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Client Alert

FDA & Life Sciences Practice Group

February 22, 2011

Acquisition Price Metric Proposed for Medi-Cal Rx Reimbursement

Plan Would Impose California Price Reporting Obligations on Drug and Biologics Manufacturers

California Governor Jerry Brown has released a draft set of amendments to the state's Medi-Cal code that would add "average acquisition price" (AAP) to the set of data from which Medi-Cal pharmacy reimbursement is determined. The proposed amendments also open the door to unspecified price reporting obligations to California along the lines of those in Texas, New Mexico, Vermont and Maine.

The proposal would peg California ingredient reimbursement at a state-calculated pharmacy acquisition cost plus some markup. If enacted, it is likely to generate budget savings by the state and could therefore be a precedent for other state activity in this area. Currently Alabama, Oregon and (arguably) Texas utilize cost-plus Medicaid reimbursement schemes. All other Medicaid programs base reimbursement on AWP or WAC. A recent letter from HHS Secretary Sebelius advocated that states reexamine their reimbursement methodologies to find Medicaid drug savings, specifically mentioning Alabama and the forthcoming national survey on actual acquisition costs.

AAP is not explicitly defined in the proposed amendments. Instead, it is left to the discretion of the California Department of Health Care Services (Department) to determine based on (i) a markup to a volume weighted AAP, (ii) a markup to a national pricing benchmark provided by CMS or (iii) the AAP proposed by a vendor retained by the state to survey drug pricing information.

Drug manufacturers (and wholesalers) would be required to submit "drug price information" to the Department or the vendor. The proposed amendments do not define or limit the type, frequency or form of information manufacturers would be required to submit. These determinations appear to be left to the discretion of the Department. The extent to which manufacturers would be able to provide input or influence the state in establishing the reporting requirements is unknown. Failure to submit required information "may result in an AAP not being established for reimbursement purposes for providers." This could suggest that reimbursement would be suspended for noncompliant manufacturers' products. The proposed amendments provide for confidentiality of manufacturer data submissions.

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Pharmacy providers would be required to submit to the Department or to the vendor "invoice prices and all current and future discounts, rebates, and refunds known to the provider that would apply to the acquisition price of the drug products." Provider data submission would be enforced through a $2 per script penalty for noncompliance.

Significantly, this proposed legislation comes on the heels of previous efforts by California to reduce pharmacy reimbursements. Indeed, California and the Obama Administration are currently before the U.S. Supreme Court regarding a plaintiff's ability to challenge the adequacy of a state's Medicaid payment rates through a private right of action. This legislative proposal does not directly impact the issue at stake in that litigation, but it is clear that California will be creative in its attempts to establish Medicaid cost control.

Any new state-specific price reporting requirements could be onerous and expensive for manufacturers. Moreover, given the size of California's Medicaid market and the potential for other states to follow California's lead, implementation of AAP-based reimbursement could have significant commercial consequences for many drugs and biologics.

The proposed amendments have not yet been introduced in either California legislative chamber. If the amendments are introduced and passed, they will need to be approved by CMS through a Medicaid state plan amendment before they become effective. We will alert you to new developments as they arise.

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