KING & SPALDING

Client Alert

FDA & Life Sciences Practice Group

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Final ACA Medicaid Drug Pricing Rule Published:

Changes to 5i, Bundling, RCP and Other Provisions Leave a Lot for Manufacturers to Consider

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On Thursday, January 21, the Centers for Medicare & Medicaid Services (CMS or "the Agency") published its long-awaited final rule with comment period implementing the Medicaid pricing and reimbursement provisions of the Patient Protection and Affordable Care Act ("ACA") and related legislation. A display copy of the final rule ("ACA Final Rule" or "Rule"), an astonishing 657 pages long, can be found **here**. The Federal Register is expected to publish its single-spaced, three-column version of the ACA Final Rule on February 1, 2016.

The ACA Final Rule has an effective date of **Friday, April 1, 2016** (which CMS believes will provide "adequate time for implementation"), and applies *prospectively* from that date.

One aspect of the proposed rule remains open for comment: the definition and identification of line extension products. The Agency is accepting additional comments on these issues *only*. Comments are due to CMS no later than **Friday, April 1, 2016 by 5 pm ET**. Rule at 5.

This Client Alert addresses the most important provisions of the ACA Final Rule affecting drug and biologics manufacturers, and provides King & Spalding's initial impressions and thoughts about policy, implementation, legality and impact. The page numbers provided refer to the display copy of the ACA Final 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**.

According to a CMS **press release**, the ACA Final Rule "clarifies many of the changes made to the Medicaid Drug Rebate Program by the Affordable Care Act and provides drug manufacturers with the regulatory guidance necessary to ensure proper calculation and reporting of drug product and pricing information." The Agency estimates that over the next 5 years (2016-2020), the ACA Final Rule will save state and federal governments approximately $2.7 billion, and cost drug manufacturers and states approximately $431 million. Rule at 613.

There is a lot in this lengthy Rule for drug and biologics manufacturers to consider and implement. We at King & Spalding stand ready to help our clients and friends understand, interpret and apply these complex Medicaid Drug Rebate Program requirements. We hope this Client Alert and our redline of the final regulations will be useful roadmaps to you and your company.

Highlights

- Provisions of this Rule are effective in less than three months, on April 1, 2016
- Presumed inclusion remains acceptable; buildup is not required
- Definition of "retail community pharmacy" *not* expanded to include entities "conducting business as" RCPs
- 5i "not generally dispensed" ratio changed from 90/10 to 70/30
- Price reporting and rebating in Territories to begin April 1, 2017
- Best Price excludes *all* sales to 340B covered entities, at whatever price and for whatever purpose
- Bundled arrangements are triggered by *contingent* price concessions
- Lots of regulatory ink on a simple patient assistance concept: the patient receives the value and no intermediary gets a price concession
- More comments on the definition of line extension sought, alternative URA calculation remains the same, and line extension analysis only applies if both drugs are sold by the same manufacturer
- "Narrow exception" created for certain drugs that should be treated as noninnovators
- Authorized Generic ("AG") transfer sales included in primary AMP only under certain narrow, unlikely and torturously supported circumstances
- Manufacturers are permitted to restate base date AMP until April 1, 2017
- FUL levels will never fall below NADAC-type calculations for the same drugs

Average Manufacturer Price

- CMS reversed the position it took in the proposed rule with regard to buildup vs. presumed inclusion. For a number of reasons, CMS will not require that manufacturers use the buildup methodology to calculate AMP, but may instead rely on the assumption that presumed inclusion is reasonable. Rule at 141-156. Note that CMS did not *mandate* the use of presumed inclusion, merely refused to require buildup, and permitted the use of presumed inclusion. We expect that this will come as a relief to most manufacturers, despite the upward pressure this methodology puts on Medicaid rebates, because buildup would have been an expensive, inaccurate and unreliable departure from established practice.
- Retail community pharmacy ("RCP")

- The Agency withdrew its proposal to include in the definition of RCP those "entities that conduct business as" wholesalers or RCPs (specifically, specialty pharmacies, home infusion pharmacies and home health care providers). Rule at 163. This is a somewhat stunning reversal from the proposed rule, in which CMS claimed it was compelled to add a "conducting business as" category to RCP based on the statutory language.

- CMS did so, it claims, because these three types of entities could fall under the existing definition of RCP, and the expansion was not required. Rule at 163. Therefore, where these entities (a) do not dispense medications primarily through the mail, and (b) qualify as independent, chain, supermarket or mass merchandizer pharmacies that are licensed and dispense to the general public at retail prices, sales to them would be included in standard AMP. Rule at 164-165.

- Manufacturers of 5i products should be particularly pleased by this turnabout. Had the "conducting business as" entities been included in the set of RCPs used to determine whether a 5i product is "not generally dispensed" to RCPs (see below), many drugs on the "not generally dispensed" margin would have been forced to use the standard AMP methodology and suffer the attendant increased Medicaid rebate liability.

