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E-ALERT | Health Care

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CMS ISSUES PROPOSED RULE TO IMPLEMENT DRUG PRICING AND REBATE PROVISIONS OF THE AFFORDABLE CARE ACT

On February 2, 2012, the Centers for Medicare & Medicaid Services (CMS) published a proposed rule that would implement sections of the Affordable Care Act (ACA) and make other revisions to the Medicaid Drug Rebate Program (MDRP). The proposed rule addresses a broad range of issues related to the determination of average manufacturer price (AMP), determination of best price, treatment of line extension drugs, treatment of authorized generics, exclusions of nominal price from best price, rebate calculations under new formulas, requirements for manufacturers, federal upper reimbursement limits, and requirements for states. In addition, the proposed rule includes many new or revised definitions. This alert summarizes the significant areas where the proposed rule departs from the status quo.

WHAT'S NEW IN THE PROPOSED REGULATION

- The proposed rule includes rebate calculation formulas as revised by the ACA and provides for new rebates to Medicaid managed care organizations.
- CMS defines "retail community pharmacies," now the crux of the definition of AMP under the ACA, as being "licensed as a pharmacy by the State" and dispensing "medications to the general public at retail prices." CMS clarifies that specialty pharmacies, home infusion pharmacies and home healthcare providers should be considered retail community pharmacies and so sales to them are included within AMP.
- CMS proposes to require that, to include sales to wholesalers in AMP, a manufacturer must document that the product was ultimately resold to a retail community pharmacy and cannot rely on a policy of "presumed inclusion."
- CMS proposes that a manufacturer that holds the new drug application (NDA) for an authorized generic drug must include, in its calculation of AMP, sales of authorized generic drugs that have been sold or licensed to other manufacturers authorized to sell the drug acting as a wholesaler, as well as sales directly to wholesalers.
- The proposed rule would revise the definition of "United States" to include the territories, meaning that sales in the territories would be included in the MDRP both for purposes of price reporting and payment of rebates.
- CMS proposes to exclude from the definition of "covered outpatient drug" any drug product for which a National Drug Code (NDC) is not required by the FDA or that is not listed electronically with the FDA; any drug product or biological used for a medical indication which is not a medically accepted indication; and over-the-counter products that are not drugs.
- The proposed rule provides that "covered outpatient drugs," on which MDRP rebates are paid, do not include drugs, biologic products, or insulin that are billed as bundled services with, and that

are "provided as part of or incident to and in the same setting as," certain services such as inpatient hospital, outpatient hospital, and physician services.

- Under the proposed rule, in order to qualify as "bona fide service fees," fees must be paid by manufacturers to wholesalers, retail community pharmacies, or group purchasing organizations (GPOs).
- The proposed rule provides that a manufacturer's calculation of AMP will exclude "[s]ales to PBMs [pharmacy benefit managers], including their mail order pharmacy's purchases."
- Because inhaled, infused, instilled, implanted, and injectable drugs (so called "5i drugs") are not generally dispensed through a retail community pharmacy, a manufacturer's calculation of AMP for a 5i drug must also include several additional sales, discounts, rebates, payments, and other transactions otherwise excluded from AMP. Also, CMS proposes that it is the manufacturer's responsibility to identify, on a monthly and quarterly basis, which covered outpatient drugs are 5i drugs. Manufacturers would look first to the FDA's Routes of Administration list to identify the delivery method and then assess whether 90 percent or more of the sales of the drug during a reporting period were to entities other than retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies.
- CMS explains that it views voluntary sub-ceiling prices charged to 340B entities to be outside the 340B program and thus includable in best price.
- The proposed rule excludes purchases by certain college or university family planning or health clinics and certain non-profit clinics that serve the 340B population from best price calculations.
- CMS proposes a definition of line extension, for which the ACA provides an alternative rebate calculation that takes into account the prices of other drugs in the line, as a drug in oral solid dosage form that has obtained FDA approval "as a change to the initial brand name listed drug in that it represents a new version of the previously approved listed drug." CMS also provides examples of line extensions, to include "a new ester, a new salt, or other noncovalent derivative; a new formulation of a previously approved drug; a new combination of two or more drugs; or a new indication for an already marketed drug," regardless of whether it is approved under an NDA or a supplemental NDA. The CMS proposal excludes a new strength of the initial brand name drug from the definition.
- CMS proposes imposing civil monetary fines of $10,000 per drug per day if a manufacturer fails to submit its quarterly or monthly AMP for a product within 30 days of the end of a rebate period.

