KING & SPALDING

Client Alert

FDA & Life Sciences Practice Group

January 30, 2012

CMS Proposes ACA Medicaid Drug Pricing Rule:

Many Proposed AMP, BP and URA Requirements for Manufacturers are Onerous to Implement and Costly to Satisfy

On Friday, January 27, the Centers for Medicare & Medicaid Services ("CMS" or "the Agency") published its long-awaited proposed rule implementing the Medicaid pricing and reimbursement provisions of the Patient Protection and Affordable Care Act ("ACA") and related legislation. A display copy of the proposed rule ("ACA Proposed Rule") can be found here. The Federal Register is expected to publish its single-spaced, three column version on February 2.

The ACA Proposed Rule addresses many of the government pricing questions that drug and biologics manufacturers, wholesalers and pharmacies have been wrestling with since the passage of health care reform in March of 2010. The scope of the rulemaking is broad and does provide manufacturers with greater insight into CMS's position on critical issues, but it also leaves many questions unanswered and will likely increase drug manufacturers' rebate liability and cost of compliance.

CMS does not speak to the question of retroactive applicability of any of the provisions in the ACA Proposed Rule.

Comments are due to CMS no later than **April 2, 2012 at 5 pm**. Many elements of the ACA Proposed Rule merit close scrutiny and comment by industry. King & Spalding is ready to assist to you and your company in preparing comments for CMS.

This summary includes the most important provisions of the ACA Proposed Rule affecting manufacturers. The page numbers provided refer to the display copy of the proposed rule. We have also prepared two tools for your convenience: a detailed **table of contents** is available here, and a **redline of the proposed Medicaid Drug Rebate Program regulations** (42 C.F.R. § 447.500 *et seq.*) is available here.

We will soon publish mini-whitepapers on several of the important aspects of the ACA Proposed Rule, and will hold a free audio conference in the near future to discuss our impressions and answer questions.

For more information, contact:

John D. Shakow
+1 202 626 5523
jshakow@kslaw.com

Patrick Morrisey
+1 202 626 3740
pmorrisey@kslaw.com

Christina Markus
+1 202 626 2926
cmarkus@kslaw.com

Preeya Noronha Pinto
+1 202 626 5547
ppinto@kslaw.com

Josh T. O'Harra
+1 202 626 5582
j'oharra@kslaw.com

Elizabeth F. Gluck
+1 202 626 5585
egluck@kslaw.com

King & Spalding
Washington, D.C.
1700 Pennsylvania Avenue, NW
Washington, D.C. 20006-4707
Tel: +1 202 737 0500
Fax: +1 202 626 3737

www.kslaw.com

Highlights

- The AMP "**default rule**" was rejected; manufacturers will have to trace sales to RCPs
- Non-5i drugs not distributed through RCPs are given a **new category of eligible purchasers**
- No provision for estimating **lagged ineligible sales** in AMP
- ACA **base AMP restatement permitted** under certain circumstances
- 5i "not generally dispensed" status proposed to be **continually reassessed by manufacturers**
- Definition of **bundled sale expanded** to include noncontingent discounts "in a bundled sale"
- The definition of **"line extension" is very broad**
- Line extension URA **calculation process is consistent with the statute** and prior CMS guidance
- Application of line extension URA calculation process may require **coordination with other manufacturers**
- CMS proposes to **expand the Rebate Program to include the U.S. territories** – both for rebates and for calculations. This is a significant departure from current regulations
- The ACA Proposed Rule recognizes that a primary manufacturer's authorized generic sales to a secondary manufacturer should often be **included in the primary manufacturer's AMP**; however, there are exceptions to this rule
- Referral to the **OIG and significant civil money penalties are proposed for late filers**
- The Agency proposes the elimination of Estimated Acquisition Cost in favor of **Actual Acquisition Cost** for state reimbursement
- CMS did not propose a **smoothing methodology for FULs**
- The ACA Proposed Rule sets out CMS's proposed approach to **Federal offset of increased rebates**

