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Life Sciences Health Industry Alert

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Health Reform Update: Focus on Prescription Drug Price Regulation

While Congress continues to debate the "big picture" issues of broad-scale health care reform, pending bills in both the House of Representatives and Senate contain proposals to amend federal prescription drug price regulation programs such as the Medicaid rebate statute, the Public Health Service ("PHS") Act's Section 340B program, and Medicare Part D. This update provides an overview of the current proposals in this area and highlights important issues for prescription drug manufacturers, distributors, and dispensers. At this juncture, there are three keys bills under consideration: the Senate HELP Committee bill (S. 1796); the Senate Finance Committee bill (S. 1679), and the House consensus bill (H.R. 3962), which was passed by the House on November 7, 2009. While the bills have many common elements, there are also key differences that will need to be reconciled, and not all of the provisions described below may be enacted. At Appendix A, we have included a chart which compares the drug pricing provisions in the key current bills.

I. Medicaid Rebate Program Amendments

A. Changes to Medicaid Minimum Rebate Percentages

The Medicaid rebate statute currently requires a minimum rebate on single source and innovator multiple source drugs equal to 15.1 percent of the drug's average manufacturer price ("AMP"), and a rebate on noninnovator multiple source drugs of 11 percent of the AMP. Each of the key bills would increase the minimum rebate percentages.

The Senate HELP bill (S. 1796) would increase the minimum rebate for single source and innovator multiple source drugs to 23.1 percent of the AMP, except that hemophilia clotting factor and drugs approved exclusively for pediatric uses would pay a minimum rebate of 17.1 percent of AMP. Rebates on noninnovator multiple source drugs would be increased to 13 percent of AMP.

By contrast, H.R. 3962 increases the minimum rebate for single source and innovator multiple source drugs to 23.1 percent of AMP,[1] but does not contain any exceptions or adjustments for rebates on noninnovator products.

B. Additional Rebate for New Formulations of Existing Drugs

The rebate statute currently requires an "additional rebate" for single source and innovator multiple source drugs, which requires the manufacturer to pay the difference between the current AMP and the AMP during a "base period" as adjusted for inflation. The effect of the additional rebate is to penalize price increases that exceed the rate of inflation. The statute currently provides that each drug product represented by a unique 9-digit national drug code ("NDC") has its own unique "base period." Thus, new formulations of existing drugs, which typically have their own 9-digit NDC, often have lower "additional rebate" liability.

The Senate HELP bill does not define "new formulation," except that it clearly includes extended release versions of products and excludes new formulations of orphan drugs. For new formulations, however, the additional rebate is calculated based on the highest additional rebate for any strength of the original product.

Section 1742 of the House bill limits the definition of new formulations to "line extensions" of oral dosage forms. "Line extensions" are defined similarly to the Senate bill, although earlier versions would have limited the definition to extended release versions of existing products. The House bill is otherwise similar to the Senate bill.

C. Maximum Rebate Cap

The Senate HELP bill includes a provision which may provide some relief for situations where "excessive" additional rebates can actually result in total rebates that exceed the AMP for the product. Specifically, the bill would place a cap on the total rebate amount equal to 100 percent of AMP.

D. Redefinition of AMP, Use in Pharmacy Reimbursement, and AMP Transparency

Generally speaking, the AMP is currently defined as the average price paid by wholesalers for sales to the retail pharmacy class of trade. 42 U.S.C. § 1396r-8(a). The Deficit Reduction Act ("DRA") contemplated that CMS would further clarify this definition through regulations, provided for the use of AMPs to determine federal upper limits ("FULs") on pharmacy reimbursement, and contemplated the public disclosure of manufacturer AMP data on a website. CMS promulgated regulations which provide significantly more detail with respect to the calculation of AMP, both in terms of the classes of trade and types of concessions within the calculation. See 72 Fed. Reg. at 39142 (July 17, 2007). However, retail pharmacies remained concerned about the potential use of AMPs calculated pursuant to that regulation in the determination of federal upper limits ("FULs") on pharmacy reimbursement, and obtained a judicial injunction as well as a legislative delay of the implementation of AMP-based FULs.