CALCULATION OF AMP FOR DRUGS OTHER THAN 5I DRUGS

The proposed rule would enact new requirements regarding the AMP calculation applicable to most covered outpatient drugs.

Under the proposed rule's definition, a covered outpatient drug's AMP is "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to retail community pharmacies, and by retail community pharmacies that purchase drugs directly from the manufacturer" (emphasis added). The ACA's revisions to the statute also included certain payments, discounts, rebates, and other transactions that are either explicitly included in or excluded from the calculation of AMP. The proposed rule adopts these provisions and includes additional guidance described below.

Sales Included in Calculation of AMP

- Sales to Retail Community Pharmacies: Under CMS's proposed definition, a retail community pharmacy is "an independent pharmacy, a chain pharmacy, a supermarket pharmacy, and a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices." The definition explicitly "does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers." Direct sales to retail community pharmacies are included in AMP.
- Sales to Wholesalers: CMS proposes to define a "wholesaler" as "a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies." CMS specifies that this includes, but is not limited to, "manufacturers, repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer's and distributor's warehouses, chain drug warehouses, and wholesale drug warehouses), independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions." Wholesalers are not limited to entities with a state license. Sales to wholesalers for drugs distributed to retail community pharmacies are included in AMP.
    - No "Presumed Inclusion Policy" for Sales to Wholesalers: CMS proposes to reject the policy that would allow manufacturers to include sales to wholesalers in AMP unless there is adequate documentation that the drugs were subsequently resold to an excluded entity (i.e., to an entity other than a retail community pharmacy). Instead, CMS proposes to require that manufacturers include sales to wholesalers in AMP only if the manufacturer can document that the product was ultimately resold to a retail community pharmacy. CMS acknowledges that this approach may be burdensome for manufacturers. It will be especially so for situations involving authorized generics, where (as discussed below) a primary manufacturer would be required to identify data identifying the purchasers from a secondary manufacturer in order to calculate the AMP of a branded drug.
- Other Sales: In addition, CMS proposes including the following sales in the definition of AMP:
    - Sales to Other Manufacturers: The proposed rule's calculation of AMP would include sales to other manufacturers that are acting as wholesalers (as defined above) for drugs that are distributed to retail community pharmacies.
    - Sales to Entities Conducting Business as Wholesalers or Retail Community Pharmacies: CMS proposes that the calculation of AMP include sales "to entities that conduct business as wholesalers or retail community pharmacies, which includes but is not limited to specialty pharmacies, home infusion pharmacies and home healthcare providers." While specialty pharmacies, home infusion pharmacies and home healthcare providers are not listed in the definition of a "retail community pharmacy," they may offer drugs to the general public at retail prices. CMS proposes including these additional transactions in the calculation of AMP to account for the fact that certain covered outpatient drugs are primarily or solely dispensed through entities that are not explicitly mentioned in the definition of "retail community pharmacy," and that, if these transactions were not included in the calculation of AMP, it would be very difficult to calculate AMP for certain covered outpatient drugs.
    - Sales of Authorized Generic Drugs: In the context of authorized generic drugs, CMS proposes to define a primary manufacturer as the "manufacturer that holds the NDA of the authorized generic drug" and a secondary manufacturer as a manufacturer authorized to sell the drug by the primary manufacturer, but does not hold the NDA. The primary manufacturer's calculation of AMP must include "sales of authorized generic drugs that have been sold or

licensed to a secondary manufacturer, acting as a wholesaler," as well as sales directly to wholesalers.