- An entity that is a retail community pharmacy that provides home delivery, but that does not offer prescriptions primarily through the mail, is included in standard AMP. Rule at 161. A single entity that owns both a retail community pharmacy and a mail order pharmacy, however, must be treated as two different entities for standard AMP calculation purposes. *Id.*

- Sales included in and excluded from standard AMP

  - Sales to RCPs that give rise to TRICARE, Medicaid, SPAP and Part D rebates are to be *included* in standard AMP. Rule at 189, 201. There has been back and forth confusion regarding the treatment of these underlying commercial sales that give rise to excluded rebates. This provision of the ACA Final Rule should put that confusion to rest. Further, exclusion of SPAP rebates was specifically added to the regulations. Rule at 234.

  - Sales to standard AMP eligible entities in the Territories (and associated price concessions) must be included in standard AMP beginning April 1, 2017. Rule at 191.

  - Sales to charitable and not for profit pharmacies are excluded from standard AMP. Rule at 199. CMS has provided a link to an IRS publication that lists charitable and not for profit entities, with the clear expectation that manufacturers will research their customers against this list.

  - CMS reaffirmed its belief that price appreciation credits are retroactive price adjustments, cannot be bona fide service fees, and should be included in standard AMP when paid to wholesalers or RCPs. Rule at 206.

  - While customary prompt pay discounts paid to wholesalers are excluded from standard AMP, they are to be *included* when paid to RCPs. Rule at 208.

- Good faith is not an explicit condition of the exclusion of return transactions from standard AMP, but it is implicit in the regulation, CMS said, noting that returns intended to "manipulate prices" are not excludable from standard AMP. Rule at 210. Manufacturers are generally permitted to ignore the cost of returned goods; manufacturer may reasonably assume the cost of those goods with reference to internal price allowance accounting procedures. Rule at 212. Replacement product for returned goods may also be ignored in standard AMP, as long as no payment was received for the replacement product. Rule at 213-214.

- PBM and PBM mail order sales are excluded from standard AMP. Rule at 215. If a PBM owns a standard-AMP eligible entity, such as an RCP, manufacturers must make inclusion/exclusion determinations accordingly. Rule at 216-218. Absent knowledge that a PBM rebate or payment is being passed through to a standard AMP eligible entity, we may presume that it is not being passed through. Rule at 218.

- Sales to patients continue to be excluded from standard AMP. Rule at 221.

- The Agency briefly addressed non-I drugs (generally oral solids) that are not distributed through RCPs. For these "crack" drugs (*i.e.*, those that fall through the crack between the two methodologies), many manufacturers have been defaulting to the 5i AMP methodology for calculation. CMS blithely tells manufacturers of these drugs to base their AMP calculations on "any [standard] AMP eligible sales," that is, "to entities that meet the definition of a retail community pharmacy." Rule at 281. CMS believes that through reasonable assumptions, including presumed inclusion, manufacturers of "crack" drugs will find a comfortable home in standard AMP. We fear that there may be so few RCP sales for these products – if any at all, there is no minimum number in this final rule – that whatever AMP is calculated will look nothing like the average price the manufacturer receives for these products.

- If a manufacturer has no product sales in a given month, the manufacturer should carry forward the most recently reported positive monthly AMP calculation, but still report an AMP units value of zero. Rule at 455. This is important to ensure the integrity of the FUL system.

5i Average Manufacturer Price

- CMS backtracked from its requirement in the proposed rule that drugs be identified as one of the five i's with reference to the FDA's Routes of Administration file, saying that manufacturers can make their own determinations as to whether or not their products qualify as 5i. Rule at 237.

- "Not generally dispensed to RCPs"

  - CMS stepped back from its overly restrictive 90/10 standard (excluding from 5i AMP any drug for which 10% or more sales went to RCPs) to a more reasonable 70/30 standard. Rule at 244. Therefore, a 5i product with 70% or more of its sales to non-RCPs would be deemed to be "not generally dispensed to RCPs" and subject to the 5i AMP methodology. *Id.* A Medicare Part B standard was rejected because the "usually self-administered" test is 50/50, not 70/30. Rule at 248.

- The 70/30 determination is to be made with reference to *units*, not dollars, and is to be made at the NDC-9 level. Rule at 245. The determination is to be made and reported to CMS *monthly*, and, remarkably, products that switch month-to-month must be included in quarterly AMP *as calculated* (*e.g.*, month 1: standard AMP, month 2: 5i AMP; month 3: standard AMP). Rule at 260-261 and 263. The potential for monthly AMP variability and quarterly calculated AMPs that look nothing like any of the monthly AMPs is very real. Manufacturers may, but are not required to, smooth the 70/30 determination over a period of time, such as a year, which may reduce methodology variation, but that is by no means guaranteed. Rule at 246.

