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MEDICAID DRUG REBATE PROGRAM 'REFORM': KEY CONSIDERATIONS AND IMPLEMENTATION TIPS FOR PHARMACEUTICAL AND BIOTECH MANUFACTURERS

March 30, 2010

On March 23, 2010, President Obama signed H.R. 3590, the "Patient Protection and Affordable Care Act" ("PPACA"), into law. This legislation includes significant revisions to Section 1927 of the Social Security Act (42 U.S.C. § 1392r-8), which governs the Medicaid Drug Rebate Program ("MDRP"). Following the enactment of PPACA, H.R. 4872, the "Health Care and Education Reconciliation Act of 2010" was enacted into law on March 30, 2010, "reconciling" and revising portions of PPACA. The term "PPACA" used herein shall refer to PPACA as amended by H.R. 4872. We have set forth below some key considerations and implementation tips to assist pharmaceutical and biotech manufacturers in understanding the impact of this legislation with respect to the MDRP. In addition, we have outlined the significant changes to the MDRP in the sidebars, organized by their respective effective dates.

1. Assess the Preparedness of Your Government Pricing Function

• PPACA makes significant changes to the definition of average manufacturer price ("AMP") and to the formulae and methodologies used to calculate MDRP rebates.

• Among other things, AMP would be redefined to replace the concept of "distributed to the retail pharmacy class of trade" with the concept of "distributed to community retail pharmacies." This change likely will require revisions to policies, procedures, systems, and processes regarding, for example, coding of particular classes of trade as "eligible" or "ineligible" for purposes of the AMP calculation. It also may have unintended consequences on the calculation of AMP for certain products that are not traditionally sold to community retail pharmacies, including, for example, drugs and biologicals that are purchased by physicians for administration in their offices.

IMPORTANT DATES

EFFECTIVE JANUARY 1, 2010

For rebate periods beginning after December 31, 2009, the following changes apply. Although the retroactive effective date may be subject to legal challenge and/or may not be implemented by CMS, manufacturers should assume for now that they will be required to comply with this date.

REBATE PERCENTAGE INCREASES

• Generally, the minimum "basic" rebate percentage for single source ("S") and innovator multiple source ("I") drugs is increased from 15.1% of AMP to 23.1% of AMP. This "basic" rebate component of the Unit Rebate Amount ("URA") would continue to be the greater of this minimum rebate amount or the difference between AMP and Best Price, and this "basic" rebate component would be added to the "additional" rebate component to calculate the URA.

• Notwithstanding the above change, the minimum "basic" rebate percentage for clotting factor with a separate furnishing fee and for "S" or "I" drugs approved exclusively for pediatric indications is increased to 17.1% of AMP.

• The URA percentage for non-innovator multiple source ("N") drugs is increased from 11% of AMP to 13% of AMP.

• Certain of the MDRP changes under PPACA, such as the increases to the basic rebate percentages, the change to calculation of "additional" rebates for new formulations of existing drugs, and the extension of MDRP rebates to utilization by beneficiaries of Medicaid managed care plans, according to their terms, are effective for rebate periods beginning after December 31, 2009. As a practical matter, although the delayed passage of the law may leave these retroactive effective dates subject to legal challenge, CMS may attempt to enforce these effective dates and calculate 1Q10 unit rebate amounts ("URA") based on the higher "basic" rebate percentages and potentially higher "additional" rebates.

2. Determine the Potential Impact on Your Financial Liability

• The extension of MDRP rebates to Medicaid Managed Care Organization ("MCO") utilization and increases to the MDRP rebate percentages represent relatively straightforward increases to manufacturers' MDRP liability that should be assessed for financial impact. (In addition, Medicaid enrollment will likely increase as a result of other provisions of PPACA.) But there also may be "hidden" increases that manufacturers should consider.

• Various discounts to certain entities previously considered "retail pharmacy class of trade" (such as mail-order pharmacies and hospital outpatient pharmacies) will no longer be included in AMP calculations, potentially resulting in relatively higher AMPs, and, thus higher Medicaid rebates, to the extent these entities received greater discounts than "community retail pharmacies." There may be crossover from this impact into other programs, such as the 340B Program (to be addressed in a forthcoming client communication), as well as state programs that rely on AMP for rebate and/or reimbursement purposes.