- Transactions Excluded from the Calculation of AMP: In addition to retaining exclusions for customary prompt pay discounts, Medicaid rebates, and free goods, the proposed rule would provide new, clarified, or substantially revised exclusions for the following sales, discounts, rebates, payments, and other transactions from the calculation of AMP, to the extent that they are not "received by, paid, by, or passed through to, a retail community pharmacy."
  - Sales Outside the United States: The proposed rule would revise the definition of "United States" to include the territories, meaning that sales in the territories would no longer be considered "outside the United States."
  - Sales to Entities that Are Not Retail Community Pharmacies: The proposed rule clarifies that the following entities are not within the definition of a "retail community pharmacy," and so sales to these entities are excluded from the calculation of AMP:
    - Hospitals and hospital pharmacies
    - HMO and MCO-operated pharmacies
    - Long-term care facility pharmacies
    - Mail order pharmacies
    - Clinics and other outpatient facilities
    - Government pharmacies (pharmacies owned or operated by the Federal, State, county, or municipal government)
    - Charitable and not-for-profit pharmacies (501(c)(3) organizations)
    - Insurers
    - Hospices
    - Prisons
    - Physicians
    - Patients
  - Bona Fide Service Fees: The proposed rule would exclude fees meeting the definition of "bona fide service fees," from the calculation of AMP. The proposed rule frames the bona fide service fees identified in the ACA, i.e., "distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative service agreements and patient care programs (such as medication compliance programs and patient education programs)," as examples of types of fees that may meet the definition of a "bona fide service fee," provided they meet the extant four-part test set forth in the Deficit Reduction Act (DRA) regulation. That four-part test is as follows: The fee (1) represents fair market value (2) for a bona fide, itemized service actually performed on behalf of the manufacturer (3) that the manufacturer would otherwise perform (or contract for) in the absence of the service arrangement and (4) that is not passed on in whole or in part to a client or customer of an entity. Under the proposed rule, in order to qualify as "bona fide service fees," fees must be paid by manufacturers to wholesalers, retail community pharmacies or GPOs. While this limitation makes sense in the context of AMP, which typically includes only sales to wholesalers or retail community pharmacies, it is not clear what the impact of this proposed limitation will be in the context of best price, which also relies on the same definition.

- Returned Goods: The proposed rule would exclude reimbursements for returned goods from the calculation of AMP and adopt the ACA's definition of these payments: "Reimbursement by the manufacturer for recalled, damaged, expired, or otherwise unsalable returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction." However, the rule would exclude these payments only to the extent that the payments cover the costs of returning the goods. CMS does not define certain terms, such as "recalled," "damaged," "expired," and "unsalable," suggesting that they should be defined in accordance with standard industry practice.
- Medicare Coverage Gap Discount: The calculation of AMP excludes "discounts, rebates, or other price concessions provided under the Medicare Coverage Gap Discount Program."
- PBM Price Concessions: The proposed rule provides that a manufacturer's calculation of AMP will exclude "[s]ales to PBMs, including their mail order pharmacy's purchases." This exclusion applies to "payments received from and rebates or discounts provided to PBMs, including their mail order pharmacy's purchases to the extent that no part of the rebates, discounts or payments are received by, paid by, or passed through to retail community pharmacies." PBMs are explicitly excluded from the definition of a "retail community pharmacy."
- Prices to other Federal Programs: CMS proposes that the exclusion for Federal Programs explicitly apply to TRICARE Retail Pharmacy Program prices.
- Consumer Benefits: The proposed rule would exclude the following benefits provided to consumers from the calculation of AMP, provided that the full value is passed on to the consumer and the pharmacy (or another entity) does not receive any price concession:
  - Manufacturer coupons
  - Manufacturer vouchers
  - Manufacturer-sponsored drug discount card programs
  - Manufacturer-sponsored patient refund/rebate programs
- Copayment and Patient Assistance Programs: The proposed rule would specifically exclude from the determination of AMP "[g]oods provided free of charge under Manufacturer copayment assistance programs and patient assistance programs." This exclusion applies only if the provision of free goods is not contingent on future purchases.

CALCULATION OF AMP FOR 5I DRUGS

Calculation of AMP for 5i drugs is complicated by the fact that such drugs are not generally dispensed through a retail community pharmacy. Therefore, the statute allows for a wider range of transactions to be included in the calculation of AMP for these drugs. Under the proposed rule, it is the manufacturer's responsibility to identify which covered outpatient drugs are 5i drugs. CMS proposes that manufacturers must use the FDA's Routes of Administration list (available on the CMS website) to determine whether a covered outpatient drug is a 5i drug.