Average Manufacturer Price

- CMS considered and rejected a "presumed inclusion" policy that would have permitted manufacturers to assume sales to wholesalers, without evidence to the contrary, were distributed to retail community pharmacies ("RCPs"). The Agency proposes to reject the "default rule" under which manufacturers have operated since the beginning of the Medicaid Drug Rebate Program ("MRDP"). As proposed, manufacturers will have to trace all sales through wholesalers to RCPs, whether or not there is a chargeback or other data trail, which will involve investments in infrastructure and reform of manufacturers' relationships with wholesalers. Pages 45-49.

- In general, non-5i AMP includes sales and price concessions to wholesalers for drugs distributed to RCPs and to RCPs themselves. Recognizing that certain non-5i covered outpatient drugs are not distributed through RCPs (particularly REMS drugs), the ACA Proposed Rule created another category of includable purchasing entities to permit the calculation of AMP for these drugs. Sales and price concessions to entities that "conduct business as wholesalers or RCPs, including but not limited to specialty pharmacies, home infusion pharmacies and home healthcare providers," are proposed to be included in AMP. It is unclear whether this category applies exclusively to these particular products, or if sales of all drugs to these entities will be included. Pages 43-45 and 49-51.

- Under the ACA Proposed Rule, manufacturers must include in the determination of AMP: discounts, rebates, payments or other financial transactions that are received by, paid by, or passed through to, RCPs where it has evidence or documentation demonstrating that such discounts have been passed through to the pharmacy. CMS recognizes that it is unsure the extent to which a manufacturer knows that such transactions occur, but nonetheless asserts that this requirement is consistent with the language of Section 1927(k)(1)(B)(ii) of the Social Security Act, as revised by the ACA. Page 50.

- In rewriting § 447.504, CMS proposed a list of 22 entities or transactions that are to be excluded from non-5i AMP. Pages 51-63.

- "Prices" to the TRICARE Retail Pharmacy Program are proposed to be excluded from AMP. Refunds paid to the Department of Defense are therefore to be ignored in AMP. Use of the word "prices," however, suggests that manufacturers will not be required to "back-out" underlying commercial sales from AMP. This represents a shift in the position CMS took in MDRP State Release No. 152 (September 9, 2009). Pages 51-52.

- The ACA Proposed Rule reiterates the 12-month estimation mechanism for lagged eligible price concessions that CMS published in MDRP Release No. 83 (February 3, 2011). However, CMS continues to define the numerator of the estimation ratio as "total lagged price concessions over the most recent 12-month period," and the denominator as "total sales subject to AMP reporting" for the same period. The total discounts over eligible sales ratio is a deviation from the Average Sales Price ("ASP") rule at 414.804(a)(3)(i): to confirm with the ASP smoothing methodology, the ratio should be *eligible* lagged discounts over eligible sales. Pages 105-107.

- Estimation or smoothing of lagged AMP-ineligible sales is not mentioned in the ACA Proposed Rule. Manufacturers should seek to remedy this problem in the final rulemaking.

- Manufacturers may report a revised ACA base date AMP to CMS within the first four full calendar quarters following the publication of an ACA Final Rule. Any recalculated base date AMP must be based on "verifiable pricing records" and may only reflect the changes to AMP contained in the new regulations. Manufacturers may elect to report new base date AMPs on a product-by-product basis. Pages 103-104.

- In a surprise development, the ACA Proposed Rule includes two newly defined terms, "Average Unit Price" and "Net sales." The term "Average Unit Price" does not appear elsewhere in the preamble or the proposed regulations. The words "net sales" appear in the monthly AMP smoothing guidance and the regulations under the "calculation of monthly AMP." Pages 41-42, 105, and 191.

