- (f) Reporting requirements for payments during the transition periods. States that are eligible for a transition period described in paragraph (e) of this section, and that make payments that exceed the limit under paragraph (b)(1) of this section, must report annually the following information to CMS:
- (1) The total Medicaid payments made to each facility for services furnished during the entire State fiscal year.
- (2) A reasonable estimate of the amount that would be paid for the services furnished by the facility under Medicare payment principles.

[66 FR 3176, Jan. 12, 2001, as amended at 66 FR 46399, Sept. 5, 2001; 67 FR 2611, Jan. 18, 2002]

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) CMS 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) CMS 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) CMS will identify the sources used in compiling these lists.
- (b) Specific upper limits. The agency's payments for multiple source drugs identified and listed in accordance with paragraph (a) of this section must not

#### § 447.333

exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the agency plus an amount established by CMS that is equal to 150 percent of the published price for the least costly therapeutic equivalent (using all available national compendia) that can be purchased by pharmacists in quantities of 100 tablets or capsules (or, if the drug is not commonly available in quantities of 100, the package size commonly listed) or, in the case of liquids, the commonly listed size.

[52 FR 28658, July 31, 1987]

# § 447.333 State plan requirements, findings and assurances.

- (a) *State plan*. The State plan must describe comprehensively the agency's payment methodology for prescription drugs.
- (b) Findings and assurances. Upon proposing significant State plan changes in payments for prescription drugs, and at least annually for multiple source drugs and triennially for all other drugs, the agency must make the following findings and assurances:
- (1) *Findings*. The agency must make the following separate and distinct findings:
- (i) In the aggregate, its Medicaid expenditures for multiple source drugs, identified and listed in accordance with §447.332(a) of this subpart, are in accordance with the upper limits specified in §447.332(b) of this subpart; and
- (ii) In the aggregate, its Medicaid expenditures for all other drugs are in accordance with § 447.331 of this subpart.
- (2) Assurances. The agency must make assurances satisfactory to CMS that the requirements set forth in §§ 447.331 and 447.332 concerning upper limits and in paragraph (b)(1) of this section concerning agency findings are met.
- (c) Recordkeeping. The agency must maintain and make available to CMS, upon request, data, mathematical or statistical computations, comparisons, and any other pertinent records to support its findings and assurances.

 $[52~{\rm FR}~28658,~{\rm July}~31,~1987]$ 

### § 447.334 Upper limits for drugs furnished as part of services.

The upper limits for payment for prescribed drugs in this subpart also apply to payment for drugs provided as part of skilled nursing facility services and intermediate care facility services and under prepaid capitation arrangements.

### §447.342 [Reserved]

PREPAID CAPITATION PLANS

#### § 447.362 Upper limits of payment: Nonrisk contract.

Under a nonrisk contract, Medicaid payments to the contractor may not exceed—

- (a) What Medicaid would have paid, on a fee-for-service basis, for the services actually furnished to recipients: plus
- (b) The net savings of administrative costs the Medicaid agency achieves by contracting with the plan instead of purchasing the services on a fee-for-service basis.

[48 FR 54025, Nov. 30, 1983]

RURAL HEALTH CLINIC SERVICES

## § 447.371 Services furnished by rural health clinics.

The agency must pay for rural health clinic services, as defined in §440.20(b) of this subchapter, and for other ambulatory services furnished by a rural health clinic, as defined in §440.20(c) of this subchapter, as follows:

- (a) For provider clinics, the agency must pay the reasonable cost of rural health clinic services and other ambulatory services on the basis of the cost reimbursement principles in part 413 of this chapter. For purposes of this section, a provider clinic is an integrat part of a hospital, skilled nursing facility, or home health agency that is participating in Medicare and is licensed, governed, and supervised with other departments of the facility.
- (b) For clinics other than provider clinics that do not offer any ambulatory services other than rural health clinic services, the agency must pay for rural health clinic services at the reasonable cost rate per visit determined