§ 447.512 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, in the aggregate, the amount that would result from the application of the specific limits established in accordance with §447.514 of this subpart. If a specific limit has not been established under §447.514 of this subpart, then the rule for "other drugs" set forth in paragraph (b) of this section 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 §447.514 of this subpart must not exceed, in the aggregate, payment levels that the agency has determined by applying the lower of the—

(1) EAC plus reasonable dispensing fees established by the agency; or

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

§ 447.514 Upper limits for multiple source drugs.

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

(i) The FDA has rated two or more drug products as therapeutically and pharmaceutically equivalent in its most current edition of "Approved Drug Products with Therapeutic Equivalence Evaluations" (including supplements or in successor publications), regardless of whether all such formulations are rated as such and only such formulations shall be used when determining any such upper limit.