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CMS Finalizes Long-Awaited Covered Outpatient Drug Rule

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The ***Centers for Medicare & Medicaid Services ("CMS")*** recently issued a final rule implementing provisions of the ***Patient Protection and Affordable Care Act of 2010 ("ACA")*** that pertain to Medicaid reimbursement for covered outpatient drugs ("CODs") and the Medicaid drug rebate program (the "COD Rule"). The COD Rule both clarifies and creates a dramatic shift in Medicaid drug policy, including by:

- increasing the rebates that manufacturers of CODs pay to participate in Medicaid by increasing the minimum rebate percentages for single-source drugs, innovator multiple source drugs, and non-innovator multiple source drugs to levels set by the ACA;

- adopting the ACA's revised definition of Average Manufacturer Price ("AMP"), which substitutes the terms "retail community pharmacy" and "wholesaler" for the term "retail pharmacy class of trade" and identifies specific entities that drug manufactures must include and exclude when determining AMP;

- purporting to clarify drug manufacturers' reporting responsibilities by aligning the definition of Best Price and with the definition of AMP; and

- updating the Federal Upper Limit or "FUL" formula for the payment of certain generic drugs to include application of a higher multiplier to the FUL in situations where the FUL is less than the average retail community pharmacies' drug acquisition cost.

Perhaps most strikingly, the COD Rule replaces "estimated acquisition cost" with "actual acquisition cost" or "AAC" as the basis by which state Medicaid agencies should determine their ingredient cost reimbursement to pharmacies. The definitional change reflects a "longstanding concern by the [U.S. Department of Health and Human Services Office of Inspector General ("OIG")] that states continue to overpay for Medicaid CODs" and memorializes the recognition of the federal government—including CMS, OIG, and Congress—that "using a commercially published reference price as the basis for Medicaid pharmacy reimbursement has been problematic for both the states and the federal government because reimbursement based on published compendia prices, as

discussed in several reports issued by the OIG, is often significantly inflated, and not necessarily reflective of a pharmacy's actual purchase price for a drug." Replacing EAC with AAC will, at least in theory, "provide a more accurate estimate of the prices available in the marketplace, while assuring sufficient beneficiary access."

In adopting a cost-based approach to pharmacy reimbursement, CMS simultaneously replaced the regulatory term "dispensing fee" with the term "professional dispensing fee" in order to "reinforce [the agency's] position that the dispensing fee should reflect the pharmacist's professional services and costs to dispense the drug product to a Medicaid beneficiary." Indeed, going forward, "when states are proposing changes to either the ingredient cost reimbursement or professional dispensing fee reimbursement, they are required to . . . consider the impacts of both the ingredient cost reimbursement and the professional dispensing fee reimbursement when proposing such changes" to ensure that pharmacy providers' total reimbursement satisfies the "access to care" requirements prescribed by federal Medicaid law.

The COD Rule "will continue to allow the federal and state governments the flexibility to provide adequate reimbursement for the cost of CODs under the Medicaid program," meaning that AACs and professional dispensing fee amounts likely will vary (sometimes widely) from one state to another. Judging by the 400-plus public comments generated by the proposed COD Rule, the forthcoming changes to the Medicaid pharmacy program promise to generate controversy among policymakers, the provider community, manufacturers, and Medicaid stakeholders, not to mention administrative challenges and handwringing by legislators and Medicaid officials alike.

The COD Rule takes effect on April 1, 2016. State Medicaid agencies are required to submit State Plan Amendments demonstrating compliance with the rule by June 30, 2017 to be effective no later than April 1, 2017.

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