5i Average Manufacturer Price

- To identify potential 5i drugs (*i.e.*, inhalation, infusion, instilled, implanted and injectable drugs), CMS proposes that manufacturers use Food and Drug Administration ("FDA") defined "Routes of Administration" as a guide. The proposed rule includes a non-exhaustive list of 102 methods of administration that would qualify as 5i. Manufacturers should be able to compare this list to the "Dosage and Administration" section in their products' labels to identify potential 5i drugs. Pages 63-68.

- To determine whether a drug is "not generally dispensed through a retail community pharmacy," CMS proposes to rely on a "90 percent" principle: if 90 percent or more of the manufacturer's sales (unclear whether this is dollars or units) of a 5i drug are to an entity other than a wholesaler for distribution to RCPs or directly to RCPs, the drug would be classified as "not generally dispensed" through RCPs. CMS proposes that manufacturers evaluate this percentage on a monthly and quarterly basis. Such frequent evaluation would be difficult for manufacturers to perform, cause a product's 5i status (and therefore likely AMP) to vary greatly, and make the additional rebate comparison to base date AMP variable and highly unreliable. This proposal will likely be one of the most significant areas of focus for manufacturers. Pages 68-71.

- All sales, rebates, discounts, or other transactions proposed for inclusion in the determination of AMP are included in 5i AMP, as are all sales, rebates, discounts, or other transactions provided to physicians, PBMs (including mail order), HMOs, insurers, hospitals, clinics, mail order pharmacies, long term care providers and hospices. The ACA Proposed Rule does not provide a specific list of entities excluded from 5i AMP. Pages 71-72.

Best Price

- The ACA Proposed Rule includes several proposed changes to the Best Price regulations. Notably, CMS proposes to remove the list of prices included in Best Price and to replace it with a broad instruction to include "all prices and associated rebates, discounts, or other transactions that adjust prices either directly or indirectly" except for specifically enumerated exclusions. Page 74.

- CMS proposes to exclude from Best Price unsalable returned goods and associated reverse logics or returns processing costs. This is a new exclusion. However, CMS did not propose to update § 447.505(d), which states that Best Price is net of (*i.e.*, includes) returns. This may be an oversight, but will need clarification. Page 180-181.

- Sales to 340B covered entities for purchases "outside the program," such as purchases under a Medicaid carve out, are proposed to be included in Best Price. Currently, all prices to 340B covered entities are excluded under 1396r-8(c)(1)(C)(i)(I). CMS is proposing to exclude only prices "charged under the 340B drug pricing program" and invites comment on instances in which covered entities purchase outside the program. Pages 75-76.

- CMS proposes to add to the regulation the two new statutory customer categories that may purchase product at Best Price-exempt nominal prices: (1) tax-exempt or State-owned or operated entities that provide services to the same types of populations as 340B covered entities; and (2) public, nonprofit entities or student health centers that provide family planning services. The HHS Secretary continues to refuse to propose additional categories, as she is entitled to do under law. Pages 78-79.

AMP and Best Price

- CMS appears to propose to expand the definition of a bundled sale. Previously, CMS guidance could be understood to say that non-contingent arrangements did not give rise to the creation of a bundle. As proposed, all discounts "in a bundled sale, including but not limited to those discounts resulting from a contingent arrangement," are subject to bundle reallocation. This suggests that a discount arrangement does not have to have any contingency element to be considered to be "in" a bundled sale. Pages 15-16.

- The ACA Proposed Rule limits the types of entities that may be paid excludable *bona fide* service fees to "wholesalers, retail community pharmacies, or any other entity that conducts business as a wholesaler or a retail community pharmacy" for both AMP and Best Price. *See* proposed §§ 447.502, 504(c)(14) and 505(c)(16). The proposed regulations incorporate the specific example fees from the ACA, and the preamble suggests that these fees must meet the existing regulatory test for *bona fide* service fees. Group purchasing organization ("GPO") administrative fees may also be eligible for exclusion, provided they satisfy all other elements of the *bona fide* service fee definition. CMS further stated that retroactive price adjustments or price appreciation credits (the subject of an ongoing qui tam suit) should not be considered *bona fide* service fees. We would be pleased to discuss this issue with interested parties in greater depth. Pages 15 and 56-57.