Several of the current legislative proposals would make additional significant adjustments to the AMP methodology, the upper limits, and existing provisions regarding the transparency of manufacturer AMP data. Under S. 1796, the AMP would only take into account direct and indirect sales to "retail community pharmacies." Retail community pharmacies would include independent, chain, supermarket, and mass merchandiser pharmacies, but would specifically exclude mail order, nursing home, long term care, hospital, clinic, charitable, and government pharmacies, as well as pharmacy benefit managers. H.R. 3962 would exclude these classes of sales from the AMP calculation as well, but does not provide a definition of retail community pharmacies.

In addition to these class of trade amendments, both bills contain amendments relating to particular types of price concessions and other financial relationships between manufacturers and their customers. The bills would exclude from the AMP calculation customary prompt pay discounts to wholesalers, bona fide service fees to wholesalers or retailers (including specifically in the Senate bill, distribution service fees, inventory management fees, stocking allowances, and fees associated with patient care programs such as medication compliance and education programs), and reimbursement for recalled or unsalable returned goods. On the other hand, the Senate bill specifically includes any financial transactions received by or passed through to retail community pharmacies.

Both bills would also amend the provisions relating to FULs. The Senate bill strikes the mandate that CMS establish a FUL when there are two or more equivalent products, and instead authorizes FULs set at 175 percent of the weighted average of the AMPs for equivalent multiple source drug products available on a nationwide basis. Under the House bill, the FUL would be set at 130 percent of the weighted average of the AMPs. These provisions would also necessitate that manufacturers report to CMS the total number of units associated with AMP calculations.

On the other hand, the bills appear to reflect a moderate retreat from the AMP transparency contemplated by the DRA, in that they would amend the law to provide for public disclosure of the weighted average AMP for multiple source products, rather than individual manufacturers' AMPs.

E. Medicaid Rebates for Medicaid Managed Care Utilization

The Medicaid rebate statute currently exempts utilization dispensed through Medicaid managed care organizations ("MCOs") from Medicaid rebates, and the MCOs are free to negotiate their own rebates in connection with their formulary management activities.

Bills in both the House and the Senate include provisions which would subject Medicaid managed care utilization to traditional Medicaid rebates. The Senate HELP bill would require Medicaid MCOs to report utilization (excluding utilization subject to PHS 340B discounts) to the states, and the states would in turn bill the manufacturer for the rebates, presumably with the current quarterly fee-for-service utilization. The House bill likewise contemplates that MCOs will report utilization to the states, who will bill for that utilization along with quarterly fee-for-service utilization.

II. Medicare Part D

A. Medicaid Rebates for Dual Eligibles to Fund Coverage Gap Reduction

As part of the implementation of the Medicare Part D benefit, dual-eligible Medicaid patients obtained low-income subsidies for Part D coverage and states were in essence relieved of providing Medicaid drug benefits for these patients. At the same time, the states also ceased receiving Medicaid rebates for these patients, and Congressional critics have argued that manufacturer rebates provided to Part D plans for dual eligible utilization are less than the Medicaid rebates previously received.

The House bill contains provisions to address this issue by, in essence, mandating that manufacturers pay Medicaid-level rebates with respect to Part D utilization of dual-eligible patients. These rebates in turn are earmarked toward funding a gradual reduction in the "coverage gap" or "donut hole" under the Part D benefit.

Specifically, the House bill would require that manufacturers enter into a rebate agreement with the Secretary as a condition to the manufacturers' products being considered covered Part D drugs during 2011. (Manufacturers would also be required to provide rebates for 2010 utilization as a condition of 2011 coverage.) Both brand and generic drugs would be subject to these rebates. Rebates would be due with respect to utilization dispensed to "rebate eligible individuals," which would include full benefit dual eligibles in 2010 as well as subsidy-eligible individuals beginning in 2015. PDP sponsors would report such utilization data to CMS.

The amount of the required rebate would be equal to the difference between the Medicaid rebate amount and the "average Medicare drug program rebate eligible amount." The latter figure essentially represents the average Medicare Part D rebate for the product, as computed by CMS based on data reported by PDP plans. CMS is also authorized to estimate this amount based on bid and utilization information, subject to reconciliation.

