KING & SPALDING

Client Alert

FDA & Life Sciences Practice Group

February 3, 2012

Proposed ACA Medicaid Drug Pricing Rule:

A Roadmap for Manufacturers of Drugs and Biologics

On Friday, January 27, the Centers for Medicare & Medicaid Services (CMS) posted its long-awaited proposed rule implementing the Medicaid pricing and reimbursement provisions of the Patient Protection and Affordable Care Act (ACA) and related legislation. The Federal Register published the proposed rule ("ACA Proposed Rule") on February 2, which is available here. King & Spalding's January 30 summary of significant changes is available here.

CMS provided manufacturers and other stakeholders with only two months to assess and comment on the implications of the ACA Proposed Rule. The ACA Proposed Rule may affect decisions related to an array of ongoing business operations, including clinical development, product life-cycle management, mergers and acquisitions, and ongoing pricing recalculations or reviews. Given the scope and complexity of the issues presented, manufacturers must act quickly to educate relevant members of their management and government pricing teams about CMS's proposals, analyze the business implications of the ACA Proposed Rule, evaluate their systems for implementing any potential changes, and formulate strategies for submitting effective, persuasive comments. Comments are due to CMS no later than **April 2, 2012 at 5 pm**.

This roadmap suggests next steps for pharmaceutical and biologics manufacturers to consider as they digest the ACA Proposed Rule and identify implications that merit comment.

Prepare Internal Constituents

Each manufacturer has unique capabilities and internal processes for responding to and communicating regulatory changes. Still, we believe the following are some actions that all manufacturers should consider immediately:

- **Educate Senior Management.** The costs to manufacturers if this proposal becomes law as written could be substantial, in terms of increased Medicaid rebate liability (*e.g.*, territories, line extension URA) and compliance (*e.g.*, elimination of the default rule, constant reassessment of 5i "not generally dispensed").

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There are potential antitrust implications (*e.g.*, pricing coordination with other labelers who own initial brand name drugs) and increased threats of investigation and fines (*e.g.*, civil money penalties and referral to OIG of late filers). The Proposed Rule is not final. Therefore, it is premature to invest significant financial resources or enact sweeping changes to accommodate these new provisions. Management should be aware, however, of the potential for increased costs and personnel time to transition to compliance in late 2012 or early 2013. Finally, it is important to brief the individual tasked with certifying the company's Medicaid submissions about the nature of CMS's proposed changes and any attempts the company is making to modify the ACA Proposed Rule through comment.

- **Issue Spot with the Government Pricing Team.** The individual or group within your company responsible for calculating AMP and Best Price should take an immediate inventory of the systems and processes affected by the ACA Proposed Rule — both to assess the potential impact on company operations and to inform comments on the ACA Proposed Rule. It may be helpful for government pricing teams to consider the following:

  - *Review systems for tracking retail community pharmacy (RCP) indirect sales*. If CMS maintains its position that manufacturers must include in AMP only sales traceable to RCPs, then the government pricing function needs to assess internal capabilities related to identification of these transactions, and consider whether wholesaler agreements need to be modified to obtain necessary data.

  - *Identify customers or relationships that the rule did not address*. CMS re-wrote the inclusion and exclusion rules, both in the context of 5i and non-5i AMP. Manufacturers should evaluate whether they transact with any customers or maintain any business relationships that are not adequately addressed by the revised inclusion and exclusion rules. If so, manufacturers should consider submitting comments to CMS to clarify their inclusion/exclusion status.

  - *Locate data necessary to recalculate base date AMP*. Many manufacturers may benefit from revising base date AMPs, in particular those with non-5i products. CMS will permit such revision if the recalculation is "timely" (*i.e.*, within four quarters of the effective date of the final rule) and based on verifiable pricing records. Manufacturers should confirm that the necessary data are available or, if necessary, persuade CMS to create a final rule that is more accommodating of reasonable assumptions.

  - *Estimate the financial impact*. To the extent practicable, manufacturers should model the financial impact of the new AMP and Best Price rules. This assessment should extend beyond just Medicaid rebate liability. For example, state Supplemental rebate amounts may also change. These changes may have implications for a product's inclusion on a state's Preferred Drug List or other formularies. Also, manufacturers with ASP products should consider whether the new AMP rules could trigger an ASP price substitution, and model the potential effect of that substitution on reimbursement.

- **Reevaluate Existing Assumptions and Interim Policies.** In the absence of CMS regulations following the enactment of ACA and the 5i legislation, manufacturers had to develop various assumptions to support their AMP calculations. The ACA Proposed Rule provides additional guidance, but in its proposed state lacks the force and effect of law. Manufacturers who adopted assumptions should evaluate whether their

interim positions were too aggressive or too conservative in light of the ACA Proposed Rule, and consider revising those assumptions (while at the same time recognizing that the rules are not yet final).

