipettes or other devices used in the laboratory to denude, micromanipulate, hold, or transfer human gametes or embryos for assisted hatching, intracytoplasmic sperm injection (ICSI), or other assisted reproduction methods.

(b) *Classification.* Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, and clinical testing).

§ 884.6140 Assisted reproduction micropipette fabrication instruments.

(a) *Identification.* Assisted reproduction micropipette fabrication devices are instruments intended to pull, bevel, or forge a micropipette or needle for intracytoplasmic sperm injection (ICSI), in vitro fertilization (IVF) or other similar assisted reproduction procedures.

(b) *Classification.* Class II (special controls) (design specifications, labeling requirements, and clinical testing).

§ 884.6150 Assisted reproduction micromanipulators and microinjectors.

(a) *Identification.* Assisted reproduction micromanipulators are devices intended to control the position of an assisted reproduction microtool. Assisted reproduction microinjectors are any device intended to control aspiration or expulsion of the contents of an assisted reproduction microtool.

(b) *Classification.* Class II (special controls) (design specifications, labeling requirements, and clinical testing).

§ 884.6160 Assisted reproduction labware.

(a) *Identification.* Assisted reproduction labware consists of laboratory equipment or supplies intended to prepare, store, manipulate, or transfer human gametes or embryos for in vitro fertilization (IVF), gamete intrafallopian transfer (GIFT), or other assisted reproduction procedures. These

include syringes, IVF tissue culture dishes, IVF tissue culture plates, pipette tips, dishes, plates, and other vessels that come into physical contact with gametes, embryos or tissue culture media.

(b) *Classification.* Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, and clinical testing).

§ 884.6170 Assisted reproduction water and water purification systems.

(a) *Identification.* Assisted reproduction water purification systems are devices specifically intended to generate high quality, sterile, pyrogen-free water for reconstitution of media used for aspiration, incubation, transfer or storage of gametes or embryos for in vitro fertilization (IVF) or other assisted reproduction procedures. These devices may also be intended as the final rinse for labware or other assisted reproduction devices that will contact the gametes or embryos. These devices also include bottled water ready for reconstitution available from a vendor that is specifically intended for reconstitution of media used for aspiration, incubation, transfer, or storage of gametes or embryos for IVF or other assisted reproduction procedures.

(b) *Classification.* Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, water quality testing, design specifications, labeling requirements, biocompatibility testing, and clinical testing).

§ 884.6180 Reproductive media and supplements.

(a) *Identification.* Reproductive media and supplement are products that are used for assisted reproduction procedures. Media include liquid and powder versions of various substances that come in direct physical contact with human gametes or embryos (including water, acid solutions used to treat gametes or embryos, rinsing solutions, sperm separation media, supplements, or oil used to cover the media) for the purposes of preparation, maintenance, transfer or storage. Supplements are specific reagents added to media to enhance specific properties of the media (e.g., proteins, sera, antibiotics, etc.).

(b) *Classification.* Class II (special controls) (mouse embryo assay information, endotoxin testing, sterilization validation, design specifications, labeling requirements, biocompatibility testing, and clinical testing).

§ 884.6190 Assisted reproductive microscopes and microscope accessories.

(a) *Identification.* Assisted reproduction microscopes and microscope accessories (excluding microscope stage warmers, which are classified under assisted reproduction accessories) are optical instruments used to enlarge images of gametes or embryos. Variations of microscopes and accessories used for these purposes would include phase contrast microscopes, dissecting microscopes and inverted stage microscopes. This device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 884.9.

(b) *Classification.* Class I.

Dated: August 25, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

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DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 570

[Docket No. FR-4269-F-01]

RIN 2528-AA06

Hispanic-Serving Institutions Work Study Program

AGENCY: Office of the Assistant Secretary for Policy Development and Research, HUD.

ACTION: Final rule.

SUMMARY: On February 25, 1998, HUD published an interim rule that broadened the eligibility for public and private non-profit two-year institutions of higher education to participate in the Hispanic-serving Institutions Work Study Program (HSI-WSP). This final rule makes final that interim rule without changes.

EFFECTIVE DATE: October 13, 1998.

FOR FURTHER INFORMATION CONTACT: Jane Karadbil, Office of University Partnerships, U.S. Department of Housing and Urban Development, Room 8110, 451 Seventh Street, SW, Washington, D.C. 20410, telephone (202) 708-1537, extension 218. Hearing- or speech-impaired individuals may call HUD's TTY number (202) 708-1455, or 1-800-877-8399 (Federal Information Relay Service TTY). (Other than the "800" number, these are not toll-free numbers.) Ms. Karadbil can also be contacted via the Internet at Jane__R__Karadbil@hud.gov.

