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Price Reporting and Governmental Rebate Issues Arising from the Healthcare Reform Law—an Early Assessment

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With the passage of the Patient Protection and Affordable Care Act (the Healthcare Reform Law) three months ago, pharmaceutical manufacturers are continuing to assess how the changes to their price-reporting responsibilities are affecting their business models and operations. Among the issues facing manufacturers are concerns pertaining to the implementation of Medicaid Drug Rebate Program price-reporting changes, as well as the nascent developments with respect to the Medicare Part D Coverage Gap Discount Program.[1]

MEDICAID DRUG REBATE PROGRAM REVISIONS

Increase in Minimum Unit Rebate Amount

The increase in the minimum unit rebate amount raises certain operational issues. Retroactively effective as of January 1, 2010, the minimum unit rebate amount for innovator products has increased from 15.1% to 23.1% of average manufacturer price (AMP). This retrospective change has already created systems issues; the Centers for Medicare & Medicaid Services (CMS) has stated that it cannot calculate the unit rebate amount for the first calendar quarter of 2010. Given the systems issues CMS is facing in determining what the correct unit rebate amount should be, manufacturers should be especially careful that their systems are generating the correct unit rebate amount to avoid potential False Claims Act liability for inaccurate calculation. Moreover, manufacturers should be particularly diligent in their verification of the accuracy of dates of service during their review of state claims, as the unit rebate amount will differ significantly from one quarter to the next.

Nongovernmental Payer Implications

From a longer term strategic perspective, manufacturers need to consider how this change in the minimum unit rebate amount affects their contracting strategy. Those nongovernmental customers that had previously accepted discounts around 15.1% because they recognized that deeper discounts could set a new best price may now expect discounts reflecting the higher minimum unit rebate amount.

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[1] For further information regarding the changes to the 340B program, please see Morgan Lewis's April 14, 2010 LawFlash, "Healthcare Reform Law Leads to Significant Changes to the 340B Program," available at http://www.morganlewis.com/pubs/WashGRPP_340BProgram_LF_14apr10.pdf. LawFlashes on additional Healthcare Reform Law issues are available at http://www.morganlewis.com/healthcarereform.

Manufacturers will need to decide whether to increase their discounts or change the rationale supporting their current discount percentage.

Supplemental Rebate Implications

Manufacturers are also likely to face increased pressure from states to enter into supplemental rebate agreements. CMS has stated in guidance to state Medicaid directors that it will use the full 8% increase in the unit rebate amount as an offset to the federal government's federal financial participation in state programs. This will be true even in cases where a manufacturer's historic unit rebate amount exceeded 15.1%. In other words, if a manufacturer's unit rebate amount for a particular product was 17% (i.e., the difference between AMP and best price exceeded 15.1%), the state will now only receive 15.1%. The federal government will receive the remaining portion of the rebate up to 23.1%. With this loss of rebate revenue, states will likely reinforce their supplemental rebate programs to make up for the difference.

SPAP Implications

Contracts such as those with state pharmaceutical assistance programs (SPAPs) often incorporate by reference the Medicaid Drug Rebate Program unit rebate amount calculations. What may have seemed acceptable under prior law may not be as acceptable with the increased minimum unit rebate amount. Due to the increased cost of participating, manufacturers may want to seek renegotiations (or even changes in pertinent laws or regulations, if need be), or consider terminating their participation in these voluntary SPAPs.

PAP Implications

Manufacturers may also deem this change to be a salutary one insofar as their patient assistant programs (PAPs) are concerned. Current Medicaid Drug Rebate Program rules require manufacturers to apply an indigence test as part of the structure of their PAPs in order to avoid best price implications of offering patients financial assistance. A number of manufacturers, however, find it unduly burdensome to collect pertinent financial information from PAP beneficiaries. Some manufacturers instead rely on the coupon exception to AMP and best price calculations, especially for coinsurance support programs, but the PAPs do not always fit squarely within the coupon exception. For these situations, manufacturers may actually find relief in the increased unit rebate amount. When all discounts, including coinsurance support, total less than 23.1%, there is no impact on Medicaid drug rebate obligations. In other words, coinsurance support can be offered that is below the statutory minimum unit rebate amount. Under such circumstances, even if the PAP or coupon exception criteria are not met, the unit rebate amount is not increased.