B. Additional Coverage Gap Discounts

The House bill also includes a provision requiring manufacturers to subsidize drug costs during the coverage gap for "qualifying drugs" on a broader basis, in order for the "qualifying drugs" to be covered under Part D. Qualifying drugs include drugs approved under original new drug applications, as well as biologics and drugs covered by virtue of appeal processes, which are dispensed during the coverage gap dispensed to "qualifying enrollees" after January 1, 2010. Qualifying enrollees include Part D enrollees other than subsidy-eligible individuals.

The bill requires manufacturers to enter into a discount agreement under which the manufacturer will provide discounts to PDP sponsors for qualifying drugs. (The bill also provides limited authority for CMS to receive rebates directly during 2010.) The amount of the discount would be 50 percent of the drug-component negotiated price for the products. Such discount amounts would count toward the beneficiary's true out-of-pocket expenses.

III. PHS 340B Program Proposed Amendments

The Senate Finance committee bill (S. 1679) and the House bill contain provisions which would significantly expand the PHS 340B discount program. Under that program, manufacturers may not charge "covered entities" for covered outpatient drugs more than a maximum discounted price that is equal to the difference between a drug's Medicaid AMP and the average total Medicaid rebate.

A. Expansion of "Covered Entities" Eligible to Participate

Both the Senate and House bills authorize additional classes of health care providers to become "covered entities" eligible for 340B discounts. The Senate bill would authorize Medicare prospective payment system exempt children's and cancer hospitals that would meet disproportionate share hospital eligibility criteria, critical access hospitals, and rural referral centers with disproportionate share adjustments greater than or equal to 8 percent, to qualify as covered entities. The House bill includes these new categories, as well as also authorizing participation by title V maternal and child health grantees, community mental health service grantees, substance abuse treatment grantees, Medicare-dependent small rural hospitals, and Medicare sole community hospitals. Under the House bill, the new hospital covered entities would be subject to the existing restrictions on the use of group purchasing organizations ("GPOs") for outpatient purchasing that currently apply to disproportionate share hospitals.

B. Expansion of 340B Discounts to Inpatient Purchases

The Senate bill would also include a significant expansion to the 340B program in that it would require manufacturers to extend 340B discounts to hospital covered entities (including the new entities described above) for purposes of their inpatient use. The bill would also retain the current limitation on hospitals' use of GPOs for outpatient purchases, but would also include exceptions authorizing hospitals to use GPOs for inpatient purchases, as well as for outpatient uses pursuant to exceptions established by PHS with respect to drug shortages, manufacturer noncompliance, to facilitate the purchase of lower cost generics, and to minimize administrative burdens associated with dual inventory maintenance. However, this new authorization for inpatient 340B purchasing is not without cost to hospitals. While hospitals are permitted to use 340B purchases for any patients, they would be required to provide a credit to state Medicaid programs with respect to inpatient drugs administered to Medicaid patients within 90 days of filing their annual Medicare cost reports.[2]

C. Program Integrity

Finally, but significantly, both the House and Senate bills contemplate a potentially significant expansion with respect to the administrative oversight of the 340B program. These provisions, however, are subject to appropriations.

First, the bills authorize the Secretary to develop a system to verify the accuracy of ceiling prices calculated and charged by manufacturers to covered entities. Second, bill would require the Secretary to establish procedures for manufacturers to issue refunds to covered entities in the case of overcharges (including in the Senate bill both routine and non-routine overcharge situations). Third, the bills authorize the Secretary to develop an internet website through which covered entities may obtain the PHS prices. Fourth, the bills contemplate a system to report additional rebates that may lower PHS prices and to provide credits to covered entities in those instances. Fifth, the bills would authorize the Secretary to audit both manufacturers and wholesalers with respect to program compliance. Sixth, the bill would authorize civil money penalties ("CMPs") against manufacturers that knowingly and intentionally overcharge covered entities.