- Determination of 5i Status: CMS proposes that a "5i drug is not generally dispensed through a retail community pharmacy if 90 percent or more of the sales of the 5i drug, during the reporting period, were to entities other than retail community pharmacies or wholesalers for drugs distributed to retail community pharmacies." CMS proposes that the determination of 5i drug status be made on a monthly and quarterly basis.

- Calculation of AMP for 5i Drug: A manufacturer's calculation of AMP for a 5i drug includes all transactions generally included in a manufacturer's calculation of AMP. In addition, for a 5i drug, CMS proposes that the manufacturer include the following sales, discounts, rebates, payments, and other transactions:
  - Sales to physicians
  - Sales to pharmacy benefit managers where the PBM is not acting as an insurer, including its mail order pharmacy purchases
  - Sales to HMOs, including MCOs
  - Sales, discounts, or rebates paid directly to insurers (except for Medicaid rebates)
  - Sales to hospitals
  - Sales to clinics and outpatient facilities (for example, surgical centers, ambulatory care centers, dialysis centers, mental health centers)
  - Sales to mail order pharmacies
  - Sales to long-term care providers, including nursing facility pharmacies, nursing home pharmacies, long-term care facilities, contract pharmacies for the nursing facility where these sales can be identified with adequate documentation, and other entities where the drugs are dispensed through a nursing facility pharmacy, such as assisted living facilities
  - Sales to hospices
  - Sales to other manufacturers who conduct business as a wholesaler or retail community pharmacy

DETERMINATION OF BEST PRICE

- Definition: The proposed rule would revise the definition of best price to be more consistent with the statutory language. Under the proposed definition, best price means the lowest price available from the manufacturer during the rebate period "to any wholesaler, retailer, provider, HMO, nonprofit entity, or governmental entity in the United States in any pricing structure in the quarter for which AMP is calculated."
- Prices Included in Best Price: The proposed definition would eliminate the currently existing regulatory list of prices, rebates, discounts, and other transactions that are to be included in best price. Instead, best price would include "all prices and associated rebates, discounts, or other transactions that adjust prices either directly or indirectly," unless otherwise excluded.
- Prices Excluded from Best Price: CMS proposes revisions to the transactions excluded from best price to be consistent with exclusions from AMP. The proposed rule would recodify exclusions from best price, amend language to comport with similar language in the AMP exclusions, and add new payment exclusions. The most notable revisions to the best price exclusion list are as follows:
  - Prices Charged to 340B Entities: The current exclusion for prices charged to 340B entities excludes "any price" charged to a 340B entity. CMS proposes to limit the exclusion to "[p]rices charged under the 340B drug pricing program." Preamble discussion suggests that CMS views voluntary sub-ceiling prices charged to 340B entities to be outside the 340B program and thus includable in best price.
  - Bona Fide Service Fees: As discussed above, the proposed definition of bona fide service fees is limited to fees paid to wholesalers, retail community pharmacies or GPOs. There is no discussion of how similar fees paid to other entities are to be treated for best price purposes.

- Nominal Price Sales: The proposed rule provides two new entities whose purchases of drugs at nominal prices may be excluded from best price calculations:
  - "A public or non-profit entity or facility at an institution of higher learning whose primary purpose is to provide health care services to students of that institution, and provide family planning services.
  - An entity that:
    - Is described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of that Act or is State-owned or operated; and
    - Is providing the same services to the same type of population as a 340B entity but is not in receipt of 340B grant funds.
- Exclusions to Conform to AMP: CMS proposes several new exclusions from best price that are intended to provide more consistency between the calculations of AMP and best price. Those exclusions relate to:
  - Manufacturer vouchers
  - Goods provided for free under manufacturer-sponsored patient refund/rebate programs
  - Sales outside the United States
  - Discounts provided under the Medicare Coverage Gap Discount program

