KING & SPALDING

Client Alert

FDA & Life Sciences Practice Group

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CMS Holds External Stakeholders Meeting Regarding the Development of National Average Drug Acquisition Cost

On Thursday, August 4, 2011, the Centers for Medicare and Medicaid Services (CMS) held a Stakeholders Meeting on the development of its new pricing metric, the "national average drug acquisition cost" or "NADAC." *See* **Meeting Agenda** and **Meeting Slide Presentation**. This meeting followed an announcement by CMS on Friday, July 8, 2011, that it had selected a contractor to conduct monthly surveys of retail pharmaceutical prices and payments. ***See* CMS Announcement** and **K&S Client Alert: CMS Takes Steps to Implement Average Acquisition Cost**.

In its July 8 announcement, CMS described the two parts of the survey project, which will be pursued concurrently. Part I focuses on the creation of a list of *consumer prices* for covered outpatient drugs sold by retail community pharmacies. Part II orders the creation of a list of retail community pharmacy *ingredient costs*. NADAC will be prepared from the data generated in Part II. The Stakeholders Meeting dealt exclusively with Part II of the survey.

Background

Joseph Fine (Technical Director, Division of Pharmacy, CMS) moderated the Stakeholders Meeting. He explained that CMS's creation of the NADAC metric was influenced significantly by a white paper drafted by the American Medicaid Pharmacy Administrators Association and the National Association of Medicaid Directors in November, 2009. *See* **White Paper**. This White Paper was developed in response to the announcement that First Databank would cease publication of AWP in September of 2011. In the absence of AWP, state Medicaid programs sought a new drug reimbursement standard. A price benchmark based on actual acquisition cost data was identified as a viable option that fulfilled legal and practical requirements. Alabama and Oregon have already begun using actual acquisition cost proxies for pharmacy reimbursement. CMS hopes to create a similar *national* standard in NADAC.

NADAC Methodology

Representatives from CMS contractor Myers & Stauffer described the proposed survey methodology, which remains subject to change. In general, every month the contractor will survey a sample of retail pharmacies, collect acquisition cost data, develop an acquisition cost database for the data,

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categorize, review and analyze the data, and use the data to compute NADACs for each drug or group of covered drugs.

The surveyed pharmacies will be a random, nationwide sample of approximately 2,000 to 2,500 pharmacies per month. The sample will include independent, chain, and specialty pharmacies in all states and the District of Columbia. Separate monthly surveys will be conducted and separate NADACs published for independent and chain pharmacies, on the one hand, and specialty pharmacies on the other, recognizing the critical differences between these types of entities. Closed door, mail and long term care pharmacies are excluded from the survey methodology due to their unique cost and reimbursement structures. Presently, there is no plan to develop survey methodologies for these types of entities.

Pharmacy participation is voluntary, but CMS hopes for a very high response rate. In an effort to encourage participation, survey response will not require the filling out of forms. Rather, pharmacies will be asked to copy and submit thirty days of actual wholesaler invoice records, from which the per unit acquisition cost data will be pulled by the contractor. Some wholesalers may make records available to CMS directly, with pharmacies' consent. Reporting by chain purchasing warehouses on behalf of individual chain pharmacies will reflect the purchases of the individual pharmacies only, not for the chain as a whole. Cost information submitted to CMS may be designated as "confidential" and therefore exempt from disclosure under the Freedom of Information Act.

NADAC will be the mean average invoice price paid to wholesalers by the surveyed pharmacies. Whether direct purchases from manufacturers will be captured in NADAC was not addressed. 340B pricing will be excluded; how IHS/FSS pricing will be treated is under consideration. The contractor will weight the NADAC calculations to reflect the distribution of utilization in each sector surveyed. As with Average Sales Price (ASP) and the 340B ceiling price, there will be a lag between purchase date and publication of NADAC: in this case, a lag of two months. CMS and the contractor are considering month-to-month smoothing mechanisms to reduce potential price volatility. A NADAC reference file will be published monthly for use by the states (and, presumably, private payors). CMS hopes to have the first of these files published by the end of 2011. The exact contents of this file were not announced. No information identifiable to a pharmacy will be published.

All Medicaid covered outpatient drugs will be subject to NADAC: innovator and non-innovator, single source and multisource. A NADAC will be computed for each "drug group," which consists of drugs with the same name, strength and dosage form. The data will be scrubbed to remove obsolete NDCs and free goods.

A special purpose survey will be conducted at least annually to examine off-invoice discounts (*e.g.*, discounts, rebates, and contingent free goods). The special purpose survey will request information from a smaller set of pharmacies than the larger NADAC survey, and require more work by the pharmacists to fill out. The contractor will examine how off-invoice price concessions trend over time, and assess whether they impact the reliability of NADAC as a benchmark price. There are no current plans to incorporate the results of this survey into the NADAC: at this point, CMS seeks only to understand how off-invoice discounts operate at the pharmacy level.

Neither CMS nor the contractor recommended specific multiples of NADAC that states might use in setting reimbursement. Nor did they distinguish between the use of single source NADAC and multiple source NADAC in reimbursement. Significantly, when a state does utilize this revised pricing metric and establishes a multiple for NADAC for payment purposes, it will need to comply with separate adequate access provisions of the Medicaid statute.

Observations

- Any impact of NADAC as a price benchmark on state Medicaid reimbursement methodologies must be effectuated by state plan amendments; thus, the publication of the NADAC files will not have an immediate or unilateral impact on Medicaid reimbursement methodologies.
- The two month lag in price data reporting may mean that current NADAC will not accurately reflect current market prices of covered drugs.
- Splitting the surveys into invoice price and off-invoice price concessions, and not cross-walking and integrating the two, may make it impossible for NADAC to reflect an accurate net pharmacy acquisition cost.
- The presence of manufacturer-specific information in the NADAC reference file could have anticompetitive implications. Manufacturers should watch closely what data fields other than the aggregated NADAC are made part of the reference file.
- Calculating NADAC by "drug group" will likely sweep multiple source innovator products into averages with authorized generics and generic competitors. Query whether CMS will develop a more rigorous NDC-specific grouping system than "drug name, strength and dosage form."
- States that move from an AWP- or WAC-based reimbursement approach to one based on NADAC may reduce the delta between acquisition and reimbursement costs, particularly for generic products. Courts have held that the size of this delta is one factor in determining if a drug manufacturer has engaged in manipulation of government reimbursement.
- Pharmaceutical manufacturers will want to watch development, implementation and use of NADAC carefully as it may affect brand/generic incentives and cause innovator manufacturers to rethink retail pharmacy strategies.

Comments Welcomed

Comments and questions regarding the NADAC methodology may be submitted to CMS at RPS@CMS.hhs.gov. There is no specific due date for these comments. CMS will soon publish a draft survey and hold a meeting to discuss the results of the draft survey. Manufacturers, wholesalers, pharmacies, and other stakeholders hoping to influence this process through comments are advised to prepare and submit them as soon as practicable.

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King & Spalding has a great deal of expertise in pharmaceutical price reporting and drug reimbursement issues. Our attorneys have been intimately involved in the design, development, implementation, interpretation and enforcement of many of the current price reporting and drug reimbursement systems, including ASP, AMP, Best Price and Medicare Part D. We also represent manufacturers on highly sensitive and complex investigations on price reporting and fraud and abuse compliance matters and have been involved in some of the highest profile cases involving the pharmaceutical industry. Our attorneys would be pleased to discuss the contents of this alert in greater detail.