SUPPLEMENTARY INFORMATION:

I. Paperwork Reduction Act

The information collection requirements contained in this final rule were submitted to the Office of Management and Budget (OMB) for review under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) and have been assigned OMB control number 2528–0182. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection displays a valid control number.

II. Background

The Hispanic-serving Institutions Work Study Program (HSI-WSP), which is authorized by section 107(c) of the Housing and Community Development Act of 1974, as amended (42 U.S.C. 5307, 88 Stat. 647), makes grants to institutions of higher education for the purposes of providing assistance to economically disadvantaged and minority students who participate in community development work study programs and are enrolled in full-time undergraduate programs in community or economic development, community planning, or community management.

On April 9, 1997 (62 FR 17492), HUD issued a final rule governing the program. The final rule limited eligibility for HUD's HSI-WSP to only public or private institutions of higher education that offer two-year associate degrees and qualify as HSIs. While the statute authorizing the program does not require it, HUD decided to determine qualification by using the definition of an HSI contained in section 316 of the Higher Education Amendments of 1992 (20 U.S.C. 1059c; 106 Stat. 448, 473). Under that definition, an HSI is an institution that has an enrollment of undergraduate full-time students that is at least 25 percent Hispanic, of which not less than 50 percent of the Hispanic students are low-income individuals (i.e., 150 percent of the poverty level) who are first generation college students (i.e., whose parent(s) did not complete a baccalaureate degree) and another 25 percent are either low-income individuals or first generation college students. The U.S. Department of Education determines the eligibility of specific institutions as HSIs and issues a list of institutions meeting this definition. HUD's final rule noted that a list of HSI-WSP-eligible community colleges that are included in the U.S. Department of Education's list of HSIs

would appear with each Notice of Funding Availability (NOFA) for the program. Only institutions on the list, or HSI-WSP-eligible institutions subsequently added to the list prior to that NOFA's application deadline, were eligible to apply for HSI-WSP funds.

Through issuance of an interim rule on February 25, 1998 (63 FR 9682), HUD eliminated the use of the U.S. Department of Education's list to determine eligibility and, instead, allowed institutions to certify that they meet the statutory definition. The process for an institution to be put on the U.S. Department of Education's list is a multi-step process, and HUD's use of the list meant that some Hispanic-serving institutions were not eligible for HUD's HSI-WSP. HUD determined that it might have been unfairly penalizing institutions if it relied on a potentially out-of-date and overly restrictive eligibility list. HUD decided, therefore, not to base eligibility on the U.S. Department of Education's list, but instead to allow applicants to certify to HUD that they are eligible to apply for the HSI-WSP.

The February 25, 1998 interim rule provided for a 60-day public comment period. No comments were received. Accordingly, this rule makes final the interim rule as it was published on February 25, 1998.

III. Findings and Certifications*Environmental Impact*

In accordance with 24 CFR 50.19(b)(9) of the HUD regulations, the policies and procedures contained in this rule relate only to training grants and technical assistance, and therefore, are categorically excluded from the requirements of the National Environmental Policy Act.

Regulatory Flexibility

The Secretary, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed and approved this final rule, and in so doing, certifies that it will not have a significant economic impact on a substantial number of small entities. The rule only affects applicants and participants in the Hispanic-Serving Institutions Work Study Program and will not have any meaningful economic impact on any other entity.

Federalism Impact

The General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, *Federalism*, has determined that the policies and

procedures contained in this rule will not have substantial direct effects on States or their political subdivisions, or the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government. As a result, the rule is not subject to review under the Order. Specifically, the rule solicits participation by institutions of higher education in creating community development work study programs for some of their economically disadvantaged and minority students. The rule does not impinge upon the relationships between the Federal government and State or local governments.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4; approved March 22, 1995) (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments, and on the private sector. This final rule does not impose any Federal mandates on any State, local, or tribal governments, or on the private sector, within the meaning of the UMRA.

The Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance program number is 14.513.

List of Subjects in 24 CFR Part 570

Administrative practice and procedure, American Samoa, Community development block grants, Grant programs—education, Grant programs—housing and community development, Guam, Indians, Lead poisoning, Loan programs—housing and community development, Low and moderate income housing, New communities, Northern Mariana Islands, Pacific Islands Trust Territory, Pockets of poverty, Puerto Rico, Reporting and recordkeeping requirements, Small cities, Student aid, Virgin Islands.

Accordingly, the interim rule published on February 25, 1998, at 63 FR 9682, is adopted as final.

Dated: September 2, 1998.

Xavier D. Briggs,

Deputy Assistant Secretary for Research, Evaluation and Monitoring.

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