

agency pursuant to such determination until the request has been disposed of, except that the filing of the request shall not affect any authority which the agency may have to suspend assistance or otherwise to withhold or defer payments under the grant during proceedings under this subpart. This paragraph does not require the awarding agency to provide continuation funding during the appeal process to a grantee whose noncompeting continuation award has been denied.

(d) Upon receipt of a request for review, the head of the agency or his or her designee will make a decision as to whether the dispute is reviewable under this subpart and will promptly notify the grantee and the office responsible for the adverse determination of this decision. If the head of the agency or his or her designee determines that the dispute is reviewable, he or she will forward the matter to the review committee appointed under § 50.405.

(e) The agency involved will provide the review committee appointed under § 50.405 with copies of all relevant background materials (including applications(s), award(s), summary statement(s), and correspondence) and any additional pertinent information available. These materials must be tabbed and organized chronologically and accompanied by an indexed list identifying each document.

(f) The grantee shall be given an opportunity to provide the review committee with additional statements and documentation not provided in the request for review described in paragraph (b) of this section. This additional submission, which must be organized and indexed as indicated under paragraph (e) of this section, should provide only material that is relevant to the review committee's deliberation of the issues in the case.

(g) The review committee may, at its discretion, invite the grantee and/or the agency staff to discuss the pertinent issues with the committee and to submit such additional information as the committee deems appropriate.

(h) Based on its review, the review committee will prepare a written decision to be signed by the chairperson and each of the other committee mem-

bers. The review committee shall send the written decision with a transmittal letter to the grantee and shall send a copy of both to the official responsible for the adverse determination. If the 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

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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*,

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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 74, 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.

Subpart F—Responsibility of Applicants for Promoting Objectivity in Research for Which PHS Funding Is Sought

AUTHORITY: 42 U.S.C. 216, 289b-1, 299c-3.

SOURCE: 60 FR 35815, July 11, 1995; 60 FR 39076, July 31, 1995, unless otherwise noted.

§ 50.601 Purpose.

This subpart promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research funded under PHS grants or cooperative agreements will be biased by any conflicting financial interest of an Investigator.

§ 50.602 Applicability.

This subpart is applicable to each Institution that applies for PHS grants or cooperative agreements for research and, through the implementation of