New Rebates for Medicaid Managed Care Organization Utilization

The new rebate associated with Medicaid managed care organization (MCO) utilization also raises various implementation issues. As of March 23, 2010, Medicaid MCO enrollee utilization of covered outpatient drugs is to result in manufacturer rebate payments to the states. States are required to furnish data regarding this utilization to manufacturers, and manufacturers are required to pay rebates corresponding to this utilization. To obtain this data, effective March 23, 2010, states are required to include in their contracts with Medicaid MCOs a requirement that the MCOs furnish enrollee drug utilization data to the state. It is unclear how those states with contracts that renew annually and do not provide for automatic modification upon a change of law will be able to comply with this new statutory provision, should the Medicaid MCOs not voluntarily cooperate.

Issues Regarding the Reliability of Data

Even upon contract amendment, many Medicaid MCOs are not capable of providing the data needed by the states. Medicaid MCO encounter data is often less than 100% reliable, and the information systems of many MCOs will require modifications before they will be able to organize utilization data in a manner that will be usable by the states.

For instance, Medicaid MCOs will find it especially challenging to implement the Healthcare Reform Law provisions prohibiting receipt of duplicate price concessions pertaining to 340B entity utilization, since 340B entities have already presumably benefited from 340B pricing. As Medicaid MCOs were not previously required to keep track of which of their providers were 340B-covered entities, the new provisions mean that the Medicaid MCOs will need new IT systems that can identify 340B-covered entities and flag when drugs have been subject to 340B pricing.

Although this requirement went into effect on March 23, it will likely be some time before any substantial number of Medicaid MCOs will be in compliance with this provision. In light of these likely issues, and the significant size of Medicaid managed care (by some estimates, 70% of the total Medicaid market), manufacturers need to exercise increased vigilance and develop robust validation tools to validate state utilization data.

Strategic Implications

From a strategic standpoint, manufacturers may consider negotiating revisions to their contracts with Medicaid MCOs, so as to avoid paying rebates twice on the same utilization. Many manufacturers have existing agreements with MCOs, including those with a Medicaid line of business, to pay them rebates in exchange for favorable formulary status. However, under the new statutory framework, manufacturers will now be paying twice for covered outpatient drug utilization by Medicaid MCO beneficiaries—once to the MCO and once to the state—thus possibly resulting in a financial loss on such business. Yet, some MCOs have already stated that they will decline any request to renegotiate such rebates because they do not receive the rebates paid to the states. Moreover, they still have an obligation to be prudent purchasers, so as to ensure that they can continue to successfully bid on state Medicaid contracts. In addition, existing MCO IT data systems may not currently distinguish whether a plan is commercial or Medicaid. Thus, the data may not currently exist to allow for contract renegotiations.

Line Extensions

Manufacturers with existing line extensions or with plans to launch new line extensions will face certain operational complexities associated with the new law. Line extensions are new solid, oral formulations of innovator products, expressly including extended-release formulations. It is unclear what other reformulations would qualify as line extensions under the statute. For these drugs, the supplemental rebate paid for price increases greater than the CPI-U (sometimes referred to as the CPI-U penalty) is subject to modification, depending upon pricing of the original formulation of the product. If the supplemental rebate for the original formulation, calculated as a percentage of the original formulation's AMP, is higher than the line extension's supplemental rebate percentage, the original formulation's supplemental rebate percentage is used in the calculation.

For instance, it is possible that the pricing of a new formulation would not trigger the CPI-U penalty, but the pricing for the original formulation results in a CPI-U penalty of 2% of AMP. In such case, the AMP of the new formulation is multiplied by 2% to determine the new formulation's CPI-U penalty. In other

words, manufacturers are not allowed to press the "reset button" in terms of price increases subject to the CPI-U penalty once they launch a line extension.