- In making the 70/30 determination, manufacturers must include as sales to RCPs those to specialty pharmacies, home infusion pharmacies and home health care providers *that otherwise qualify as RCPs*. Rule at 254. They are not automatically included as "conducting business as" RCPs. As noted above, the effect of this reversal will be to keep many infused, injected, implanted, instilled and inhaled products in the 5i AMP calculation.

- CMS rejected suggestions to provide for two base date AMPs for products that might fluctuate between the standard and 5i methodologies. Rule at 256. Not only does the statute not provide for two base date AMPs, CMS said, but the smoothing permitted in the 70/30 determination should obviate the concern about base date AMP – current quarter AMP mismatch. *Id.* We are concerned, however, about the effect on inflation penalty calculations of a product the base AMP for which is calculated under the 5i methodology, but that has a quarter (or several quarters) under the standard AMP due to 70/30. The unwarranted inflation penalty rebate could be enormous under this circumstance.

- The Agency agreed to add an indicator to DDR to reflect which methodology was used by the manufacturer to calculate AMP. Rule at 263.

- 5i methodology inclusion/exclusion rules

  - Aiming to track the standard AMP inclusion/exclusion provisions of the regulation, the ACA Final Rule creates a new §447.504(e) that set out the entities that are to be excluded from 5i. Rule at 270. §447.504 now has four subsections addressing inclusion/exclusion:

    - 504(b) – included in standard AMP;
    - 504(c) – excluded from standard AMP;
    - 504(d) – included in 5i AMP; and
    - 504(e) – excluded from 5i AMP.

  - 5i AMP includes sales to and associated transactions with all of the standard AMP eligible entities and, in addition, those entities listed in 504(d). Essentially, 5i AMP includes all sales to any purchaser other than those articulated in §447.504(e).

  - The list of 5i AMP excluded entities mirrors that of Best Price excluded entities extremely closely, with just a few differences:

    - Customary prompt pay discounts to wholesalers are excluded from 5i AMP, but not Best Price.

- All sales to patients are excluded from 5i AMP, but only direct sales to patients are excluded from Best Price.
- Sales to government, charitable and not-for-profit pharmacies are specifically excluded from 5i AMP but aren't specifically mentioned in the Best Price inclusion/exclusion rules.
- All *bona fide* service fees ("BFSFs") paid to any provider are excluded from Best Price, but only those paid to wholesalers and RCPs are excluded from 5i AMP. Remarkably, this was intentional. CMS believes it lacks the statutory authority to exclude BFSFs paid to entities other than wholesalers and RCPs from 5i AMP, and mistakenly, believes the universe of applicable fees to be those for distribution services, inventory management, product stocking and administrative service and patient care programs. Rule at 272. This ignores the many, many other types of service fees manufacturers pay to 5i eligible entities such as PBMs, insurers, hospitals and others. The rule, as written, would have us include any service fees paid to these entities in 5i AMP whether they were *bona fide* or not.
- All sales to and associated transactions with PBMs are included in 5i AMP. In Best Price, only those PBM sales and transactions with a PBM's mail order pharmacy, or those PBM transactions that are designed to affect the price at the retail or provider level are to be included. Most manufacturers assume that their transactions with PBM non-mail order are indeed designed to affect the downstream price, so are included in Best Price, making the treatment in 5i AMP and Best Price the same.

Quarterly AMP Calculation

- CMS set out a methodology for the calculation of quarterly AMP ("a weighted average of monthly AMPs in that quarter"). Rule at 286. Specifically, where the subscript refers to each of the months in the quarter, Quarterly AMP =

$$\frac{(AMP_1 \text{ times } Units_1) + (AMP_2 \text{ times } Units_2) + (AMP_3 \text{ times } Units_3)}{(Units_1 + Units_2 + Units_3)}$$

- As noted above, the AMP methodology may vary month-to-month (if for instance, a 5i product is found to be not generally dispensed to RCPs in one month and not in the next). Rule at 260-261 and 263. In these circumstances, actual calculated monthly AMPs are to be used in the formula above to calculate quarterly AMP.

Best Price

- The ACA Final Rule does not specifically address when "stacking" must be undertaken, but instead relies on the "all price concessions that adjust the price realized by the manufacturer" language to effectuate a stacking requirement. Rule at 290.

- The Agency obliquely recognized the value of value-based purchasing arrangements, and said that it is "considering how to provide more specific guidance on [value-based arrangements], including how such arrangements affect a manufacturer's best price." Rule at 291.

- A specific exclusion from Best Price for "direct sales to patients" was added. Rule at 293. No explanation, however, was given as to why indirect sales to patients (non-entities, after all) would be included in Best Price.

- The ACA Final Rule makes several adjustments to the Best Price rules to align them with the AMP rules, specifically with regard to manufacturer patient assistance and free goods programs. Rule at 294-297.

