

paragraph (a) of this section in State FY 2000 that exceeded the amount that would have been under the upper payment limit described in paragraph (b) of this section if that limit had been applied to that year.

(2) *General rules.* (i) The amount that a State's payment exceeded the upper payment limit described in paragraph (b) of this section must not increase.

(ii) A State with an approved State plan amendment payment provision effective on one of the following dates and that makes payments that exceed the upper payment limit described in paragraph (b) of this section to providers described in paragraph (a) of this section may follow the respective transition schedule:

(A) For State plan provisions that are effective after September 30, 1999 and were approved before January 22, 2001, payments may exceed the upper payment limit in paragraph (b) of this section until September 30, 2002.

(B) *For approved plan provisions that are effective after October 1, 1992 and before October 1, 1999, payments during the transition period may not exceed the following—*

(1) For State FY 2003: State FY 2003 UPL + .75X.

(2) For State FY 2004: State FY 2004 UPL + .50X.

(3) For State FY 2005: State FY 2005 UPL + .25X.

(4) For State FY 2006; State FY 2006 UPL.

(C) *For approved plan provisions that are effective on or before October 1, 1992, payments during the transition period may not exceed the following:*

(1) For State FY 2004: State FY 2004 UPL + .85X.

(2) For State FY 2005: State FY 2005 UPL + .70X.

(3) For State FY 2006: State FY 2006 UPL + .55X.

(4) For State FY 2007: State FY 2007 UPL + .40X.

(5) For State FY 2008: State FY 2008 UPL + .25X.

(6) For the portion of State FY 2009 before October 1, 2008: State FY 2009 UPL + .10X.

(7) Beginning October 1, 2008: UPL described in paragraph (b) of this section.

(D) For State plan provisions that were effective after September 30, 1999,

submitted to CMS before March 13, 2001, and approved by CMS after January 21, 2001, payments may exceed the limit in paragraph (b) of this section until the later of November 5, 2001, or 1 year from the approved effective date of the State plan provision.

(iii) When State FY 2003 begins after September 30, 2002, the reduction schedule in paragraphs (e)(2)(ii)(C)(1) through (e)(2)(ii)(C)(7) will begin on State FY 2003.

(iv) If a State meets the criteria in paragraph (e)(2)(ii) of this section and its State plan amendment expires before the end of the applicable transition period, the State may continue making payments that exceed the UPL described in paragraph (b) of this section in accordance with the applicable transition schedule described in paragraph (e)(2)(ii) of this section.

(v) A State with an approved State plan amendment payment provision that makes payments up to 150 percent of the UPL described in paragraph (b)(1) of this section to providers described in paragraph (a)(2) of this section does not qualify for a transition period.

(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 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