- **Evaluate Your Portfolio Under Proposed Rules.** CMS relied heavily on FDA designations for purposes of defining the sets of products subject to different AMP rules. Manufacturers should research and identify potential 5i products, line extensions, and pediatric-only products. Based on the proposed line extension definition, it is expected that many more products than originally thought will be subject to the Alternative AMP calculation. Both the original drugs and the line extension counterparts in your portfolio should be identified. To the extent your company no longer owns the original product, consider challenging CMS's proposal that would require you to exchange proprietary pricing data with a competitor to determine your rebate liability.

- **Evaluate Your Contracts Under Proposed Rules.** Manufacturer agreements with wholesalers, distributors, PBMs, and others should be examined for adherence to the *bona fide* service fee and bundling treatment. For many manufacturers, the inclusion of *non-contingent* discounts in bundle aggregation and allocation would be a departure from current practice. Assess the impact of such a rule on your contracts and consider objecting to the practice in comments.

- **Prepare to File Written Comments.** Manufacturers have less than two months to craft comprehensive, thoughtful and persuasive comments to attempt to head off some of the more egregious or misplaced rules CMS seeks to enact (due April 2). We find that cross-divisional review and brainstorming of the elements of the ACA Proposed Rule often best identify the significant issues for comment. Further, such review can identify unique issues that are unlikely to be addressed by trade groups in their comments. CMS is particularly responsive to instances where parties can document and empirically describe administrative or operational burdens. Under the Administrative Procedure Act (APA), federal agencies are required to provide the public with adequate notice of a proposed rule followed by a meaningful opportunity to comment on the rule's content. 5 U.S.C. § 553 (b)-(c). Agencies should set forth sufficiently detailed descriptions of the proposed changes in order to facilitate comment, as well as provide enough time for the public to submit comments given the nature and complexity of the proposals. Many of the proposed changes are arguably much broader than the statute authorizes and could have far-reaching implications if finalized. Companies should read the Proposed Rule critically, consider whether the scope of the proposed changes warrants an extension of the comment period, and draft comments with an eye toward preserving legal challenges to the process.

Consider Implications for Ongoing Activities

The ACA Proposed Rule can affect issues outside the government pricing function. It is difficult to predict with certainty what other areas could be impacted by the new regulations. Some possible unintended consequences include:

- **Merger and Acquisition Activity.** Manufacturers considering strategic acquisitions should analyze the unique Medicaid rebate liability issues related to products that would be acquired. For example, is an

acquisition target product 5i? Is it a line extension? Are base date AMP data available for recalculation purposes?

- **Clinical Development and FDA Approval.** Manufacturers will want to review the financial impact of Medicaid rebate policy on the development of pipeline products. For example, the bias against oral solid dosage form line extensions could affect how line extensions are formulated, and the preferential treatment for pediatric-only indications (*i.e.*, the birth to 16 years of age cohort) could affect clinical trial design or product label negotiations with FDA.

- **Ongoing Reviews or Recalculations.** Manufacturers currently conducting pricing reviews may want to consider recalculation methodologies in light of the positions articulated by CMS in the Proposed Rule. Although we do not believe that CMS will require recalculation and resubmission of AMPs and BPs in the post-Q1 2010 period (it did not after the publication of the DRA final rule, for instance), some manufacturers might find retroactive application of post-ACA final rule methodologies to be advantageous, and should consider taking advantage of the 12-quarter restatement window.

- **Focus on Enforcement Activity.** To the extent a manufacturer's fee-for-service arrangements include price appreciation credits that are considered *bona fide* service fees, it should be aware of the position taken by CMS on page 57 of the display copy of the ACA Proposed Rule, 77 Fed. Reg. at 5332 (Feb. 2, 2012).

- **Coalition for Legal Challenges.** To the extent your company identifies an objection to the aspects of the ACA Proposed Rule that will disproportionately affect you and a set of other manufacturers (for instance, in a particular product class or with a unique distribution system), consider creating a coalition to create focused comments on a particular area. Common advocacy on an issue of public policy is protected under the antitrust laws. Not only can this be cost-effective, but the participation of several manufacturers on a single strong comment can be particularly persuasive to CMS.

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The ACA Proposed Rule reflects a number of statutory interpretations and policy choices by CMS that are ripe for manufacturer comment. The King & Spalding government pricing team is prepared to help clients interpret these proposals and prepare submissions to CMS. Please reach out to any member of the team and we would be glad to provide assistance.