- Sales to other manufacturers for use in a clinical trial are included in Best Price, but only where the manufacturer is a Best Price eligible entity. Rule at 298. Manufacturers are only Best Price eligible entities when they meet the definition of "wholesaler," that is, when they are engaged in the wholesale distribution of prescription drugs to RCPs. Therefore, when the purchasing manufacturer uses the drugs in a clinical trial, it is not engaged in the wholesale distribution of drugs and those sales are therefore not Best Price eligible. *Id.*

- Sales to Best Price eligible entities in the Territories must be included in Best Price beginning April 1, 2017. Rule at 193. This rule has the potential to cause significant disruption of sales arrangements within the Territories as manufacturers pull back discounts to Territorial purchasers that would set Best Price throughout the nation. Further, much remains to be seen as to how certain Territorial government mandated price concessions will be treated by CMS in the next year. If these price concessions are not deemed to be Best Price ineligible (as are government-mandated prices within the 50 states and D.C.), manufacturers may have to broadly reconsider the cost of marketing their products in the Territories.

- CMS abandoned its proposed language that would have included in Best Price only the 340B prices charged "under the 340B Drug Pricing Program." CMS recognized that under the statute, *any* prices charged to a covered entity (including sub-ceiling sales and inpatient sales to disproportionate share hospitals) are Best Price ineligible. Rule at 304. This is very good news for manufacturers, who, under the proposed rule, faced the prospect of having to evaluate each sale to a covered entity as having been 'under the program' or face significant Best Price exposure. Further, CMS appears to believe that inpatient prices to the non-DSH hospital covered entities are Best Price exempt. Rule at 308. It is unclear whether HRSA would agree with this conclusion because drugs for inpatients are not included in the 340B program. We will have to wait and see how HRSA reacts to this CMS provision.

- The Agency revised §447.508 to more closely align the nominal sales exception from Best Price with language in PPACA. Rule at 323. CMS refused to expand the list of entities subject to the Best Price nominal sales exception. Rule at 324. It also refused to publish a list of entities subject to the exception. Rule at 326-327.

Average Manufacturer Price and Best Price

- *Bona fide* service fees ("BFSFs")

    - CMS recognized that its three proposed definitions were inconsistent, and streamlined to adopt and refer to the definition in §447.502 throughout. In addition, CMS clarified in the ACA Final Rule that BFSF analysis must be conducted on fees to entities other than wholesalers and RCPs, but not on fees paid to entities that are not AMP or Best Price eligible, as appropriate. Rule at 30 and 36.

    - One of the seminal questions regarding BFSFs since the passage of the ACA is whether the four service fees listed at 1927(k)(1)(B)(i)(II) are either (a) BFSFs without any further analysis, or (b) potential BFSFs that must be subjected to the four part regulatory test. Most of us suspected the latter due to the language in the proposed rule. Unfortunately, the ACA Final Rule leaves open the possibility that (a) may be the correct answer:

- "[W]e believe that the examples provided in the [ACA] (including stocking allowances) … are bona fide service fees and sufficient to provide manufacturers with a general sense of the types of such fees." Rule at 35.

- "Furthermore, fees, including but not limited to, distribution service fees, inventory management fees, product stocking allowances, fees associated with administrative service agreement and patient care programs (such as medication compliance programs and patient education programs) and other fees paid to GPOs that meet the definition of bona fide service fees as defined in this final rule, are excluded from the calculation of AMP and best price." Rule at 42.

Assuming "that meet the definition of bona fide service fees," above, modifies just fees paid to GPOs, these two sentences, taken together, do not definitively tell us that the four statutory examples definitively must be subjected to the four part test. This is disappointing and confusing. One wonders how a system that does not require the application of the BFSF test to certain fees will operate fairly and competently.

- The determination of fair market value must be articulated by the manufacturer and made contemporaneously with the payment of the fee. Rule at 40. Manufacturers may rely on "any" documentation to establish FMV, "provided that it makes clear the methodologies or factors the manufacturer used" in making the FMV determination. Rule at 39. This would appear to include, if sufficient, documentation demonstrating rigorous negotiation with the service provider. Rule at 38. CMS refused to establish a safe harbor for the calculation of fair market value, saying it lacked the authority to do so. Rule at 40.

- CMS refused to permit manufacturers to rely on the AKA GPO safe harbor as a proxy for BFSF determination. Rule at 40.

- Bundled arrangements

  - Recognizing that noncontingent arrangements should not require the application of bundle math, CMS withdrew the "but not limited to" language of the proposed rule's definition. Rule at 46. This is a very welcome development. Manufacturers now can concentrate their efforts on identifying arrangements that truly deserve to be called "bundles" – that is, those with price concessions contingent on purchase or performance requirements – and on allocating those contingent discounts appropriately.

  - Bundled arrangements can be based on the purchase of a product that is not a covered outpatient drug: the regulatory definition was modified to include "product." Rule at 49.

  - "Bundled arrangement" = "bundled sale." The terms are interchangeable. Rule at 49.

