

CHAPTER III—DEPARTMENT OF HEALTH AND HUMAN SERVICES

<i>Part</i>		<i>Page</i>
300	Uniform administrative requirements, cost principles, and audit requirements for Federal awards (EFF. until 10-01-25)	241
300	Uniform administrative requirements, cost principles, and audit requirements for Federal awards (EFF. 10-01-25)	241
301–375	[Reserved]	
376	Nonprocurement debarment and suspension	245
382	Requirements for drug-free workplace (financial assistance)	248
383–399	[Reserved]	

PART 300—UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR FEDERAL AWARDS (EFF. until 10-01-25)

AUTHORITY: 5 U.S.C. 301, 2 CFR part 200.

SOURCE: 79 FR 75889, Dec. 19, 2014, unless otherwise noted.

EFFECTIVE DATE NOTE: At 89 FR 80061, Oct. 2, 2024, part 300 was revised, effective Oct. 1, 2025. The revised part 300 text follows the current part 300.

§ 300.1 Adoption of 2 CFR Part 200.

Under the authority listed above, the Department of Health and Human Services adopts the Office of Management and Budget (OMB) Guidance in 2 CFR part 200, and has codified the text, with HHS-specific amendments in 45 CFR part 75 and the following provisions of 2 CFR part 200: §§ 200.1 (definitions of Modified Total Direct Cost, Equipment, and Supplies), 200.313(e), 200.314(a), 200.320, 200.333, 200.344, 200.414(f), and 200.501. Thus, this part gives regulatory effect to the OMB guidance and supplements the guidance as needed for the Department.

[89 FR 80061, Oct. 2, 2024]

EFFECTIVE DATE NOTE: At 89 FR 80061, Oct. 2, 2024, Part 300 was revised, effective Oct. 1, 2025. For the convenience of the user, the revised text is set forth as follows:

PART 300—UNIFORM ADMINISTRATIVE REQUIREMENTS, COST PRINCIPLES, AND AUDIT REQUIREMENTS FOR FEDERAL AWARDS (EFF. 10-01-25)

Sec.

Subpart A [Reserved]

Subpart B—General Provisions

300.106 Adoption of 2 CFR part 200.
300.112 Conflict of interest.

Subpart C—Pre-Federal Award Requirements and Contents of Federal Awards

300.218 Special provisions for awards to for-profit organizations as recipients.
300.219 Special provisions for awards to Federal agencies.

Subpart D—Post Federal Award Requirements

300.300 Statutory and national policy requirements.
300.305 Federal payment.
300.308 Revision of budget and program plans.
300.315 Intangible property.

Subpart E—Cost Principles

300.414 Indirect costs.

HHS SELECTED ITEMS OF COST

300.477 Independent research and development costs.
300.478 Shared responsibility payments.

APPENDICES I THROUGH VIII TO PART 300 [RESERVED]

APPENDIX IX TO PART 75—PRINCIPLES FOR DETERMINING COSTS APPLICABLE TO RESEARCH AND DEVELOPMENT UNDER GRANTS AND CONTRACTS WITH HOSPITALS

APPENDICES X THROUGH XII TO PART 300 [RESERVED]

AUTHORITY: 5 U.S.C. 301, 2 CFR part 200.

Subpart A [Reserved]

Subpart B—General Provisions

§ 300.106 Adoption of 2 CFR part 200.

The Department of Health and Human Services adopts the Office of Management and Budget (OMB) guidance in 2 CFR part 200, with the additions included in this part and part 376 of this chapter. Thus, this part gives regulatory effect to the OMB guidance and supplements the guidance as needed for the Department.

§ 300.112 Conflict of interest.

In addition to 2 CFR 200.112, the following requirements apply:

(a) HHS agencies' conflict of interest policies must:

(1) Address conditions under which outside activities, relationships, or financial interests are proper or improper;

(2) Provide for advance notification of outside activities, relationships, or financial interests, and a process of review as appropriate; and

(3) Outline how financial conflicts of interest may be addressed.

(b) Agencies with Public Health Service (PHS) funded research will ensure that any conflict-of-interest policies

§ 300.218

are aligned with the requirements of 42 CFR part 50, subpart F.

Subpart C—Pre-Federal Award Requirements and Contents of Federal Awards

§ 300.218 Special provisions for awards to for-profit organizations as recipients.

(a) *For-profit organizations.* This section contains provisions that apply to awards to for-profit organizations. These provisions are in addition to other applicable provisions of this part, or they make exceptions from other provisions of this part for awards to for-profit organizations.

(b) *Prohibition against profit.* Except for awards under the Small Business Innovation Research (SBIR) and Small Business Technology Transfer Research (STTR) programs (15 U.S.C. 638), no HHS funds may be paid as profit to any recipient even if the recipient is a for-profit organization. Profit is any amount in excess of allowable direct and indirect costs.

(c) *Program income.* Except for grants for research, program income earned by a for-profit organization may not be used to further eligible project or program objectives except in the SBIR and STTR programs.

(d) *For-profit organization audits.* (1) For-profit organizations that receive awards (including for-profit hospitals) have two options regarding audits:

(i) A financial related audit of a particular award in accordance with GAGAS, in those cases where the for-profit organization receives awards under only one HHS program; or, if awards are received under multiple HHS programs, a financial related audit of all awards in accordance with GAGAS; or

(ii) An audit that meets the requirements contained in 2 CFR 200, subpart F.

