decision is adverse to the grantee's position, the transmittal letter must state the grantee's right to appeal to the Departmental Appeals Board under 45 CFR part 16.

[54 FR 34770, Aug. 22, 1989, as amended at 63 FR 66063, Dec. 1, 1998]

Subpart E—Maximum Allowable Cost for Drugs

AUTHORITY: Sec. 215, Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216).

SOURCE: 40 FR 34514, Aug. 15, 1975, unless otherwise noted.

§ 50.501 Applicability.

This subpart is applicable to programs or projects for health services which are supported in whole or in part by Federal financial assistance, whether by grant or contract, administered by the Public Health Service. It applies to Federal funds and to non-Federal funds which are required to be expended as a condition to receiving Federal funds under such programs or projects.

§ 50.502 Definitions.

As used in this subpart:

(a) *Public Health Service* means the Office of the Assistant Secretary for Health, Health Resources and Services Administration, National Institutes of Health, Centers for Disease Control, Alcohol, Drug Abuse and Mental Health Administration, Food and Drug Administration, and all of their constituent agencies.

(b) *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.

(c) *Program funds* means (1) Federal funds provided through grant or contract to support a program or project covered by § 50.501, and (2) any non-Federal funds that are required as a condition of such grant or contract to be expended to carry out such program or project.

(d) *Provider* means one who furnishes medical or pharmaceutical services or supplies for which program funds may be expended under any of the programs or projects described in § 50.501.

(e) *Acquisition cost* means the price generally and currently paid by providers for a drug marketed or sold by a particular formulator or labeler in the package size of drug most frequently purchased by providers, as determined by the Secretary on the basis of drug price information furnished by the Department.

[40 FR 34514, Aug. 15, 1975, as amended at 49 FR 38109, Sept. 27, 1984]

§ 50.503 Policy.

It is the policy of the Secretary that program funds which are utilized for the acquisition of drugs be expended in the most economical manner feasible. In furtherance of this policy, the Secretary has established, in 45 CFR part 19, a procedure for determining the Maximum Allowable Cost for drugs which are purchased with program funds.

§ 50.504 Allowable cost of drugs.

(a) The maximum amount which may be expended from program funds for the acquisition of any drug shall be the lowest of

(1) The maximum allowable cost (MAC) of the drug, if any, established in accordance with 45 CFR part 19, plus a dispensing fee determined by the Secretary in accordance with paragraph (b) of this section, to be reasonable;

(2) The acquisition cost of the drug plus a dispensing fee determined by the Secretary, in accordance with paragraph (b) of this section, to be reasonable; or

(3) The provider's usual and customary charge to the public for the drug; *Provided*, That the MAC established for any drug shall not apply to a brand of that drug prescribed for a patient which the prescriber has certified, in accordance with paragraph (c) of this section, is medically necessary for that patient; *And Provided further*, That where compensation for drug dispensing is included in other costs allowable under the applicable program statute and regulations, the terms and conditions of the grant or contract, and the applicable cost principles prescribed in 45 CFR part 75, subpart E, no

separate dispensing fee will be recognized.

(b) In determining whether a dispensing fee is reasonable, the Secretary will take into account:

(1) Cost components such as overhead, professional services, and profits,

(2) Payment practices of third-party payment organizations, including other Federal programs such as titles XVIII and XIX of the Social Security Act; and

(3) Any surveys by States, universities or others of costs of pharmacy operations and the fees charged in the particular area.

(c) A certification by a prescriber, pursuant to paragraph (a) of this section, that a brand of drug is medically necessary for a particular patient shall be in the prescriber's own handwriting, in such form and manner as the Secretary may prescribe. An example of an acceptable certification is the notation ''brand necessary''. A procedure for checking a box on a form will not constitute an acceptable certification.

[40 FR 34514, Aug. 15, 1975, as amended at 81 FR 3006, Jan. 20, 2016]

Subpart F—Promoting Objectivity in Research

AUTHORITY: 42 U.S.C. 216, 289b–1, 299c–4; Sec. 219, Tit. II, Div. D, Pub. L. 111–117, 123 Stat. 3034.

SOURCE: 76 FR 53283, August 25, 2011, unless otherwise noted.

§ 50.601 Purpose.

This subpart promotes objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded under Public Health Service (PHS) grants or cooperative agreements will be free from bias resulting from Investigator financial conflicts of interest.

§ 50.602 Applicability.

This subpart is applicable to each Institution that is applying for, or that receives, PHS research funding by means of a grant or cooperative agreement and, through the implementation of this subpart by the Institution, to each Investigator who is planning to participate in, or is participating in, such research; provided, however, that this subpart does not apply to SBIR Program Phase I applications. In those few cases where an individual, rather than an Institution, is applying for, or receives, PHS research funding, PHS Awarding Components will make case-by-case determinations on the steps to be taken, consistent with this subpart, to provide a reasonable expectation that the design, conduct, and reporting of the research will be free from bias resulting from a financial conflict of interest of the individual.

§ 50.603 Definitions.

As used in this subpart:

Disclosure of significant financial interests means an Investigator's disclosure of significant financial interests to an Institution.

Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

FCOI report means an Institution's report of a financial conflict of interest to a PHS Awarding Component.

Financial interest means anything of monetary value, whether or not the value is readily ascertainable.

HHS means the United States Department of Health and Human Services, and any components of the Department to which the authority involved may be delegated.

Institution means any domestic or foreign, public or private, entity or organization (excluding a Federal agency) that is applying for, or that receives, PHS research funding.

Institutional responsibilities means an Investigator's professional responsibilities on behalf of the Institution, and as defined by the Institution in its policy on financial conflicts of interest, which may include for example: activities such as research, research consultation, teaching, professional practice, institutional committee memberships, and service on panels such as Institutional Review Boards or Data and Safety Monitoring Boards.

Investigator means the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design,