- CMS proposes to exclude from AMP and Best Price patient coupons, vouchers, rebate/refund, co-payment assistance and patient assistance program products. CMS does not mandate specific exclusion criteria (*e.g.*, that these benefits be offered to low-income individuals) as it had in the preamble to the DRA Final Rule. The text of the proposed regulation is unclear since certain exclusions, such as co-payment support or patient rebates, appear only to be excludable when tied to the provision of free goods. Pages 61-63.

- CMS proposes to expand the exclusion for recalled, damaged, expired, or otherwise unsalable returned goods both by expanding this exclusion to Best Price and by excluding costs related handling, processing, reverse logistics, and drug destruction. According to the preamble, these exclusions from AMP and Best Price remain limited to instances where the return is made in "good faith." Pages 58-59.

Line Extensions

- CMS has proposed that, for purposes of assessing whether a specific drug product is a "line extension," *both* that product and the initial brand name product must be oral solid dosage forms. Pages 81-82.

- The proposed definition of "line extension" relies on (1) the FDA's definition of "active moiety" (a concept used for certain market exclusivity determinations) and (2) a list of "chemical types" that FDA unilaterally assigns in its Drugs@FDA database. This proposed definition is extremely broad. Read literally, it could include, for example, two products that contain different active ingredients but have a common active moiety, as well as new solid oral dosage forms developed for an entirely new indication. New strengths of an initial brand name drug, however, would be excluded from the "line extension" definition. Pages 81-89.

- There is no meaningful discussion in the preamble of practical implications of the definition of "line extension." For example, if Manufacturer A markets an initial brand name drug (using the proposed definition), and Manufacturer B independently develops a product containing the same active ingredient, is Manufacturer B's product a line extension? Does the type of marketing application matter (505(b)(1) vs. 505(b)(2) NDA)? Page 25.

- CMS has proposed a manual process to review FDA information and "compile a master list of all initial brand name listed drugs and their line extensions by NDC." CMS would update the master list on a quarterly basis, and match the master file against CMS' drug file for the initial three quarters. Thereafter, manufacturers would have to identify and report which NDCs represent initial brand name drugs and which are line extensions. Pages 87-88.

- The per-unit Medicaid rebate due for a line extension is proposed to be the greater of two calculations: (1) the "Standard URA" for the line extension calculated just like any other innovator drug, or (2) the "Alternative URA" which is calculated with reference to the highest additional rebate of any strength of the initial brand name drug. Note that the Alternative URA is the entire URA for a line extension, not merely the additional rebate for the line extension. The ACA Proposed Rule contains a detailed example of the process by which the URA for a line extension is determined. Pages 81 and 89-94.

- Both the Standard URA and the Alternative URA are subject to the 100% of AMP cap. Page 91.

- If the manufacturer of a line extension product were to sell its initial brand name drug to another manufacturer, under the ACA Proposed Rule, the selling manufacturer would be required to obtain all necessary product and pricing data from the purchasing manufacturer to compute the line extension's Alternative URA. Pages 90-91.

- CMS has proposed that if the initial brand name drug has been terminated, manufacturers would be relieved of the obligation to calculate an Alternative URA. Page 90.

Other Medicaid Rebate Issues

- CMS proposes to define a drug "exclusively for pediatric indications" to mean a drug product approved by the FDA exclusively with indications for children from birth to 16 years (and only when this specific pediatric age cohort appears in the "Indication and Usage" section of the FDA-approved labeling). Under the proposed rule, drugs without this explicit age labeling will not qualify for the minimum rebate percentage of 17.1%. The ACA Proposed Rule does not contemplate an appeal process for challenging a determination by CMS that a drug is not exclusively for pediatric indications. Pages 31-32 and 80.