(2) For-profit organizations that receive annual awards totaling less than the audit requirement threshold in subpart F are exempt from HHS audit requirements for that year, but records must be available for review by appropriate officials of Federal agencies or the GAO. (See § 200.501).

2 CFR Ch. III (1–1–25 Edition)

(e) *Applicability.* The provisions of § 200.315(e) do not apply to for-profit organizations.

§ 300.219 Special provisions for awards to Federal agencies.

(a) An HHS agency must have explicit statutory authority that makes Federal agencies eligible for awards.

(b) All provisions of 2 CFR part 200, this part, and other HHS regulations apply to Federal entities receiving Federal awards, except for the following:

(1) Except for grants for research, any program income earned by a Federal institution must be used under the deduction alternative. Any program income earned after the period of performance should be returned to the United States Treasury.

(2) No salary or fringe benefit payments may be made from HHS agency funds to support career, career-conditional, or other Federal employees (civilian or uniformed services) without permanent appointments at a Federal institution receiving an award. While the level of effort required for the project must be allowed by the recipient as part of each individual's official duties, salary costs associated with an individual participating in an official capacity as a Federal employee under an award to that Federal institution are not allowable costs under an HHS award.

(3) Federal agencies may not be reimbursed for indirect costs under Federal awards.

Subpart D—Post Federal Award Requirements

§ 300.300 Statutory and national policy requirements.

In addition to 2 CFR 200.300(a), the following requirements apply:

(a) It is a public policy requirement of HHS that no person otherwise eligible will be excluded from participation in, denied the benefits of, or otherwise subjected to discrimination in the administration of HHS programs, activities, projects, assistance, and services, to the extent doing so is prohibited by Federal statute.

(b) HHS will follow all applicable Supreme Court decisions in administering its award programs.

(c) In the statutes listed in paragraphs (c)(1) through (13) of this section that HHS administers which prohibit discrimination on the basis of sex, the Department interprets those provisions to include a prohibition against discrimination on the basis of sexual orientation and gender identity, consistent with the Supreme Court's decision in *Bostock v. Clayton County*, 590 U.S. 644 (2020), and other Federal court precedent applying *Bostock's* reasoning that sex discrimination includes discrimination based on sexual orientation and gender identity. This provision is interpretive and does not impose any substantive obligations on entities outside the Department. This paragraph (c) interprets the following HHS authorities that prohibit discrimination on the basis of sex:

(1) *8 U.S.C. 1522*. Authorization for programs for domestic resettlement of and assistance to refugees.

(2) *42 U.S.C. 290cc-33*. Projects for Assistance in Transition from Homelessness.

(3) *42 U.S.C. 290ff-1*. Children with Serious Emotional Disturbances.

(4) *42 U.S.C. 295m*. Title VII Health Workforce Programs.

(5) *42 U.S.C. 296g*. Nursing Workforce Development.

(6) *42 U.S.C. 300w-7*. Preventive Health Services Block Grant.

(7) *42 U.S.C. 300x-57*. Substance Use Prevention, Treatment, and Recovery Services Block Grant; Community Mental Health Services Block Grant.

(8) *42 U.S.C. 708*. Maternal and Child Health Block Grant.

(9) *42 U.S.C. 5151*. Disaster relief.

(10) *42 U.S.C. 8625*. Low Income Home Energy Assistance Program.

(11) *42 U.S.C. 9849*. Head Start.

(12) *42 U.S.C. 9918*. Community Services Block Grant Program.

(13) *42 U.S.C. 10406*. Family Violence Prevention and Services.

(d)(1) A grant applicant or recipient may rely on applicable Federal protections for religious freedom and conscience, and application of a particular provision(s) of this section to specific contexts, procedures, or services shall

not be required where such protections apply.

(2) A grant applicant or recipient that seeks assurance consistent with paragraph (d)(1) of this section regarding the application of particular provision(s) of this part to specific contexts, procedures, or services may do so by submitting a notification in writing to the HHS awarding agency, the Office of the Assistant Secretary for Financial Resources (ASFR), or the Office for Civil Rights (OCR). Notification may be provided by the grant applicant or recipient at any time, including before an investigation is initiated or during the pendency of an investigation. The notification must include:

(i) The particular provision(s) of this section from which the applicant or recipient asserts they are exempt under Federal religious freedom or conscience protections;

(ii) The legal basis supporting the applicant's or recipient's exemption should include the standards governing the applicable Federal religious freedom and conscience protections, such as the provisions in the relevant statute from which the applicant or recipient is requesting an exemption; the Church, Coats-Snowe, and Weldon Amendments; the generally applicable requirements of the Religious Freedom Restoration Act (RFRA); and

(iii) The factual basis supporting the applicant's or recipient's exemption, including identification of the conflict between the applicant's or recipient's religious or conscience beliefs and the requirements of this section, which may include the specific contexts, procedures, or services that the applicant or recipient asserts will violate their religious or conscience beliefs overall or based on an individual matter related to a particular grant.

(3) A temporary exemption from administrative investigation and enforcement will take effect upon the applicant's or recipient's submission of the notification—regardless of whether the assurance is sought before or during an investigation. The temporary exemption is limited to the application of the particular provision(s) of the relevant statute as applied to the specific contexts, procedures, or services identified