

Federal Court Clarifies Medicaid Rebate Reporting Requirements for New Strengths

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Pharmaceutical manufacturers participating in the Medicaid Drug Rebate Program (MDRP) must report pricing and product information to the U.S. government, paying separate rebates to state Medicaid program for each “strength” and “dosage form” of single source and innovator multiple source products. However, neither “strength” nor “dosage form” is defined in the MDRP statute, regulations, or Centers for Medicare & Medicaid Services (CMS) guidance, leaving a gap in the legal landscape for which manufacturers are permitted to adopt a reasonable interpretation for when similar products are the same or different products for MDRP purposes.

In a welcome development for pharmaceutical manufacturers, a recent California district court case directly addressed the definition of “strength,” holding that products with different concentrations or total amounts of the active ingredients in a product have different “strengths.”¹ This ruling acknowledges the gap in CMS regulation and guidance, holding that both concentration and total amount of an active ingredient are considered separate bases for determining when products must be reported separately and to which separate Medicaid rebates, including the inflation penalty, may attach.

Though technical in nature, this is an important opinion in the landscape of lifecycle and rebate liability management. Market access professionals will immediately recognize that this case holding will aid manufacturers in making their reasonable assumptions and planning for their Medicaid rebate liability when bringing new products to market. The case is especially relevant for injectable covered outpatient drugs and can make a material difference on the inflation penalty component of Medicaid rebate liability incurred by participating manufacturers. Pharmaceutical manufacturers should review their portfolios for the potential impact of this ruling on their product development and pipeline planning.

Recent Litigation

Medicaid rebate liability, including the inflation penalty, is determined with respect to each “strength” and “dosage form” of a single source or innovator multiple source product.

A recent case directly addressed the definition of “strength” as applied to the MDRP, centering on a manufacturer’s practice of reporting prices and calculating rebates separately for two products: a 10-ml vial and a three-ml vial of a drug, each with the same active ingredient and concentration but a different

total amount of active ingredient based on the different sizes. In this case, a physician relator brought a novel *qui tam* action under the False Claims Act, alleging that this practice falsely represented that the products had different “strengths.”

The government declined to intervene, signaling that the relator’s allegations were weak from the start.

Ruling on the manufacturer’s motion to dismiss the second amended complaint, Judge Stephen Wilson held in favor of the manufacturer who had separately reported the two products. Judge Wilson noted that “strength” was not defined in the MDRP statute, regulation, or any guidance from CMS. In the absence of any definition for this term, the court turned to other regulations referenced in the statute. Specifically, another key term in the MDRP rebate calculation, “single source drug,” is defined in reference to the Food and Drug Administration (FDA) regulations governing new drug approvals. On this basis, the court concluded it should apply the FDA definition of “strength” used for new drug applications, 21 C.F.R. § 314.3. The use of this definition was further supported by CMS’s reliance on Drugs@FDA to monitor manufacturer compliance with MDRP requirements.

These regulations define “strength” as “the amount of drug substance contained in, delivered, or deliverable from a drug product, which includes: (1) (i) The total quantity of drug substance ... and/or, as applicable (ii) [t]he concentration of the drug substance ... or (2) [s]uch other criteria the Agency establishes”

The court considered but rejected other FDA definitions of “strength” used in other contexts, including narrower definitions in the U.S. Pharmacopeia, the Structured Product Labeling System, and FDA guidance on labeling. These sources included only concentration, not total amount of product, when defining “strength.” The court declined to apply these sources to the MDRP context, noting that they are not used by CMS to monitor manufacturer compliance with the MDRP.

The court ultimately held in favor of the manufacturer, holding that a drug’s “strength” may be defined by concentration or volume. Applying this definition, the two products, with identical concentrations but different volumes, are reported separately and have separate Medicaid rebate liability.

Finally, it is worth noting that in dismissing the relator’s earlier First Amended Complaint, the court held that the relator had failed to show that the manufacturer had the required scienter, or ill intent, required to find liability under the False Claims Act. The court ruled that the manufacturer’s price reporting was “entirely consistent with [the manufacturer], in good faith, interpreting the relevant FDA regulations and concluding that [the products] had different strengths.” The court appeared to view the physician relator as exploitative, making a point to comment in its ruling on the second amended complaint that the relator “alleges that he discovered ... [the] misconduct by analyzing the Medicaid Drug Rebate Program drug database using his ‘specialized, independent knowledge’ of Medicaid and the ‘pharmaceuticals marketplace,’ as well as his experience in other False Claims Act lawsuits.”

Implications

CMS has not spoken clearly on when two products are different “strengths” under the MDRP, leaving participating manufacturers to make reasonable assumptions regarding when a product constituted a new strength for MDRP purposes. In this case, the judge held that in the absence of rulemaking or guidance on the issue, the broader FDA definition of “strength” used for new drug applications should be applied. This definition takes into account both concentration and total amount of product, requiring

separate reporting of two products with the same concentration but different volumes and therefore different total amounts of product. This is particularly relevant for injectable forms of covered outpatient drugs. Pharmaceutical manufacturers should be aware of this new case interpreting the Medicaid rebate requirements in their product development and reporting practices and document this interpretation in their compliance files when relevant to their product portfolios. Manufacturers should also monitor CMS guidance for potential updates that may follow this ruling. Finally, the opinion should be noted for its broader implications for another critical undefined term, “dosage form.”

¹ *United States ex rel. Lockwood v. Sanofi US Services, Inc. et al.*, No. 2:23-cv-05490-SVW-MRW, 2024 WL 5087330 (C.D. Cal. Dec. 09, 2024).

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