Pricing Strategy for Original Formulation

Nevertheless, manufacturers may find that they have certain options available to them to minimize their line extension supplemental rebates. As identified above, under the new law, increases in the pricing of the original formulation of a product will have a cascading effect. Not only will such pricing trigger the CPI-U penalty for that original product, but it could also result in additional rebates for the line extension. Conversely, if a manufacturer reduces the pricing of the original formulation of a product, it may be able to minimize any additional rebates paid for utilization of the line extension.

The feasibility of this approach depends upon a number of factors. For instance, there may still be an active market for the original formulation, or possibly the manufacturer is trying to incentivize use of the new formulation by creating a substantial price gap with the original formulation. However, in certain cases, manufacturers may find it beneficial to reduce the price of the original formulation.

Maximum Rebate Amount

One of the few welcome changes in the legislation is a cap on the value of the unit rebate amount at the product's AMP. Previously, there was no statutory limit on the magnitude of the unit rebate amount, which sometimes resulted in unit rebate amounts exceeding AMP, i.e., essentially manufacturers were paying the states to utilize their products. Some manufacturers dealt with this issue by including in their price reporting policies the stated assumption that the unit rebate amount could never exceed AMP. Manufacturers have justified such a policy because a unit rebate amount in excess of AMP is inconsistent with the statute's purposes. However, the statutory underpinnings of such an argument were never assured. Manufacturers can now rely upon the literal wording of the statute instead. Manufacturers that did not cap the unit rebate amount at AMP previously will need to update their policies and their calculation methodologies to account for the change in law.

Notably, manufacturers can still incur a net loss on sales involving Medicaid beneficiaries. The size of the unit rebate amount could still be large enough to reduce AMP to a price below the manufacturer's costs. The change in law simply prevents states from actually profiting from utilization of a product at the manufacturer's expense. Continued vigilance is still warranted to avoid setting a best price at a point that will result in an unfavorable net sales value to the Medicaid population.

New Covered Outpatient Drugs

Manufacturers of certain types of products may find that newly created coverage of their products is a mixed blessing. Effective January 1, 2014, coverage is mandated under Medicaid for smoking cessation agents, barbiturates, and benzodiazepines. With mandatory coverage, manufacturers of these products should see some increase in sales volume attributable to the Medicaid population. However, with governmental reimbursement come compliance responsibilities. One such obligation relates to the 340B program. Any manufacturer joining the Medicaid Drug Rebate Program must also participate in the 340B program, meaning that some portion of their increased revenues will be offset by reduced revenues attributable to 340B-covered entity purchases.

Furthermore, while manufacturers of these products may have previously determined that statutes such as the Anti-Kickback Statute did not apply to them because these products were not covered, these

statutes will now become squarely applicable. Accordingly, these manufacturers will need to reexamine their sales and marketing practices and other operating procedures to determine what changes may be necessary before signing the Medicaid Drug Rebate Agreement. Similarly, manufacturers seeking to avoid exposure to False Claims Act suits relating to purported promotion of off-label uses of their products may need to revisit their marketing materials and strategies to confirm compliance. In other words, for some manufacturers, there could be significant transitional costs associated with benefiting from this new statutory coverage mandate.

Opting Out an Option?

For some manufacturers, the decision may be that these new compliance obligations do not justify what may be minimal increases in sales; however, opting out is not as easy as it may appear. The Medicare Part D rules incorporate by reference the definition of "covered outpatient drugs" found within the Medicaid Drug Rebate Statute. Accordingly, Medicare Part D plans may begin covering products on January 1, 2014, irrespective of whether a manufacturer chooses to sign a Medicaid Drug Rebate Agreement. While opting out of the Medicaid Drug Rebate Program would relieve a manufacturer of also being required to participate in the 340B program, there would be no way to ensure exclusion under Medicare Part D. Therefore, compliance with the Anti-Kickback Statute and similar laws may still be necessary.