- CMS proposes to expand the definitions of "States" and "United States" to include the U.S. territories: Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa. These proposed changes have two effects: first, they expand the number of Medicaid programs able to claim manufacturer rebates; second, they expand the universe of transactions manufacturers must include in AMP and Best Price (currently, sales and rebates to customers in the territories are excluded). Pages 33-34.

- From the inception of the MDRP, participating manufacturers were exempted from paying drug rebates for drugs dispensed to individuals enrolled in Medicaid MCOs. The ACA required manufacturers to pay rebates on drugs dispensed to individuals enrolled in Medicaid MCOs if the MCO is responsible for payment of such drugs. To implement this statutory change, CMS proposes to require states to obtain utilization data from each Medicaid MCO (including information on the total number of units of each dosage form, strength and package size by NDC of each covered outpatient drug dispensed to Medicaid MCO enrollees) and use this data to request quarterly rebates from manufacturers. Under the ACA Proposed Rule, states are also required to report the utilization data separately in their quarterly utilization reports to CMS. CMS articulates a proposed exception to the rebate requirement for drugs dispensed to individuals enrolled in MCOs if the drugs are both dispensed by HMOs, including Medicaid MCOs that contract under Section 1903(m) of the Act, and are eligible for 340B discounts. Pages 94-96.

Authorized Generics

- The Agency proposes definitions of "primary manufacturer" and "secondary manufacturer of an authorized generic drug." Page 76.

- Reflecting the language of the MDRP statute, the ACA Proposed Rule explicitly includes in the primary manufacturer's AMP all sales of its authorized generic drugs to the secondary manufacturer when the secondary manufacturer is "acting as a wholesaler." The statutory definition of "wholesaler" includes other manufacturers, but no explicit definition is given of what it means to "act as a wholesaler." This will require greater clarification in the final rule. Pages 76-77 and 181.

- The proposed § 447.506 on authorized generic drugs does *not* require that the primary's sales to the secondary be distributed to RCPs to merit inclusion in the primary manufacturer's AMP. This may reflect

CMS's awareness of the difficulty in tracing RCP purchases from a secondary manufacturer. Pages 76-77 and 181.

Manufacturer Obligations

- CMS proposes to require that it report to the Office of Inspector General any manufacturer that does not submit monthly AMP, monthly AMP units, quarterly AMP or quarterly Best Price within the 30-day reporting window. Further, it proposes to subject late filers to civil money penalties of $10,000 per day per drug. Pages 100 and 107.

- Restatements of reported Medicaid figures outside the 12 quarter/36 month refiling window are proposed to be restricted to instances in which the requested refiling is due to (i) drug category or market date change, (ii) initial product submission, (iii) reentry of a terminated manufacturer, (iv) a technical correction, that is, not based on any changes in sales transactions or related pricing adjustments, or (v) to address underpayments to states or potential liability regarding underpayments. CMS also proposes to permit out-of-quarter restatements for "good cause" (including to permit a manufacturer to revise its methodology). As written, the ACA Proposed Rule does not easily provide for restatements beyond the window to recoup manufacturer *over*payments to states. Pages 101-103.

- CMS is considering placing a limitation on how far back a manufacturer may restate under any circumstances, and invites comment on the issue. Page 102.

- If a revision request is made for monthly AMP, then under the ACA Proposed Rule a revision request would be required for the related quarterly AMP. CMS also proposes the reverse, that is, if a request is made to change quarterly AMP, changes in constituent monthly AMPs must also be requested. This latter provision effectively shortens the three-year restatement window for AMP to 34 months. Page 102.

- CMS proposes to require manufacturers to submit approved FDA application numbers for all covered outpatient drugs. These numbers will help CMS locate information related to the approval status, application, and market authorization license under which a product is marketed. This requirement reflects a change to program administration and is not specifically set forth in the text of the proposed regulations. Pages 22-23.

