CMS Issues Ten-Year Record Retention Rule for Medicaid Drug Rebate Program

On November 26, 2004, the Centers for Medicare & Medicaid Services (“CMS”) issued a final rule that requires pharmaceutical manufacturers to retain records related to rebates paid to states under the Medicaid rebate program for a period of ten years. Previously, CMS published an interim rule that imposed a temporary ten-year record retention requirement. The interim rule, which replaced a three-year record retention requirement, was scheduled to sunset on December 31, 2004. The final rule makes the ten-year requirement permanent.

Background In order for a drug to be eligible for reimbursement under the Medicaid program, the manufacturer must enter into a rebate agreement with CMS. The agreement requires that the manufacturer pay quarterly rebates to states based on a calculation of the drug’s average manufacturer price (“AMP”) and best price, as defined in Medicaid rebate statute. In 2003, CMS finalized a rule that required manufacturers to retain data to support these calculations for a period of three years following the date that data are reported to CMS.

According to CMS, however, it was “necessary to replace the 3-year provision with a 10-year provision to address concerns regarding Federal and State investigations under the [False Claims Act (“FCA”)] and related anti-fraud provisions concerning the Medicaid drug rebate program.” The FCA permits private parties, often company insiders or whistleblowers, to bring suit on behalf of the federal government to recover costs incurred by the government as a result of false claims. These suits are filed under seal and preliminary investigations often take place with no notice to manufacturers. Accordingly, manufacturers will often be unaware that an FCA lawsuit or investigation has been initiated. According to CMS, the ten-year requirement was necessary to ensure that manufacturers do not inadvertently discard relevant records while the suit is under seal.

5 69 Fed. Reg. at 68816.
6 31 U.S.C. § 3729 et seq.
7 69 Fed. Reg. at 68816.
The new rule establishes a permanent ten-year recordkeeping requirement for prescription drug manufacturers that begins on the date that manufacturers report data to CMS. The records that must be retained include written and electronic data reported to CMS, as well as “any other materials from which the calculations of the average manufacturer price and best price are derived, including a record of any assumptions made in the calculations.” A manufacturer must retain data beyond the ten-year period if the manufacturer is aware that the records are subject to an unresolved audit or government investigation. In addition, CMS restated the requirement that manufacturers must report any revisions in AMP or best price within three years from the quarter in which the data were required to be reported to CMS.

Implications for Manufacturers The new CMS rule is another example of the enforcement environment currently facing pharmaceutical manufacturers. CMS felt that it was necessary to impose the longer recordkeeping requirement to facilitate federal and state enforcement against manufacturers. This illustrates the continued intensity of government investigatory activity involving drug manufacturers.

Although generally straightforward, this rule does raise several important issues that manufacturers should consider. For example, if construed broadly, documents reflecting “assumptions made in calculations” could apply to a wide range of documents. In addition, government investigations frequently involve a wide range of documents related to price calculations, including email correspondence. Manufacturers might thus consider whether they have an appropriate document retention system in place that takes into account the time periods and scope of the new rule.

Certain aspects of the new rule remain unclear. For instance, the rule requires that manufacturers retain data revising AMP or best price for ten years following submission of the revised data. However, the rule does not state whether the ten-year clock on the original data is reset when the revision is made. Pending clarification by CMS, manufacturers might consider retaining documents, including original data that are later revised, for ten years following any revision in AMP or best price.

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8 Id. at 68818.
9 Id.
10 Id.
This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

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