(1) The manufacturer's chief executive officer (CEO);
(2) The manufacturer's chief financial officer (CFO);
(3) An individual other than a CEO or CFO, who has authority equivalent to a CEO or a CFO; or
(4) An individual with the directly delegated authority to perform the certification on behalf of an individual described in subsections (1) through (3).

(f) Recordkeeping requirements. (1) A manufacturer must retain records (written or electronic) for ten years from the date the manufacturer reports data to CMS for that rebate period. The records must include these data and any other materials from which the calculations of the AMP, the best price, customary prompt pay discounts, and nominal prices are derived, including a record of any assumptions made in the calculations. The ten-year timeframe applies to a manufacturer's quarterly and monthly submissions of pricing data, as well as any revised pricing data subsequently submitted to CMS.

(2) A manufacturer must retain records beyond the ten-year period if both of the following circumstances exist:
(i) The records are the subject of an audit or of a government investigation related to pricing data that are used in AMP, best price, customary prompt pay discounts, or nominal prices of which the manufacturer is aware.
(ii) The audit findings or investigation related to the AMP, best price, customary prompt pay discounts, or nominal price have not been resolved.

(g) Data reporting format. All product and pricing data, whether submitted on a quarterly or monthly basis, must be submitted to CMS in an electronic format.

§ 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. (1) 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.

(ii) At least two suppliers meet the criteria in paragraph (a)(1)(i) of this section.

(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 issuances.

(b) Specific upper limits. The agency’s payments for multiple source drugs identified and listed periodically by CMS in Medicaid Program issuances must not exceed, in the aggregate, payment levels determined by applying for each drug entity a reasonable dispensing fee established by the State agency plus an amount established by CMS that is equal to 250 percent of the AMP (as computed without regard to customary prompt pay discounts extended to wholesalers) for the least costly therapeutic equivalent.

(c) Ensuring a drug is for sale nationally. To assure that a drug is for sale nationally, CMS will consider the following additional criteria:

(1) The AMP of a terminated NDC will not be used to set the Federal upper limit (FUL) beginning with the first day of the month after the actual termination date reported by the manufacturer to CMS.

(2) Except as set forth in paragraph (c)(3) of this section, the AMP of the lowest priced therapeutically and pharmaceutically equivalent drug that is not less than 40 percent of the next highest AMP will be used to establish the FUL.

(3) When the FUL group includes only the brand name drug and the first new generic or authorized generic drug which has entered the market, the criteria in paragraph (c)(2) of this section will not apply.

§ 447.518 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 §447.514(a) of this subpart, are in accordance with the upper limits specified in §447.514(b) of this subpart; and

(ii) In the aggregate, its Medicaid expenditures for all other drugs are in accordance with §447.512 of this subpart.

(2) Assurances. The agency must make assurances satisfactory to CMS that the requirements set forth in §§447.512 and 447.514 of this subpart 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.

§ 447.520 FFP: Conditions relating to physician-administered drugs.

(a) No FFP is available for physician-administered drugs for which a State has not required the submission of claims using codes that identify the drugs sufficiently for the State to bill a manufacturer for rebates.

(1) As of January 1, 2006, a State must require providers to submit claims for single source, physician-administered drugs using Healthcare Common Procedure Coding System codes or NDC numbers in order to secure rebates.

(2) As of January 1, 2008, a State must require providers to submit claims for the 20 multiple source physician-administered drugs identified by the Secretary as having the highest...