The bills also contemplate improvements with respect to covered entity compliance and identification, including a system to verify current entity eligibility, the development of a unique identifier, and the imposition of sanctions where a covered entity diverts products for non-covered uses or otherwise fails to comply with program requirements.

Finally, the bills contemplate the establishment of administrative dispute resolution ("ADR") procedures to address claims of both manufacturer and covered entity noncompliance. The Senate bill specifically contemplates that these procedures would authorize discovery from manufacturers and third parties, and would permit the hearing entity to consolidate claims from multiple claimants and to allow associations to assert claims rather than the covered entities themselves. The Senate bill would also condition a manufacturer ADR claim against a covered entity upon the manufacturer having conducted an audit of the covered entity.

IV. Commentary

The most significant implications of the proposals described above for manufacturers are, of course, financial. Simply stated, the provisions will increase required manufacturer rebates and discounts, but manufacturers will need to consider the ultimate legislation enacted to determine just how much. For example, while it may be relatively simple to model the direct implications of a higher minimum rebate percentage on Medicaid fee-for-service utilization, that higher percentage may carry several indirect effects.

First, that higher rebate percentage may be applied to a broader base of utilization, which may include Medicaid managed care and Medicare Part D dual eligibles. Second, those higher percentages may yield lower 340B prices not only to existing covered entities, but also to new classes of covered entities, and for inpatient purchases of certain covered entities. Third, a higher minimum rebate percentage may result in greater pressure to provide commercial discounts insofar as the most-favored-nation effects of the best price provisions will be weaker.

On top of all of these implications of the increase in the minimum rebate percentage, manufacturers should also not lose sight of the potential impact of the changes in the AMP definition. Those changes, on their face, appear to be designed to produce higher AMPs. Thus, the higher minimum rebate percentages may be applied to higher AMPs, yielding even greater rebates. Moreover, unless manufacturers revise their base AMPs for their products in order to provide for an "apples-to-apples"

comparison for purposes of determining the additional rebate using a consistent methodology, manufacturers may also experience an artificial increase in additional rebate liability.

The proposed amendments to the additional rebate calculation for new formulations are also troublesome. Not only may they provide disincentives to the development of improved formulations of existing products, but the formula may produce inequities insofar as the additional rebate liability for a new formulation is based on the historical additional rebate liability for any strength of the product, regardless of whether that strength is comparable to the new product. The House bill may also pose a "compliance trap" for manufacturers insofar as it narrowly defines new formulations to mean extended release formulations, but does not appear to address simple dosage form changes.

The proposed legislation could also require substantial reworking of manufacturers price calculation and reporting processes. While the calculation of AMP would appear to be simpler (and the House bill may also clarify the treatment of specific types of bona fide service fees), the proposals contemplate new reporting requirements with respect to utilization and in connection with the Medicare, Medicaid, and PHS programs.

Finally, aside from the financial implications of expanded PHS 340B covered entity classes and permissible utilization, the program integrity provisions of the proposed bills may be one of the more significant changes, if they are ultimately funded through the appropriations process. Historically, the 340B program administration has been relatively informal, and the introduction of enhanced and formal oversight procedures – not to mention the possibility of civil money penalties – has significant potential to lead to disputes. Moreover, the ability of covered entities to invoke dispute resolution procedures permitting discovery, class-action like consolidation of claims, and representation by associations, is likely to significantly shift the balance of power in the administration of the 340B program.

Reed Smith will continue to monitor developments with respect to drug pricing regulation as the health care reform debate continues. In the interim, please contact Joseph W. Metro in our Washington office if you have questions in this area or concerning these proposals.

APPENDIX A:

Summary Of Drug Price Regulation Provisions In Pending Health Reform Bills

ISSUE	SENATE HELP (S. 1796)	SENATE FINANCE (S. 1679)	HOUSE (H.R. 3962)
Change in Medicaid minimum rebate percentage	23.1 percent of AMP for most single source and innovator multiple source products 17 percent of AMP for hemophilia clotting factor and products approved exclusively for pediatric uses 13 percent of AMP for noninnovator multiple source drugs	No provision	23.1 percent for single source and innovator multiple source drugs
Medicaid "additional rebate" for new formulations of existing single source and innovator products	For "new formulations" of existing drugs, additional (CPI) rebate is determined using the highest additional rebate for any strength of the existing drug New formulations not defined, but includes extended release products and excludes orphan drugs	No provision	Similar provision New formulations defined as "line extensions" of oral solid dosage forms, and no specific exclusion of orphan drugs
Medicaid maximum rebate cap	Establishes ceiling for total rebate equal to 100 percent of AMP	No provision	No provision