Revised Definition of AMP

One of the larger changes that will require an adjustment of existing policies relates to modifications to the definition of AMP. Effective October 1, 2010, AMP will be limited to sales to "retail community pharmacies" and wholesalers that sell to these pharmacies. Once in effect, the only sales that will be included are those to retail pharmacies, including independent pharmacies, chain pharmacies, or supermarket pharmacies. Expressly excluded are mail order pharmacies, hospital pharmacies, and not-for-profit pharmacies. Accordingly, the new scope of customers included in AMP is significantly narrower than the scope of customers currently recognized, and should result in higher AMPs and therefore higher unit rebate amounts.

Potential Rebasing

This new definition of AMP will require interpretation by CMS in several respects. One issue involves whether CMS will allow manufacturers to rebase their AMPs, as was permitted once previously after the Deficit Reduction Act of 2005 resulted in changes to the definition of AMP. If CMS does not allow manufacturers to do so, it may exacerbate manufacturers' CPI-U penalty exposure.

Specialty Pharmaceuticals

CMS will also have to determine how manufacturers of specialty pharmaceuticals will calculate their AMP values, given that these manufacturers often have no retail community pharmacy sales. For safety concerns and other reasons, specialty pharmaceutical manufacturers often negotiate with very narrow distribution outlets. CMS may instruct these manufacturers to use a prior quarter's AMP, but that would not address issues for newly launched specialty pharmaceuticals. In any event, if CMS's rules pertaining to specialty pharmaceuticals depart to any material degree from the wording of the statute, some of these manufacturers may even consider legal challenges to CMS's policy.

Bona Fide Service Fees

The new definition of AMP also includes a number of expressly excluded transactions, including most notably an exclusion pertaining to bona fide service fees. Through regulation, CMS has already excluded bona fide service fees from both AMP and best price. To qualify, a fee must (a) reflect the fair market value for the service; (b) be paid for the performance of a bona fide, itemized service that the manufacturer would otherwise have to perform for itself; and (c) not be passed on to any of the entity's clients or customers.

CMS's rules provide only criteria for determining if a fee paid is a bona fide service fee. They do not identify whether certain types of fees are categorically included or excluded from the scope of bona fide service fees. In contrast, the Healthcare Reform Law specifies that certain types of fees do qualify as bona fide service fees, including distribution service fees, inventory management fees, product stocking allowances, and administrative service fees. It is unclear whether fees labeled as, for example, inventory management fees will *always* qualify as bona fide service fees, or whether they must also still meet CMS's bona fide service fee criteria.

CMS's expected rulemaking with respect to bona fide service fee questions will be helpful. CMS may need to reevaluate its current definition of bona fide service fees, as the specific examples provided in the law often do not fit neatly within CMS's paradigm. For instance, a number of manufacturers would not have considered product stocking allowances to be a bona fide service fee. CMS may therefore need to broaden its definition. Additionally, CMS will need to decide if it will create two definitions of bona fide service fees—one for AMP, and another one for best price—since the statute defines the term only in the context of AMP. There would be no principled basis for making such a distinction, notwithstanding the text of the law, but it is certainly possible that CMS will include such a distinction in its proposed rulemaking. If CMS does not issue rulemaking prior to the effective date of these provisions, manufacturers will have to make reasonable assumptions about how to interpret the law until CMS issues formal guidance.

Revised Federal Upper Limit

While in large part the revisions to the provisions governing federal upper limits (FUL) do not affect manufacturer responsibilities, there is one component of these revisions that may impact price reporting requirements. The FUL applies to multiple-source drugs, i.e., drugs that are therapeutically equivalent, pharmaceutically equivalent, and bioequivalent to each other, provided that there are at least three marketed drugs that are equivalent to each other. As revised by the Healthcare Reform Law, the FUL applicable to each group of multiple source drugs is set at 175% of their weighted AMP. Ostensibly to avoid significant fluctuations from quarter to quarter, CMS is to apply a smoothing process similar to the one used for Medicare Part B average sales price. Yet, it is unclear why this statutory mandate is needed, given that CMS by regulation already requires that manufacturers undertake an AMP smoothing process. CMS may simply determine that this new statutory requirement has already been met and take no further action.