NEW AND REVISED MEDICAID DRUG REBATE CALCULATIONS

- Basic Rebate Calculations: The proposed rule includes rebate calculation formulas as revised by the ACA. For a dosage form and strength of a single source or innovator multiple source drug, the basic rebate is the product of total units paid for by the state plan in the rebate period and the greater of the following:
  - AMP minus best price OR 17.1% of AMP for
    - Clotting factors for which a separate furnishing payment is made under section 1842(o)(5) of the Social Security Act
    - Drugs approved exclusively for pediatric indications
  - AMP minus best price OR 23.1% of AMP for
    - All other single source drugs and innovator multiple source drugs
- Additional Rebate: The proposed rule provides for an additional rebate to the extent that AMP in a given rebate period increases over the base date AMP at a rate faster than the Consumer Price Index-Urban increased the month before the rebate period began.
- Total Rebate: The total rebate that a manufacturer pays to a State is the sum of the basic rebate and the additional rebate, if any. This rebate may not exceed 100% of AMP.
- Line Extensions: The proposed rule incorporates the ACA's formula for calculating the unit rebate amount (URA) for a line extension drug.
  - Definition of Line Extension: The proposed rule includes a definition of "line extension" that expands on the ACA definition, which defines "line extension" as "a new formulation of [a] drug, such as an extended release formula." Under CMS's proposed definition, a line extension is a single source or multiple source drug in an oral solid dosage form that has obtained FDA approval "as a change to the initial brand name listed drug in that it represents a new version of the previously approved listed drug." CMS proposes that examples of line

extensions include "a new ester, a new salt, or other noncovalent derivative; a new formulation of a previously approved drug; a new combination of two or more drugs; or a new indication for an already marketed drug." A drug would be a line extension drug if it satisfied the definition, regardless of whether it is approved under an NDA or a supplemental NDA. Line extension drugs would include single source or innovator multiple source drugs reformulations with abuse deterrent technologies, 3-year exclusivity, pediatric exclusivity, or orphan exclusivity, if those drugs otherwise meet the definition of a line extension drug. The CMS proposal excludes a new strength of the initial brand name drug from the definition. For an initial period of three quarters, CMS will create a master list of initial brand name drugs and line extensions through a manual matching process involving several FDA lists. Thereafter, manufacturers must determine and report the NDC for initial brand name drugs and line extensions.

- Oral Solid Dosage Form: The proposed rule defines "oral solid dosage form" as "capsules, tablets, or similar drugs products intended for oral use as defined in accordance with the FDA regulation at 21 CFR 206.3 that defines solid oral dosage form." In the preamble to the proposed rule, CMS provides a lists of dosage forms that are included in and excluded from this definition.
- Rebate Calculation for Line Extension: For a line extension, subject to the rebate cap of 100% of AMP, the rebate is the greater of:
  - Standard URA: basic rebate + additional rebate
  - Alternative URA: Line extension's AMP x highest additional rebate (as percentage of AMP) for any strength of the original drug, as calculated under the standard formula
- Report to CMS: Under the proposed rule, manufacturers are required to report the initial brand name drug to CMS along with the line extension drug, and to calculate the alternative URA unless the initial brand name drug is terminated and no longer active in the MDRP. The preamble provides additional guidance and examples to demonstrate how these calculations should be made.
- Drugs Dispensed through Medicaid MCOs: Consistent with the ACA, the proposed rule requires manufacturers to pay rebates on drugs dispensed to enrollees in Medicaid MCOs, if the MCO is contractually required to provide the drugs. Medicaid MCOs must report utilization data to States within 30 days of the end of each quarter. This data includes the "MCO identifier, National Drug Code, Period covered, Product FDA list name, Total units, Total number of prescriptions, and Amount reimbursed." Manufacturers are not required to pay rebates on covered outpatient drugs that are dispensed by HMOs or MCOs that contract under Section 1903(m) of the Social Security Act, or that were purchased under the 340B program.

DEFINITIONS

The proposed rule amends definitions of some basic terms and adds other important definitions, including the following:

- Covered Outpatient Drug: CMS proposes to exclude from the definition of "covered outpatient drug" any drug product for which an NDC is not required by the FDA or that is not listed electronically with the FDA; any drug product or biological used for a medical indication that is not a medically accepted indication; and over-the-counter products that are not drugs. Manufacturers will be required to report relevant approved FDA application numbers and drug categories for each NDC to CMS. CMS states that if a drug does not have an application number but is nevertheless a covered outpatient drug, the manufacturer must provide evidence

demonstrating that it meets the statutory definition of a covered outpatient drug. This proposal could affect the Medicaid status of Drug Efficacy Study Implementation (DESI) or other pre-1962 drugs. It is not clear how this requirement will be enforced and implemented.