- Patient assistance

- CMS undertook some housekeeping with regard to all forms of patient assistance in the ACA Final Rule. It established consistent and parallel provisions in the regulations excluding from standard AMP, 5i AMP and Best Price all benefits to patients of coupons, drug discount programs, manufacturer refund/rebate programs, copayment assistance programs and manufacturer free goods programs.

- In each of the programs, benefits to patients are excluded from all price types as long as no amount of the benefit was retained by the pharmacy, agent or other entity administering the benefit.

- Only one idiosyncratic requirement remains: manufacturer free goods programs may not be contingent on any purchase requirement to the patient. This requirement is a vestige of the free goods exclusion found elsewhere in the regulations.

- The Agency was asked if a pharmacy or other eligible entity received a price concession, and not a *bona fide* service fee, under one of these arrangements, would the cure be to include the price concession in AMP or Best Price, and leave the discount to the patient out? Or would the fact that a price concession was extended cause all discounts, including those to the patient, to be included in the pricing metrics? CMS did not answer the question. Rule at 231.

Line Extensions

- As noted above, CMS has decided *not* to finalize the proposed definition of line extension drug at this time, and seeks comment on what that definition should be. Rule at 98 and 334. CMS was apparently persuaded that its proposed definition included too many or the incorrect types of changes to a drug that would constitute a line extension. CMS is also seeking comment on the means of identification of a line extension. Rule at 335. For the moment, manufacturers are to rely on the statutory definition of line extension at section 1927(c)(2)(C) and make reasonable assumptions, as necessary, to determine if their products are line extensions. *Id.*

- The Final Rule finalizes the method of line extension URA calculation as it was proposed, and as it appears in the MDRP statute. That is, the line extension's URA is the greater of (a) the standard URA, or (b) the Alternative URA, which is the product of the line extension AMP and the highest additional rebate of any strength of the original drug. Rule at 342. The Obama Administration has suggested that it wants to revise this calculation to increase the Alternative URA, but it has become clear that to do so will require Congressional action.

- Recognizing the complexities and incentives implicated by their proposed rule, the Agency limited the line extension provision to provide that a drug by one manufacturer will *not* be treated as a line extension of a drug by a different manufacturer unless there is a corporate relationship between the two manufacturers. Rule at 338 and 344. Authorized generics marketed by the same company as the initial product may well be line extensions. Rule at 342.

- If no initial brand listed drug(s) are active in the Medicaid program, no Alternative URA can be calculated for the line extension. Rule at 340.

- Manufacturers will not be required to submit to CMS URAs or additional rebate-to-AMP ratios. Rule at 346. We will be required, however, to identify line extension drugs and the initial brand name listed drug with the highest additional rebate ratio (where there is a corporate relationship between the manufacturers of the brands). *Id.*

- While CMS is waiting to prepare guidance on the definition of a line extension drug, it said that new strengths of existing formulations, without more, do not constitute line extensions. Rule at 341. Different strengths of line extensions, however, are still line extensions subject to the Alternative URA calculation. *Id.* Additional guidance on DDR data fields for this purpose will be forthcoming.

- The Agency rejected arguments that the federal government cannot offset amounts related to the line extension rebate, and explained in detail – and with examples – how the federal offset of line extension URAs would be calculated. Rule at 348-351.

Medicaid Rebate Issues

- The ACA Final Rule reaffirms that only drugs indicated for use in children up to 16 years of age (that is, until their 17th birthday) qualify for the smaller 17.1% minimum Medicaid rebate percentage. Rule at 106. CMS rejected numerous attempts to redefine pediatric at ages above 16. How a manufacturer may establish the pediatric only indication, however, was expanded beyond "as specified in the Indications and Usage section of the FDA approved labeling" to also include through "an explanation elsewhere in the labeling that makes clear that the drug is approved for use only in the pediatric age group, or a subset of this group." Rule at 108. Further, CMS made clear that one dosage form and strength of a product (generally, one NDC-9) could qualify for the 17.1% minimum rebate percentage because of its particular label and usage, while other NDC-9s within the product family may not. Rule at 112.

- The Agency finalized its redefinitions of "State" and "United States" to include the five territories – Puerto Rico, U.S. Virgin Islands, Guam, American Samoa and the Northern Mariana Islands – **effective April 1, 2017**. Rule at 121. The extra year was given to address not insubstantial implementation concerns raised by both territories and manufacturers – according to CMS, there is nothing that can't be fixed with 12 months' lead time. The territories may exercise their waiver authority and choose not to participate in the MDRP. Rule at 121. Manufacturers will be obliged to pay rebates on Medicaid utilization in the participating territories beginning 2Q 2017, and to simultaneously include sales and price concession data in their AMP and Best Price calculations. Inclusion/exclusion rules for particular purchasers in the territories are addressed above.