State Pharmacy Reimbursement

- States currently reimburse pharmacies for covered outpatient drugs based, in part, on estimated acquisition cost ("EAC"). The EAC is the lower of (1) a percentage decrease applied to Average Wholesale Price ("AWP") or a percentage increase to Wholesale Acquisition Cost ("WAC"), or (2) the pharmacy's usual and customary charge to the public. CMS proposes to replace EAC with a new reference price — "actual acquisition cost" ("AAC") — which is based on actual pharmacy purchase price data. CMS references State support for this approach, noting that certain States have already begun to base some of their reimbursements on survey of pharmacy invoice prices. Pages 12-14; 109-111.

- CMS proposes that all States provide data to adequately support a transition to AAC. According to CMS, "[t]his supporting data could include, but is not limited to, a national survey, to create a database of actual acquisition costs that States may use as a basis for determining State-specific rates[,]" "a State survey of retail pharmacy providers[,]" "or other reliable data which reflects the pharmacy provider's price to acquire a drug." The Federal government recently began a pharmacy data collection project that might be relied upon in this context (despite its flaws). Page 126.

- In connection with the proposed change from EAC to AAC, the ACA Proposed Rule creates a new requirement that a State plan must describe the agency's payment methodology for drugs dispensed by a 340B covered entity, or by a pharmacy under contract with a participating covered entity. Page 128.

- CMS has proposed that a federal upper limit ("FUL") be established for each multiple source drug for which the FDA has rated *three* or more products therapeutically and pharmaceutically equivalent, and calculated using only therapeutically and pharmaceutically equivalent drugs. Under the ACA Proposed Rule, any other formulations of the drug listed in the FDA Orange Book that are not therapeutically and pharmaceutically equivalent to the reference listed drug, *e.g.*, "B" rated drugs, will not be used in the calculation of the FUL, nor will the AMP of an NDC which has been terminated. Pages 111-125.

- The ACA Proposed Rule establishes FUL reimbursement at 175 percent of the weighted average of monthly AMPs in the aggregate (*i.e.*, the weighted average of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drug products). Pages 117-118.

- CMS considered and rejected a specific methodology for smoothing the FULs, reasoning that changes in the AMP-based FUL caused by AMPs subject to fluctuations and variances in the generic drug market may be present even if a smoothing process were implemented above the smoothing process manufacturers are presently using for AMP. Pages 122-125.

- CMS proposes to keep the definition of "dispensing fee" unchanged, but replace the term "dispensing fee" with "professional dispensing fee" to reinforce its position that the dispensing fee should reflect the pharmacist's professional services and costs associated with the transfer of a covered outpatient drug to a Medicaid beneficiary. The ACA Proposed Rule also requires States to reconsider the fee methodology consistent with this emphasis. Page 32.

Federal Offset

- The ACA provides that the savings from increased minimum rebate percentages are to be remitted to the Federal government. The ACA Proposed Rule describes how this offset is to be undertaken for drugs that are subject to the 23.1%, 17.1% and 13% rebate percentages. Pages 96-98.

- For line extensions, CMS proposes to offset "the difference between [1] the URA for the drug calculated based on the applicable rebate percentage in section 1927 of the Act prior to the Affordable care Act and [2] the URA for the line extension drug, if greater, in accordance with the Affordable Care Act." It is unclear how the first figure will be calculated. This offset is proposed despite the fact that under the

statute, offset is triggered by increases in the minimum rebate percentage (§ 1396r-8(b)(1)(C)) and the Alternative URA is not subject to a minimum rebate percentage. Similarly, complicated offset provisions involving rebate percentages from 2009 are proposed for drugs dispensed to Medicaid managed care organizations. Pages 97-98.

- CMS does not propose to offset any portion of increased state supplemental rebates. Page 98.

* * * * *

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.