In addition, the proposed rule provides that "covered outpatient drugs" do not include drugs, biologic products, or insulin that are billed as bundled services with, and that are "provided as part of or incident to and in the same setting as," certain services. These services include inpatient services, hospice services, dental services (unless the State plan authorizes direct reimbursement to the dispensing dentist), physician services, outpatient hospital services, nursing facility and services provided by an intermediate care facility for the mentally retarded, other laboratory and x-ray services, or renal dialysis. If the drug is billed separately from the service, these exclusions do not apply.

- Noninnovator Multiple Source Drug: The proposed rule would include two additional drug products in the definition of a "noninnovator multiple source drug": (1) drugs that have not gone through the FDA process but otherwise qualify as "covered outpatient drugs," and (2) "any noninnovator drug that is not therapeutically equivalent." Significantly, the proposed rule provides that if a noninnovator drug later receives a new NDA or ANDA approval from the FDA, the manufacturer must adjust its reporting to correspond with the new product application type and submit the appropriate information.

MANUFACTURERS' REPORTS

- Failure to Report Quarterly or Monthly AMP: CMS proposes imposing civil monetary fines of $10,000 per drug per day if a manufacturer fails to submit its quarterly or monthly AMP for a product within 30 days of the end of a rebate period. In the preamble, CMS also says that it will report these manufacturers to the Office of Inspector General (OIG). CMS is also considering implementing regulations on suspension and termination proceedings for manufacturers that do not comply with AMP reporting or other MDR Program requirements.
- Quarterly Reporting Revisions: The proposed rule adds provisions to the current 12-quarter rule for reporting revisions to monthly or quarterly AMP, best price, customary prompt pay discounts, and nominal prices. Manufacturers are required to report revisions within 12 quarters of the current quarter. Requests for revisions of these calculations that are more than 12 quarters old will be considered only if the change is:
  - "[A] result of the drug category change or a market date change"
  - An initial product submission
  - "[D]ue to termination of a manufacturer from the [MDRP] for failure to submit pricing data and [the manufacturer] must submit pricing data to reenter the program"
  - "[D]ue to a technical correction, that is, not based on any changes in sales transactions or pricing adjustments from such transactions"
  - "[T]o address specific underpayments to States, or potential liability regarding those underpayments, as required by CMS or court order, or pursuant to an internal investigation, or an OIG or DOJ investigation"
- Monthly Reporting Revisions: The criteria for reporting quarterly revisions also apply for reporting monthly revisions. CMS would also require that if a revision request is submitted for quarterly or monthly AMP, then it must be submitted for the other to ensure consistency.
- Good Cause Revisions: The proposed rule would permit revised calculations of quarterly AMP, best price, customary prompt pay discounts, and nominal prices that are more than 12 quarters old if the manufacturer can show good cause and receives CMS approval. The preamble

suggests that the good cause provision would apply to situations in which a manufacturer has revised its methodology for calculating AMP and best price "outside of the 12-quarter time limit to address underpayments and potential liability regarding those underpayments that may extend out of that 12-quarter period." Based on the language of the regulation, it is unclear whether CMS would approve revisions for good cause for a reason other than a change in calculation methodology.

- Base Date AMP: The proposed rule would give manufacturers the option to revise base date AMP to conform to revisions in the definition of AMP under the DRA and the ACA. Any revision "must use actual and verifiable pricing records." Manufacturers may recalculate the base date AMP on a product-by-product basis.
- Lagged Price Concessions: Manufacturers must report revisions to quarterly or monthly AMP within 12 quarters or 36 months, unless the revisions are solely a result of lagged price concessions. In addition, when calculating monthly AMP, Manufacturers would be required to use a smoothing process similar to that used for average sales price under Medicare Part B. Manufacturers must estimate lagged price concessions "using a 12-month rolling percentage."
- AMP Units: In accordance with the ACA, manufacturers must submit a monthly report to CMS of the "total number of units that are used to calculate the monthly AMP in the same unit type as used to compute the AMP" within 30 days after the end of the month.