- Faced with comments and complaints about the proposed MCO reporting requirements, the Agency will not finalize its 30-day data submission requirements, but may offer guidance in the future. Rule at 356-357. Instead, the final rule addresses MCO data in the state reporting requirements regulation at §447.511. *Id.* While not providing specific penalties for failure to do so, CMS reminded states that they are required to ensure that the mechanism used to avoid duplicate discounting or rebates on 340B drugs applies to Medicaid MCO utilization; it is the states' responsibility to instruct their MCOs to exclude 340B units from its utilization data. Rule at 362 and 364-365. Finally, CMS called on states to include MCO utilization based on the date dispensed (date of service) rather than the claim paid date (the date for fee-for-service inclusion), because MCO utilization is susceptible to considerable lag. Rule at 367.

Drugs Subject to Reporting and Rebate Payment

- Covered outpatient drugs ("CODs")
    - The ACA Final Rule eliminates the requirement that drugs be listed electronically with FDA to qualify as CODs. Manufacturers are still required to demonstrate that their products meet the definition of a COD in Section 1927(k)(2), however. Rule at 54-55.
    - Drugs that are billed as part of a bundled service listed in Section 1927(k)(3) are CODs "if the state authorizes and provides a direct payment for the drug consistent with an approved state plan, separately from the service." Rule at 66. Therefore, a drug can be COD in one state and not in another. *Id.* Our impression of this language is that CMS is saying that if a drug *may be* billed separately by a state, the manufacturer must compute and report AMP and/or Best Price data to CMS: the state will determine if utilization is rebateable.
    - Radiopharmaceuticals are CODs if they are approved under Section 505 of the FDCA unless they aren't reimbursed separately per Section 1927(k)(3). Rule at 64.
    - Prescription prenatal vitamins and fluoride preparations are CODs, but medical foods are not. Rule at 69-70.
- CMS acknowledged that its omission of the word "original" before "NDA" in the proposed definition of a single source drug and an innovator multiple source drug was in error, but maintained that substantively, the equation of "original NDA" to "NDA" was still appropriate. Rule at 77 and 118. Nevertheless, CMS articulated a "narrow exception" to this rule that will be very important for certain manufacturers. Specifically, where a manufacturer can demonstrate that an NDA drug might more appropriately be considered a noninnovator, it can apply (before March 31, 2017) to CMS for that treatment. Examples of drugs that might qualify include: drugs approved under a paper NDA prior to the Hatch-Waxman amendments of 1984, certain types of literature-based 505(b)(2) NDA approvals and certain parenteral drugs in immediate plastic containers. CMS will issue additional guidance on the scope of the "narrow exception" in the future. Rule at 78-79.
- A product reported as a noninnovator that subsequently receives FDA approval that would require a recategorization as an innovator drug may, if launched under a new NDC-9, establish a new base date AMP based on the first full quarter after the newly approved drug's market date. Rule at 102-103.

Authorized Generics

- While the statutory definition of "wholesaler" includes "manufacturers," according to CMS, "it does not mean all manufacturers are wholesalers." Rule at 133. Only those manufacturers that are "engaged in wholesale distribution of prescription drugs to retail community pharmacies" are wholesalers. *Id.* What is meant by this is addressed (unhelpfully) only in the negative: secondary manufacturers that relabel or repackage a drug purchased from a primary manufacturer and sell that drug "to wholesalers (as opposed to engaging in the wholesale distribution to retail community pharmacies)" are *not* wholesalers. Rule at 315-316. Later in the Rule, CMS gives as an example of a manufacturer that does not qualify as a wholesaler as one that "sells [the drug] directly to retail community pharmacies." Rule at 318. So a "wholesaler" does or does not distribute to retail community pharmacies? There is no clear, positive definition of what "engaged in wholesale distribution of prescription drugs to [RCPs]" actually means. Despite this confusion, primary manufacturers are responsible for determining whether a secondary manufacturer "acts like a wholesaler." Rule at 314. Incidentally, "acts as a wholesaler" is a term mistakenly attributed by CMS to the statutory definition of wholesaler at Section 1927(k)(11), when indeed it was just part of CMS's proposed rule. Rule at 315.

- The Agency, believing that its negative definition of "wholesaler" as described above has some foundation in the statute, declares categorically that a primary manufacturer may not include in its AMP transfer sales to a secondary manufacturer who relabels the product with its own NDC. Rule at 319. Marketing an AG under its own NDC means that "the secondary manufacturer would not be acting as a wholesaler, as defined at section 1927(k)(11) of the Act." *Id*. Of course, that section says nothing about relabeling. The statutory definition of *manufacturer* includes entities that label or relabel products, and says that "manufacturer" does not include a wholesale distributor of drugs." Section 1927(k)(5). Then again, the same definition includes entities that "distribute drug products," hardly compatible with excluding wholesalers. We find it attenuated indeed to impose a "no relabeling" condition on wholesalers when one does not exist in the statute, and the support for which (in a different sub-paragraph) is so circular as to include drug distributors in the definition of "manufacturer."

