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(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.

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§ 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 FR 28658, 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.