REQUIREMENTS FOR STATES

- Data Provided by States: The proposed rule would establish standard data that States must include in invoices to manufacturers. States must provide this data within 60 days of the end of a rebate period. At a minimum, a State must provide the following in the invoice used to bill manufacturers (and must provide the same information to CMS on a quarterly basis):
  - State code
  - NDC
  - Period covered
  - Product FDA list name
  - URA
  - Units reimbursed
  - Rebate amount claimed
  - Number of prescriptions
  - Medicaid amount reimbursed
  - Non-Medicaid amount reimbursed
  - Total amount reimbursed
- Medicaid Managed Care Organizations: If a state contracts with Medicaid MCOs that include covered outpatient drugs, the state must separately report the data described above for covered outpatient drugs dispensed to MCO enrollees.
- Territories: In the preamble, CMS suggests that it would not impose these requirements on "the territories until one year after the first day after the first full quarter of the publication of the final rule."

UPPER REIMBURSEMENT LIMITS FOR MULTIPLE SOURCE DRUGS

- Criteria to Calculate FUL: In accordance with the ACA, the proposed rule would require CMS to establish and list federal upper reimbursement limits (FULs) for multiple source drugs if the "FDA has rated at least three drug products as pharmaceutically and therapeutically equivalent in its most current edition of" the Orange Book. The limit would be calculated using only pharmaceutically and therapeutically equivalent drugs and apply only to those drugs. A drug would be considered therapeutically equivalent only if it is "A" rated.
- FUL Calculations: The proposed rule would establish the FUL as "175 percent of the weighted average of the most recently reported monthly AMP" for pharmaceutically and therapeutically equivalent drugs that are "available for purchase by retail community pharmacies on a nationwide basis." The proposed rule also provides that the "monthly AMP units data will be used to calculate the weighted average of monthly AMPs for all multiple source drugs to establish the FUL," and the "FUL will be applied as an aggregate upper limit."
- Nationwide Availability: The proposed rule would require that the drug be available on a nationwide basis. Nationwide availability does not require that every therapeutically and pharmaceutically equivalent drug be available at any given retail community pharmacy. CMS states that the requirement is satisfied if a "retail community pharmacy is able to purchase at least one of the drug products" in a FUL group.
- Single Source Drugs: Because FUL calculations are made using therapeutic equivalents, CMS proposes that single source drugs should never be included in a FUL group or have a FUL.
- FUL Smoothing Process: CMS considered, but declined to adopt, a smoothing process for monthly FUL calculations similar to that required for AMP calculations. The preamble discusses several possible methods for implementing such a smoothing process and discusses the advantages and disadvantages of such a process.

STATE PLAN REQUIREMENTS, FINDINGS, AND ASSURANCES

- Data Requirements: The proposed rule includes a provision that would require States to provide adequate data to support proposed changes to reimbursement for ingredient cost or professional dispensing fees. This "adequate data" includes, but is not limited to "a State or national survey of retail pharmacy providers or other reliable data which reflects the pharmacy's actual or average acquisition cost." If a State proposes a change in ingredient cost or professional dispensing fee, it must provide supporting data "through a State plan amendment through the formal review process." In addition, CMS suggests that revisions to one aspect of the reimbursement formula--ingredient cost or professional dispensing fee--must account for the other. If applicable, States must comply with other federal regulations, such as those pertaining to consultation with the Indian Health Service or tribal organizations.
- Specific Methodologies: The proposed rule requires state Medicaid plans to comprehensively describe payment methodologies for prescription drugs for three entities: (1) 340B covered entities, (2) contract pharmacies under contract with 340B covered entities, and (3) Indian Health Service, tribal and urban pharmacies. CMS suggests that states should examine when professional dispensing fees differ for these organizations to determine whether the differences are appropriate.

Comments on the proposed rule are due April 2, 2012. Please contact one of the attorneys listed below if you would like assistance in drafting comments or have questions regarding implementation of the disclosure requirements.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our health care practice group:

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