Disclosure of Price Information

Manufacturers may be somewhat relieved by the changes to the AMP disclosure obligations binding on CMS. Previously, CMS was to post on its website manufacturer AMPs at the individual drug level. However, CMS has been under a court order enjoining it from implementing this provision. As revised by the Healthcare Reform Law, CMS is now required to post only the weighted average of the AMPs for

multiple-source drugs, meaning that pricing data for individual products should continue to remain confidential.

MEDICARE PART D COVERAGE GAP DISCOUNT PROGRAM OBLIGATIONS

Manufacturers will need to develop entire new systems to address the rebate requirements of the Medicare Part D Coverage Gap Discount Program. Effective January 1, 2011, manufacturers of innovator products must enter into an agreement with CMS to provide Medicare Part D beneficiaries discounts of 50% of the "negotiated price" of their products. The negotiated price is the price that Medicare Part D plans arrange with network pharmacies to accept as payment in full for a drug. This price is net of any price concessions available to the beneficiary from the Part D plan at the point of sale, including manufacturer rebates. Failure to enter into such an agreement will, absent extenuating circumstances, result in noncoverage of all of the manufacturer's outpatient products that could otherwise be covered under Part D.

Data Accrual and Transmission

Although manufacturers will have certain operational obligations upon implementation, the initial steps of the payment process do not involve the manufacturer. Part D plans adjudicate claims at the point of sale to ensure that beneficiaries receive the discount at that time. Part D plans subsequently submit encounter data to CMS, which intends to hire a contractor to review and validate these submissions. The contractor will submit invoices to the manufacturers based on the encounter data, and, as currently proposed, manufacturers will have 14 days to make payment to each Part D plan with utilization of the manufacturer's products. CMS has suggested, but not yet committed to, quarterly submission of invoices to manufacturers.

Will Validation Be Possible?

Manufacturers will get some information to validate the claims received, though it is unclear what data set CMS currently intends to furnish. As currently proposed, even if a manufacturer disagrees with CMS's data, it must make timely payment to the Part D plans and then separately undergo the dispute resolution process. Manufacturers will be required to maintain records supporting the propriety of their payments, and the support for any disputes they may institute, for 10 years. Failure to comply with the program's rules will result in a 25% surcharge on manufacturer liability.

No Anti-Kickback Statute Liability

These rebate payments are accorded favorable treatment in some respects. They are excluded from AMP and best price considerations. Additionally, they are exempt from Anti-Kickback Statute liability. However, the law only offers these protections for the specified amount of 50% of the negotiated price. Additional discounts manufacturers may wish to offer beneficiaries would not fall within the same protected status.

Operational Challenges

This developing regulatory framework raises a number of operational and strategic issues. From an operational standpoint, manufacturers will need to ensure that they have the infrastructure necessary to validate the Part D data and process invoices. This includes proper staffing, development of policies and procedures, and creation of an appropriate IT system. Notably, it is CMS, not the statute, that is

requiring that payments be made within 14 days, irrespective of any bona fide dispute. In contrast, under the Medicaid Drug Rebate Program, manufacturers have 38 days to process invoices, and can dispute the invoices rather than pay them. Some manufacturers have expressed concerns to CMS that the new Part D system does not resemble the Medicaid Drug Rebate Program closely enough.