ISSUE	SENATE HELP (S. 1796)	SENATE FINANCE (S. 1679)	HOUSE (H.R. 3962)
AMP Redefinition: Classes of Trade	AMP only takes into account direct and indirect sales to "retail community pharmacies" Retail community pharmacies defined to include independent, chain, supermarket, and mass merchandiser pharmacies Retail community pharmacies defined to exclude long term care, mail order, hospital, clinic, nursing home, charitable, and government pharmacies, and PBMs	No provision	Sales to long term care, mail order, nursing home, managed care, HMOs, insurers and PBMs excluded from AMP Sales to hospitals, clinics and physicians excluded from AMP except for inhalation/infusion drugs or where Secretary determines necessary to calculate an AMP
AMP Redefinition: Excluded Concessions	AMP does not take into account prompt pay discounts, bona fide service fees (including distribution service fees, inventory management fees, stocking allowances, or patient care program fees), reimbursement for returns Financial transactions passed through to the retail pharmacy	No provision	AMP does not take into account prompt pay discounts, bona fide service fees, or reimbursement for returns
Federal Upper Limits on Pharmacy Reimbursement	175 percent of the weighted average of the AMPs for equivalent multiple source drug products available on a nationwide basis Manufacturers report AMP units	No provision	130 percent of the weighted average of the AMPs for equivalent multiple source drugs Manufacturers report AMP units
AMP Transparency	CMS to develop website to disclose weighted average AMP	No provision	Similar provision
Medicaid rebates for Medicaid managed care utilization	Manufacturers to provide Medicaid rebates for Medicaid MCO utilization MCOs report utilization to states Utilization excludes PHS 340B utilization	No provision	Similar provisions
Medicaid rebates for Part D dual eligibles	No provision	No provision	Manufacturers must pay Part D rebates for dual eligible (and in 2015, subsidy eligible) utilization equal to difference between Medicaid rebate amount and average Medicare Part D rebate amounts under agreement with Secretary Funding to support reduction of coverage gap
Coverage gap rebates	No provision	No provision	Manufacturers of brand name drugs to provide rebates for utilization by non-subsidy eligible individuals during the coverage gap, equal to 50 percent of the drug component of the negotiated price.

ISSUE	SENATE HELP (S. 1796)	SENATE FINANCE (S. 1679)	HOUSE (H.R. 3962)
PHS 340B Program – New covered entities	No provision	Adds children's' and cancer hospitals that meet disproportionate share hospital eligibility criteria, critical access hospitals, and rural referral centers with disproportionate share adjustments greater than or equal to 8 percent	Similar provision to Senate bill Also adds title V maternal and child health grantees, community mental health service grantees, substance abuse treatment grantees, Medicare-dependent small rural hospitals, and Medicare sole community hospitals
PHS 340B Program – Inpatient hospital Discount eligibility and GPO use	No provision	Allows 340B hospitals to purchase at 340B prices for inpatient use Permits continuing inpatient GPO use, as well as outpatient GPO use for short supply, generic purchases, and to minimize dual inventory burdens Requires hospitals to credit Medicaid programs for inpatient utilization	No provision
PHS 340B Program – Program Integrity	No provision	Establishment of system to verify accuracy of prices by PHS Required refunds Internet portal for 340B price information Authorization for manufacturer audits and civil money penalties Improvement in systems for verifying entity eligibility Administrative dispute procedures, including discovery, claim consolidation, and association representation of covered entities	Similar provisions

1 The original version of the House bill would have increased the minimum rebate to 22.1 percent.

2 The original House bill (H.R. 3200) included a similar expansion of 340B program discounts to inpatient hospitals, but the provision does not appear in H.R. 3962.)

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