• The public disclosure of AMP, which was required by the DRA, continues to be enjoined in connection with ongoing litigation in *National Ass'n of Chain Drug Stores v. Sebellius*, Civ. Action No. 1:07cv02017 (RCL) (D.D.C.). However, it is possible that the litigation may be mooted in light of the redefinition of AMP under PPACA, thus permitting the disclosure of *noninnovator* drugs' AMPs, as outlined in the sidebars.

IMPORTANT DATES

EFFECTIVE JANUARY 1, 2010 (cont'd)

"ADDITIONAL" REBATE CALCULATION FOR NEW FORMULATIONS OF EXISTING DRUGS

• For a new formulation/"line extension" of an "S" or "I" drug that is a "oral solid dosage form," such as (but apparently not limited to) an extended-release formulation, the manufacturer's "additional" rebate obligation will become the greater of: (1) the "additional" rebate amount calculated under the historical formula and (2) the product of (i) the new formulation's AMP for the current rebate period, (ii) the highest "additional" rebate for any strength of the original "S" or "I" drug, calculated as a percentage of the new formulation's AMP for the current rebate period, and (iii) the number of units for the new formulation invoiced for rebate payment by the state Medicaid plan.

MAXIMUM REBATE

The URA for "S" and "I" covered outpatient drugs is capped at 100% of its AMP for the rebate period.

FEDERAL "RECAPTURE" OF REBATE INCREASES

Increases in MDRP rebate payments to the states due to the increased minimum "basic" rebate percentages and the changes in "additional" rebate calculations for new formulations will be "recaptured" by the federal government through corresponding reductions in Federal Financial Participation payments made to the states under Section 1903 of the Social Security Act.

IMPORTANT DATES

EFFECTIVE MARCH 23, 2010

The following provision does not have a specific effective date in PPACA; thus we have assumed that it will be effective as of the enactment date.

REBATES ON MEDICAID MCO UTILIZATION

Manufacturers' obligation to pay MDRP rebates is extended to utilization reported to the states by Medicaid MCOs, except with respect to covered outpatient drugs dispensed by 340B covered entities.

EFFECTIVE OCTOBER 1, 2010

Significantly, these changes will take effect with or without the issuance of regulations by CMS. This is in contrast to the approach taken in the DRA, which specifically directed CMS to promulgate regulations regarding the definition of AMP.

AMP REDEFINED

AMP is re-defined as the average price paid to the manufacturer for the covered outpatient drug in the United States by:

• wholesalers for drugs distributed to retail community pharmacies; and

• retail community pharmacies that purchase drugs directly from the manufacturer.

• Assessing the impact of the provisions regarding new formulations may be challenging, as there are many open questions regarding the definitions and applicability of these provisions. In a March 10, 2010 report to CMS, the Office of Inspector General ("**OIG**") attempted to evaluate the impact of calculating additional rebates of different "versions" of drugs under the MDRP.[1] The OIG stated that "new forms or strengths … of an active ingredient previously approved for marketing in the United States" were considered different "versions." The OIG also stated that it considered drugs "with variations of the same brand name (e.g., drug ABC and ABC XR, for which the 'XR' represented extended release) to be the same drug if they had the same active chemical ingredients." Although this interpretation is not binding on CMS, it may be helpful for manufacturers to consider as they assess the potential impact of this change.

• In addition to the increased MDRP liability that may result from the change in the formula for calculating "additional" rebates for new formulations of existing products, "additional" rebates for all "S" and "I" drugs could increase unless CMS allows manufacturers to recalculate their "base date" AMPs used to calculate "additional" rebates under the AMP methodology, as revised by PPACA. In connection with changes previously made by the DRA and its implementing regulations, CMS permitted manufacturers to recalculate their "base date" AMPs under the revised AMP methodology, provided they had actual data from the "base date" quarter to use in those recalculations.

3. Review and Update Your Rebate and Discount Contracts

• Several of the changes under PPACA have implications for manufacturers' rebate and discount contracting practices.