- When a single manufacturer markets both the original and authorized generic under a common NDA, the AMP and Best Price calculations are to be blended across the NDC-9s. Rule at 316-317. Of course, the ACA Final Rule doesn't provide guidance as to when two separate but affiliated companies are to be considered a "single manufacturer." Manufacturers will have to utilize reasonable assumptions to make this determination.

Manufacturer Obligations

- Civil Monetary Penalties (CMPs): CMS withdrew its proposal to automatically impose CMPs on manufacturers for late reporting of AMP and/or Best Price data. Rule at 373. Rather, the Agency will continue its current policy of referring to HHS OIG manufacturers that do not report the required data and/or that report this data untimely. Rule at 373-377.

- Suspension and Termination Procedures for Manufacturers Not in Compliance with Reporting and/or Rebate Requirements: CMS declined to finalize any suspension or termination procedures but noted that it may issue additional guidance on this issue at a later date. Rule at 379.

- Recalculations:
    - Price Adjustments Outside of the 12-Quarter Window: CMS confirmed that it is only finalizing the five categories of situations where manufacturers are permitted to restate beyond the 12-quarter time limit identified in the ACA Final Rule under §447.510(b)(1), but will continue to consider other possible scenarios for price submissions outside of the 12-quarter window, and may issue additional guidance or rulemaking in the future.
    - Recalculations for Good Cause: Based on concerns raised by commenters, including ambiguity regarding what constitutes "good cause," CMS declined to finalize the option for manufacturers to submit a recalculation request outside of the 12-quarter time limit based on good cause. The good cause recalculation option was proposed to provide a broader alternative where a manufacturer could submit such request to recalculate for reasons other than those that stem specifically from a change in the methodology for calculating AMP and/or Best Price. Rule at 381.
    - Clarification of "Underpayment:" CMS revised §447.510(b)(1)(v) to specify that a change in pricing data outside of the 12-quarter rule would be considered if the change proposed were to address specific rebate adjustments to states by manufacturers, as required by CMS or court order, or under an internal investigation (*i.e.*, a manufacturer's internal investigation), or an OIG or DOJ investigation. CMS revised the provision in response to comments arguing that CMS should not "'cherry pick' among revisions requests outside of the 12-quarter rule," and that the Agency should "consider allowing pricing changes for both overpayment and underpayment to states." CMS indicated that the change in wording was intended to reflect that the Agency would consider a change request in cases where there is an underpayment or an overpayment to the states that is discovered outside of the 12-quarter filing limit. Rule at 384-385.
    - Timeline for Closing Disputes: CMS declined to propose any time line for closing disputes, stating that the Agency may consider such time lines in the future, but it is outside of the scope of the rule. Rule at 385.
    - CMS reiterated its expectation that any revision to pricing data must be consistent across the monthly and quarterly AMP submissions. Thus, manufacturers should submit revision requests for monthly AMP changes that exceed the 36-month period in accordance with §447.510(b)(1) (which outlines the procedures for submission of quarterly revision requests by manufacturers).
- Base Date AMP:
    - Manufacturers may have one, and only one, base date AMP for a covered outpatient drug, whether that base date AMP is calculated using the standard methodology or the 5i methodology. Rule at 397-398. CMS believes that by (a) adopting a 70/30 standard rather than a 90/10 standard, and (b) allowing smoothing in the determination of "not generally dispensed," products will be unlikely to switch back and forth between the two AMP methodologies (necessitating two base date AMPs to fairly calculate the inflation rebate). Whether they are correct about this remains to be seen.

- For new products introduced after the effective date of the ACA Final Rule, the base date AMP will be calculated consistent with the current policy on calculating base date AMP. That is, if a 5i drug in the first full calendar quarter after the day the drug is first marketed meets the "not generally dispensed" threshold, the manufacturer is responsible for calculating base date AMP for that drug using the 5i AMP methodology. If a 5i drug in the first full calendar quarter after the day in which the drug is first marketed does not meet the "not generally dispensed" threshold, the manufacturer is responsible for calculating base date AMP using the standard AMP methodology. Rule at 398.

- Manufacturers will have the ability to report an ACA base date AMP, as provided in the ACA Final Rule, on a product-by-product basis, regardless of whether they chose to recalculate and report a DRA base date AMP. Rule at 391, 393. Any such recalculations must be submitted by April 1, 2017. Rule at 395. We suspect that the base date AMPs of standard AMP products will be recalculated and resubmitted more often than those of 5i AMP products because standard AMP calculations will likely result in higher AMPs than those calculated in the pre-ACA period. Higher base date AMPs are, of course, advantageous when calculating the inflation penalty part of the Medicaid URA.

- CMS will provide operational guidance on how manufacturers may report the ACA base date AMP if a manufacturer decides to recalculate its base date AMP. Rule at 399.

