

§ 447.300

(b) Each State must report the aggregate information specified under paragraph (a) of this section on a quarterly basis in accordance with procedures established by HCFA.

(c) Each State must maintain, in readily reviewable form, supporting documentation that provides a detailed description of each DSH program, the legal basis of each DSH program, and the amount of DSH payments made to each individual public and private provider or facility each quarter. This information must be made available to Federal reviewers upon request.

(d) If a State fails to comply with the reporting requirements contained in this section, future grant awards will be reduced by the amount of FFP HCFA estimates is attributable to the expenditures made to the disproportionate share hospitals as to which the State has not reported properly, until such time as the State complies with the reporting requirements. Deferrals and/or disallowances of equivalent amounts may also be imposed with respect to quarters for which the State has failed to report properly. Unless otherwise prohibited by law, FFP for those expenditures will be released when the State complies with all reporting requirements.

Subpart F—Payment Methods for Other Institutional and Non-institutional Services

SOURCE: 43 FR 45253, Sept. 29, 1978, unless otherwise noted. Redesignated at 46 FR 47973, Sept. 30, 1981. Redesignated at 58 FR 6095, Jan. 26, 1993.

§ 447.300 Basis and purpose.

In this subpart, §§447.302 through 447.334 and 447.361 implement section 1902(a)(30) of the Act, which requires that payments be consistent with efficiency, economy and quality of care. Section 447.371 implements section 1902(a)(13)(F) of the Act, which requires that the State plan provide for payment for rural health clinic services in

42 CFR Ch. IV (10–1–99 Edition)

accordance with regulations prescribed by the Secretary.

[46 FR 48560, Oct. 1, 1981, as amended at 61 FR 38398, July 24, 1996]

§ 447.301 Definitions.

For the purposes of this subpart—

Brand name means any registered trade name commonly used to identify a drug.

Estimated acquisition cost means the agency's best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers.

Multiple source drug means a drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different proprietary names or both under a proprietary name and without such a name.

[52 FR 28657, July 31, 1987]

§ 447.302 State plan requirements.

A State plan must provide that the requirements of this subpart are met.

[46 FR 48560, Oct. 1, 1981]

§ 447.304 Adherence to upper limits; FFP.

(a) The Medicaid agency must not pay more than the upper limits described in this subpart.

(b) In the case of payments made under the plan for deductibles and coinsurance payable on an assigned Medicare claim for noninstitutional services, those payments may be made only up to the reasonable charge under Medicare.

(c) FFP is available in expenditures for payments for services that do not exceed the upper limits.

NOTE: The Secretary may waive any limitation on reimbursement imposed by Subpart D of this part for experiments conducted under section 402 of Pub. L. 90-428, Incentives for Economy Experimentation, as amended by section 222(b) of Pub. L. 92-603, and under section 222(a) of Pub. L. 92-603.

[46 FR 48560, Oct. 1, 1981; 46 FR 54744, Nov. 4, 1981]

OUTPATIENT HOSPITAL AND CLINIC SERVICES

§ 447.321 Outpatient hospital services and clinic services: Upper limits of payment.

(a) *General rule.* FFP is not available for any payment that exceeds the amount that would be payable to providers under comparable circumstances under Medicare.

(b) *Application of the rule.* Payments by an agency for outpatient hospital services may not exceed the total payments received by all providers from beneficiaries and carriers or intermediaries for providing comparable services under comparable circumstances under Medicare.

[52 FR 28148, July 28, 1987]

OTHER INPATIENT AND OUTPATIENT FACILITIES

§ 447.325 Other inpatient and outpatient facility services: Upper limits of payment.

The agency may pay the customary charges of the provider but must not pay more than the prevailing charges in the locality for comparable services under comparable circumstances.

DRUGS

§ 447.331 Drugs: Aggregate upper limits of payment.

(a) *Multiple source drugs.* Except for brand name drugs that are certified in accordance with paragraph (c) of this section, the agency payment for multiple source drugs must not exceed, the amount that would result from the application of the specific limits established in accordance with § 447.332. If a specific limit has not been established under § 447.332, then the rule for "other drugs" set forth in paragraph (b) applies.

(b) *Other drugs.* The agency payments for brand name drugs certified in accordance with paragraph (c) of this section and drugs other than multiple source drugs for which a specific limit has been established under § 447.332 must not exceed in the aggregate, payment levels that the agency has determined by applying the lower of the—

(1) Estimated acquisition costs plus reasonable dispensing fees established by the agency; or

(2) Providers' usual and customary charges to the general public.

(c) *Certification of brand name drugs.* (1) The upper limit for payment for multiple source drugs for which a specific limit has been established under § 447.332 does not apply if a physician certifies in his or her own handwriting that a specific brand is medically necessary for a particular recipient.

(2) The agency must decide what certification form and procedure are used.

(3) A checkoff box on a form is not acceptable but a notation like "brand necessary" is allowable.

(4) The agency may allow providers to keep the certification forms if the forms will be available for inspection by the agency or HHS.

[52 FR 28657, July 31, 1987]

§ 447.332 Upper limits for multiple source drugs.

(a) *Establishment and issuance of a listing.* (1) HCFA will establish listings that identify and set upper limits for multiple source drugs that meet the following requirements:

(i) All of the formulations of the drug approved by the Food and Drug Administration (FDA) have been evaluated as therapeutically equivalent in the most current edition of their publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (including supplements or in successor publications).

(ii) At least three suppliers list the drug (which has been classified by the FDA as category "A" in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, including supplements or in successor publications) based on all listings contained in current editions (or updates) of published compendia of cost information for drugs available for sale nationally.

(2) HCFA publishes the list of multiple source drugs for which upper limits have been established and any revisions to the list in Medicaid program instructions.

(3) HCFA will identify the sources used in compiling these lists.