• For example, it is relatively common for payors to include Medicaid MCO utilization in commercial rebate contracts. Therefore, manufacturers may be contractually liable to pay duplicate rebates on this utilization.

• Also, the extension of MDRP rebates to Medicaid MCO utilization would not prohibit manufacturers from offering deeper discounts to Medicaid MCOs. However, whereas Medicaid rebates are exempt from manufacturers' Best Price calculations, these deeper discounts may not be.

IMPORTANT DATES

EFFECTIVE OCTOBER 1, 2010
(cont'd)

RETAIL COMMUNITY PHARMACY DEFINITION

•"Retail community pharmacy" is defined as "an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term 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"

WHOLESALER DEFINITION

• "Wholesaler" is defined as "a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including (but not limited to) manufacturers, repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer's and distributor's warehouses) independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions."

4. Analyze Whether MDRP Changes Impact Research and Development ("R&D") Business Strategy

• Provisions that may affect manufacturers' current and prospective R&D business strategies include: (1) the change in the MDRP "additional" rebate calculation that applies to new product formulations; and (2) a relatively lower minimum "basic" rebate percentage for drugs that are approved exclusively for pediatric use.

• The new formulations provision is intended to limit the ability of manufacturers to charge premium pricing for new formulations of solid oral dosage form products, as such new formulations will potentially be penalized under the MDRP for essentially the difference between the new formulation's AMP and the "base date" AMP for the original formulation, if any. Operationalizing this provision may be challenging, especially in cases where the units and strengths of the formulations are not easily converted to like measures.

• The relatively lower minimum "basic" rebate for innovator products approved exclusively for pediatric indications is intended to serve as an incentive for manufacturers to study and seek approval of products with exclusively pediatric indications. However, this provision may have the unintended consequence of acting as a disincentive to conduct further adult trials with respect to those products, once approved.[2]

SPECIFIC IMPLEMENTATION TIPS

☑ Immediately: (1) begin assessing whether systems can apply the changed rebate percentages in connection with your validation of 1Q10 URA invoices record from the states; (2) ensure that such systems are capable of implementing the changes for 2010 for MDRP purposes, while retaining the 2009 URAs for purposes of calculating 340B Program drug discounts for 1Q10 and 2Q10; and (3) begin making system changes, as appropriate.

☑ Begin analysis of the internal implementation of the new AMP definition now, rather than waiting until 3Q10 to do so. Although the AMP definitional changes do not become effective until October 1, 2010, many manufacturers likely learned from their experience implementing the changes to the MDRP made by the DRA and by its implementing regulations that the time it takes to modify policies,

IMPORTANT DATES

EFFECTIVE OCTOBER 1, 2010
(cont'd)

"INCLUDED"/"EXCLUDED"

• AMP includes "any other discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies."

• AMP excludes:

1. customary prompt pay discounts extended to wholesalers;

2. bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs);

3. reimbursement by manufacturers 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; and

4. payments received from, and rebates or discounts provided to, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy.

procedures, and systems and to train appropriate personnel may be substantial.

☑ Ensure adequate documentation of the methodologies and processes used to calculate AMP (and to otherwise comply with obligations under the MDRP) in the intervals between the dates on which changes were and will be implemented over the course of this dynamic period. This is critical because manufacturers' AMP calculations and rebate payments are subject to government audit and enforcement under a variety of statutes, and manufacturers should be prepared to demonstrate their compliance with legal requirements at these various moments in time (and AMP has changed significantly over the last several years). Also, archive the methodologies and processes previously used.

☑ Assess whether the internal government pricing group has sufficient resources to enable the group to implement these changes. This is particularly important as AMP is redefined and used more broadly by federal programs, and as additional utilization becomes subject to MDRP rebates.

☑ When evaluating resources, consider not just the MDRP changes, but various other changes under PPACA, including without limitation the changes to the 340B Program, as well as the new Medicare Coverage Gap Discount Program that may impact this group's resources. We will analyze these changes separately in forthcoming client communications.