- CMS confirmed that it does not expect manufacturers to restate their AMP and Best Price retroactively to the fourth quarter of 2010 (the effective date of the ACA) as a result of the ACA Final Rule, as the provisions of the final rule are effective on a prospective basis. Rule at 400.

- In light of the comments it received, CMS modified its position on requiring manufacturers to calculate AMP using the buildup methodology. Thus, manufacturers will be able to recalculate base date AMPs using the presumed inclusion methodology. Rule at 392.

- Manufacturers must maintain actual and verifiable documentation that supports base date AMP recalculations. CMS has adopted the same standard it used with the DRA base date AMP calculation and declined to change that standard. Rule at 393.

- *Calculation of Monthly AMP:*

  - The requirement to use the 12-month rolling percentage to estimate the value of lagged price concessions is effective on a prospective basis. Rule at 401. CMS did not propose any requirements regarding the smoothing of lagged ineligible sales, but stated that it agreed "that it is reasonable for manufacturers to make reasonable assumptions and use the same or similar methodology used for ASP calculations to smooth lagged ineligible-AMP sales when calculating the monthly AMP." Rule at 410.

Pharmacy Reimbursement and Federal Upper Limits

- The ACA Final Rule addressed provisions of the regulation regarding Actual Acquisition Cost (AAC), professional dispensing fees, pharmacy profit margin and other matters having to do with how states set pharmacy reimbursement (particularly pages 421-437) that we will not cover in this Client Alert. We will focus instead on the key aspects of the Federal Upper Limit regime.

- States that need to amends their Medicaid State Plans ("SPAs") to accommodate the FUL provisions of the ACA Final Rule may have one year from the effective date of this Final Rule (that is, until April 1, 2017) to submit a compliant SPA. Rule at 489.

- In response to comments that the 175% of the weighted average of monthly AMPs may provide a FUL reimbursement that is too low, CMS agreed to provide an exception when that amount is less than the average pharmacy acquisition cost (*e.g.*, NADAC) for those drugs. In those circumstances, CMS will utilize a higher multiplier such that the FUL reimbursement will equal the average acquisition cost. Rule at 440.

- CMS will not include 5i drugs that are not generally dispensed by RCPs in the FUL calculations, nor will it apply the FUL to 5i drugs that are not generally dispensed to RCPs. Rule at 441.

- Authorized generic products will be considered when (a) determining if three therapeutically and pharmaceutically equivalent (A-rated) products are on the market and (b) calculating the FUL. Rule at 445.

- FULs will not apply to B-rated products. Rule at 448. Furthermore, product groups that do not have the same unit type reported are not subject to FUL application. Rule at 449. The AMP of a terminated NDC will not be used to calculate a FUL, beginning on the first day of the month after the termination date reported to CMS. Rule at 453-454.

- The commenters pointed out issues relating to the AMP-based FUL files that have been made available in draft for several months. Products and product groups fall in and out of the reports; some product groups has significant price swings month-to-month; some drugs may have been placed in the incorrect product groups. Rule at 472-473. CMS responded by noting that there will be fluctuation in any upper limit calculation, that they will improve the data integrity part of the process and that defaulting to NADAC-like amounts when the FUL calculation falls below NADAC will reduce the harm of occasional price variability. Rule at 475.

- The FULs will be finalized and published in April 2016 after this ACA Final Rule is effective. Rule 480.

- No smoothing mechanism will be applied to the FULs at this time. Rule at 482.

State Plan Requirements

- States must consider both ingredient cost reimbursement and professional dispensing fee reimbursement when proposing changes to either of these components of Medicaid COD reimbursement. Rule at 487.

- States may propose tiered dispensing fees based on pharmacy type (*e.g.*, chain, non-chain, or 340B, non-340B). Rule at 490 and 513.

- States should use reliable and accurate data to establish an AAC model of reimbursement. Rule at 493. Any AAC based model must ensure that Medicaid providers are adequately reimbursed. *Id.*

- AMP-based reimbursement regimes for single source products could work, as long as they ensure that pharmacies are reimbursed at a price that reflects AAC, and take into account wholesales markup. Rule at 504. States that wish to consider AMP-based reimbursement must also consider the AMP confidentiality provisions of the Medicaid statute. Rule at 505-506.

- The Agency said that it would consider a reimbursement methodology for 340B dispensaries under which a state set ingredient cost at AMP less URA (that is, a sector-specific AAC), plus a reasonable professional dispensing fee. Rule at 514. One wonders how significant the effect on 340B covered entities would be if such a spread-less reimbursement SPA were approved.

- States may provide coverage of investigational drugs in Medicaid, and will only receive FFP for these drugs when coverage is established in the state plan. Rule at 530-531.

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The King & Spalding Government Pricing Compliance Team is ready to assist you in evaluating and implementing the provisions of the ACA Final Rule, as well as in preparing comments regarding line extensions. Please keep us in mind if there is any way we can help. For more information, please contact any of the Team members on the first page of this Client Alert, or see our **Practice at a Glance**.