Part D Plan Negotiation Strategy

The new program will also affect negotiations between Part D plans and manufacturers. Manufacturers will have a distinct preference to have all price concessions be passed through to the end-consumer, which will reduce the negotiated price and the corresponding manufacturer obligation. Part D plans, on the other hand, would prefer to retain manufacturer discounts for themselves, which lowers their unreimbursed administrative costs. Whether an agreement with the Part D plan will contain a covenant to pass through discounts to beneficiaries may therefore become a negotiation point going forward. Likewise, disputes may be instituted for invoices that are inconsistent with the agreement with the plan, once the parties do memorialize whether the discounts are to be passed along to the beneficiaries.

PAP Implications

PAP structures will also likely be affected. Manufacturers that operate an "outside of Part D" model PAP may decide to revise the qualifications of beneficiaries qualifying for enrollment, given that obtaining products through the Part D plan is now less financially burdensome. Moreover, with the increase in payments through the new coverage gap discount program, manufacturers may choose to donate less to the independent, tax-exempt organizations operating their own PAPs. In other words, resources spent on beneficiaries may to some extent be reallocated from other areas, rather than simply increased as a result of the Healthcare Reform Law.

If you have any questions or would like more information on any of the issues discussed in this LawFlash, please contact the author of this LawFlash, **Andrew D. Ruskin** (202.739.5960; aruskin@morganlewis.com), or any of the following key members of our cross-practice Healthcare Reform Law resource team:

FDA & Healthcare Practice

Joyce A. Cowan	Washington, D.C.	202.739.5373	jcowan@morganlewis.com
Kathleen M. Sanzo	Washington, D.C.	202.739.5209	ksanzo@morganlewis.com

Employee Benefits & Executive Compensation Practice

Andy R. Anderson	Chicago	312.324.1177	aanderson@morganlewis.com
Steven D. Spencer	Philadelphia	215.963.5714	sspencer@morganlewis.com

Antitrust Practice

Thomas J. Lang	Washington, D.C.	202.739.5609	tlang@morganlewis.com
Scott A. Stempel	Washington, D.C.	202.739.5211	sstempel@morganlewis.com

Business & Finance Practice –
Mergers & Acquisitions, Securities, Emerging Business & Technology

Marlee S. Myers	Pittsburgh	412.560.3310	msmyers@morganlewis.com
Scott D. Karchmer	San Francisco	415.442.1091	skarchmer@morganlewis.com
Randall B. Sunberg	Princeton	609.919.6606	rsunberg@morganlewis.com

Business & Finance Practice – Insurance Regulation			
David L. Harbaugh	Philadelphia	215.963.5751	dharbaugh@morganlewis.com
Labor & Employment Practice			
Joseph J. Costello	Philadelphia	215.963.5295	jcostello@morganlewis.com
John F. Ring	Washington, D.C.	202.739.5096	jring@morganlewis.com
Life Sciences Practice			
Stephen Paul Mahinka	Washington, D.C.	202.739.5205	smahinka@morganlewis.com
Litigation Practice – Commercial & Products Liability			
Kathleen M. Waters	Los Angeles	213.612.7375	kwaters@morganlewis.com
John P. Lavelle, Jr.	Philadelphia	215.963.4824	jlavelle@morganlewis.com
Coleen M. Meehan	Philadelphia	215.963.5892	cmeehan@morganlewis.com
Brian W. Shaffer	Philadelphia	215.963.5103	bshaffer@morganlewis.com
Litigation Practice – Corporate Investigations & White Collar Practice			
Lisa C. Dykstra	Philadelphia	215.963.5699	ldykstra@morganlewis.com
Jack C. Dodds	Philadelphia	215.963.4942	jdodds@morganlewis.com
Eric W. Sitarchuk	Philadelphia	215.963.5840	esitarchuk@morganlewis.com
Tax Controversy & Consulting Practice			
Gary B. Wilcox	Washington, D.C.	202.739.5509	gwilcox@morganlewis.com
Barton W. Bassett	Palo Alto	650.843.7567	bbassett@morganlewis.com
Washington Government Relations & Public Policy Practice			
Fred F. Fielding	Washington, D.C.	202.739.5560	ffielding@morganlewis.com

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