☑ Begin reviewing the current customer base to ascertain the extent to which the MDRP changes will affect calculations and liability under the MDRP, as well as other commercial and state contracts.

☑ Consider whether commercial contracting strategies involving community retail pharmacies and/or entities that were previously (but will no longer be) included in AMP need to be reassessed in terms of overall organizational financial impact.

☑ Review whether any products might be considered "new formulations" or "line extensions" of other products for purposes of the additional rebate changes. Because the term "new formulation" is not defined in the legislation, it is possible that it could be construed broadly to include various NDC-9s that are related to an earlier-approved product.

IMPORTANT DATES

EFFECTIVE OCTOBER 1, 2010
(cont'd)

MONTHLY OBLIGATION TO REPORT AMP UNITS

Manufacturers will be required to report to CMS on a monthly basis the number of units used to calculate the monthly AMPs for their covered outpatient drugs.

PUBLIC DISCLOSURE OF AMP AND RETAIL SURVEY PRICE INFORMATION

- The existing MDRP provision requiring CMS to post AMPs for all covered outpatient drugs to a public website is revised to require CMS instead to post the "weighted average" of the most recent monthly AMPs of multiple source drugs, i.e., innovator and non-innovator drugs that are rated therapeutically equivalent ("TE").

- The existing public disclosure provision was created by the DRA, but has been enjoined due to ongoing litigation (that may be affected by the enactment of PPACA).

- This means that AMPs for "S" drugs will not be publicly available. This also means that the specific AMPs for individual "I" and "N" drugs will not be publicly available, unless there is no other TE product to be included in the weighted average. All AMPs, however, are subject to disclosure to state Medicaid programs.

- CMS now also must post to this public website the "average retail survey price" for each multiple source drug, as may be determined through surveys performed by a vendor under contract to CMS. The provision regarding the collection of "retail survey price" information is revised to clarify that this information will be based on prices available to community retail pharmacies.

☑ Identify those affected products that are "oral solid dosage forms" for the purpose of ensuring that systems are capable of separate treatment of such products versus any non-affected products in the portfolio.

☑ Review and comment, as appropriate, to any CMS guidance defining and/or interpreting the concept of "new formulation."

☑ Even in the absence of specific statutory authority under PPACA to recalculate "base date" AMP, consider requesting that CMS authorize manufacturers to recalculate their "base date" AMPs using the revised AMP definition prior to October 1, 2010, the date on which the changes to AMP become effective.

☑ If your product(s) are traditionally physician-administered drugs and/or other drugs that are not distributed through community retail pharmacies, consider seeking guidance from CMS regarding how to calculate AMP, as such products generally remain within the definition of "covered outpatient drug". Where such guidance is not available, consider, in conjunction with legal counsel, whether any "reasonable assumptions" may be appropriate and document any such assumptions appropriately.

☑ If your product(s) is an "N" products (*i.e.* most generics), prepare for the possibly imminent public disclosure of weighted-average AMPs, and consider modeling the financial impact of discount and reimbursement strategies based on AMP.

☑ Ensure that any financial modeling takes into account cross-program implications, as such programs also are revised by PPACA. For example, under the PPACA changes to the 340B Program, there are several "new" classes of covered entities created effective as of January 1, 2010. Even if such new entities are not functionally eligible for discounted pricing as of that date, due to possible Health Resources and Services Administration implementation issues, consider whether to attempt to identify chargebacks to such entities insofar as they may need to be excluded from AMP for beginning 1Q10, to the extent that manufacturers are required to proved these newly enrolled 340B covered entities with retroactive discounts on drugs purchased after January 1, 2010.

IMPORTANT DATES

EFFECTIVE OCTOBER 1, 2010 (cont'd)

FEDERAL UPPER LIMIT ("FUL") CHANGES

• CMS is again required to establish an FUL once "three or more" therapeutically and pharmaceutically equivalent multiple source drugs are available. This is a change from the DRA, which reduced the standard to "two or more".

• An FUL shall be "no less than" 175% of the weighted average (based on utilization) of the most recently reported monthly AMPs for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. CMS is required to implement a "smoothing" process for AMPs similar to that used in the calculation of Average Sales Price for drugs covered by Medicare Part B. Interestingly, the FUL is defined as a floor and not a ceiling. This is a change from the DRA, which capped the FULs at 250% of AMP and did not have the market availability restrictions.

EFFECTIVE JANUARY 1, 2011

CALCULATION OF AMP AND BEST PRICE

AMP and Best Price each exclude discounts provided by manufacturers under the Medicare Coverage Gap Discount Program established by Section 3301 of PPACA, which commences on January 1, 2011.

☑ Review current commercial rebate and discount contracts to ascertain the extent to which Medicaid MCO utilization already is eligible for discounts under such agreements, and whether current carve-outs are adequate to address this issue. There is a potential for duplicate discounting in the event that the term of the commercial agreement extends beyond the effective date of this particular change, which, likely was March 23, 2010, the enactment date for PPACA.

☑ Review state supplemental rebate contracts and state pharmaceutical assistance program contracts to determine the extent to which such contracts rely on the MDRP pricing formulae. To the extent that such contracts rely directly on cross-references to the federal MDRP calculation, the PPACA changes may impact such program discounts as well. To the extent that such contracts independently define terms such as "AMP" and "Best Price", or refer specifically to the old basic rebate percentages, manufacturers may need to perform separate rebate calculations for such program. The latter scenario could pose significant implementation challenges, as it could require manufacturers to maintain separate classification systems (*e.g.*, one for the old "retail class of trade" and one for the new concept of "community retail pharmacies").

☑ Review contractual termination and change of law provisions in all potentially relevant contracts, with an understanding that some of the changes to the MDRP program may materially impact the business under the agreement.

☑ If your company is conducting or considering clinical trials on extended-release versions, evaluate the potential impact the MDRP changes may have on long-term product pricing and discounting strategies.

☑ Consider the long-term pricing implications of the dosage form of the product that is launched as part of the overall product lifecycle planning, with the understanding that new formulations of solid oral dosage forms may be affected by pricing implications.

☑ If your company is conducting or considering clinical trials for adult indications of pediatric products, evaluate the potential impact such indication(s) may have on MDRP liability.

IMPORTANT DATES

EFFECTIVE JANUARY 1, 2014

"EXCLUDABLE" DRUGS

- Smoking cessation drugs, barbiturates, and benzodiazepines will be removed from the list of drugs that state Medicaid programs currently may elect to exclude from Medicaid coverage, meaning that states participating in the MDRP will be required to cover these drugs and that manufacturers will be required to pay rebates on those drugs. This will also affect the list of drugs eligible for coverage under Medicare Part D, in that barbiturates and benzodiazepines will become eligible for coverage. (Smoking cessation drugs already are eligible.)

- Another provision in PPACA requires state Medicaid programs to cover nonprescribed OTC smoking cessation dugs for pregnant women as of October 1, 2010. There are some internal inconsistencies in PPACA and the MDRP statute that may cause implementation issues with respect to this requirement, including any potential rebate obligation.

For more information about this issue of IMPLEMENTING HEALTH AND INSURANCE REFORM, please contact one of the authors below or the member of the firm who normally handles your legal matters.

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This client communication is not intended to encompass all of the significant items addressed in PPACA. There are a large number of key issues contained in this legislation that manufacturers should explore, including by way of example, the creation of a pathway for approving "biosimilar" biologicals, the Medicare Coverage Gap Discount Program, transparency provisions regarding payments to health care professionals, and excise taxes on pharmaceutical and medical device manufacturers. EBG will continue to develop client communications on these topics, which will be available at www.ebglaw.com.

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[1] U.S. Dep't of Health & Human Servs., Office of Inspector Gen., "Review of Additional Rebates for Brand-Name Drugs with Multiple Versions," A-06-09-00033 (Mar. 2010).

[2] There also is a potentially incongruous interplay between this provision and the new formulation provision, to the extent that a pediatric version of a product might be deemed a "new formulation" and thus subject to an "additional" rebate calculation that uses the "base date" AMP of the original formulation, while also subject to the lower minimum "basic" rebate.

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