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The Impact of the Deficit Reduction Act of 2005 on Pharmaceutical Manufacturers

The Deficit Reduction Act of 2005 ("DRA"), signed by the President on February 8, 2006, is expected to reduce Medicaid spending by $4.7 billion between 2006 and 2010.[1] The DRA alters the Medicaid program in a number of ways that will have significant implications for pharmaceutical manufacturers, including changes in the calculation and reporting of pricing data to the Centers for Medicare & Medicaid Services ("CMS"). These amendments are discussed below.

Unless otherwise stated, the changes are effective on January 1, 2007, without regard to whether final regulations to carry out these amendments have been promulgated by that time.

I. Changes to the Calculation of AMP and Best Price

The DRA amends the Medicaid drug rebate statute[2] to implement significant changes to the reporting and calculation of average manufacturer price ("AMP") and best price for drugs covered by the Medicaid program.

Beginning in 2007, manufacturers will be required to report AMP and best price to CMS on a monthly basis.[3] Previously, AMP and best price were reported to CMS on a quarterly basis. Further, beginning on July 1, 2006, CMS will provide AMP information to state agencies and post reported AMPs on a website accessible to the public.[4] Previously, AMP data was provided to CMS on a confidential basis and could not be disclosed by the agency.

The DRA also imposes several important changes regarding how manufacturers will calculate AMP and best price. First, the calculation of AMP for a covered outpatient drug will exclude customary prompt pay discounts extended to wholesalers.[5] Second, only certain sales of covered outpatient drugs at a nominal price (defined as less than 10 percent of AMP) will be excluded from the determination of best price.[6] Previously, the exclusion applied to all sales at a nominal price, regardless of the purchaser. Under the DRA, only nominal sales to the following entities will be excluded from the best price determination:

- A facility that qualifies under the 340B program;
- An intermediate care facility for the mentally retarded;
- A state-owned or state-operated nursing facility;

[1] Pub. L. No. 109-171.
[2] Codified at 42 U.S.C. § 1396r-8.
[3] Pub. L. No. 109-171, § 6001(b)(1).
[4] § 6001(b)(1)(B).
[5] § 6001(c)(1)(C).
[6] § 6001(d)(2).

- Any other facility or entity that the Secretary determines is a safety net provider to which sales of drugs at nominal prices would be appropriate based on the following factors: (1) the type of facility or entity; (2) the services provided; (3) the patient population served; and (4) the number of other facilities or entities eligible to purchase at nominal prices in the same service area.[7]

Nominally priced sales of covered outpatient drugs made pursuant to a master agreement for procurement of drugs on the Federal Supply Schedule will still be excluded from the best price determination, regardless of the purchaser.[8]

Third, the DRA amends the Medicaid rebate statute to include authorized generics in the calculation of AMP and best price. It does this by requiring that AMP and best price include all drugs marketed under a single new drug application.[9] Previously, some brand name manufacturers sold generic versions of a brand name drug as "authorized generics" and did not include the prices of those products when calculating AMP and best price. This new provision may significantly complicate the ability of manufacturers to enter the generic market by use of an authorized generic.

II. Changes to the Reimbursement Methodology for the Medicaid Program

The statute also imposes several key changes to the reimbursement methodology of the Medicaid program, including the following:

- Upper Payment Limit: Currently, an upper reimbursement limit applies to multiple source drugs for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent. Under the DRA, the limit will apply to multiple source drugs for which two or more drugs are equivalent.[10] In addition, the upper reimbursement limit will be 250 percent of the AMP, rather than the current limit of 150 percent of the published price.[11]

- Definition of "Multiple Source Drug": Under the DRA, the term "multiple source drug" will refer to a covered outpatient drug for which there is at least one other drug sold and marketed during the rebate period that is therapeutically equivalent, pharmaceutically equivalent, and bioequivalent.[12] Current law provides that a multiple source drug is a drug for which there are two or more equivalent drugs.

III. Promulgation of Regulations and Required Surveys

The statute requires the Inspector General to review the requirements for and manner in which AMPs are determined and submit to the Secretary and Congress any recommendations for changes by June 1, 2006.[13] By July 1, 2007, the Secretary must promulgate a regulation that clarifies the requirements for and manner in which AMPs are determined, taking into account the recommendations submitted by the Inspector General.[14]

[7] *Id.*.
[8] *Id.*
[9] § 6003.
[10] § 6001(a)(1).
[11] § 6001(a)(2).
[12] § 6001(a)(3).
[13] § 6001(c)(3).
[14] *Id.*

The DRA also permits the Secretary to contract for services for the determination of retail survey prices for covered outpatient drugs that represent a nationwide average of consumer purchase prices.[15] The contract may also include notification to the Secretary when a drug that is therapeutically and pharmaceutically equivalent and bioequivalent becomes generally available.[16] Following such notification, the Secretary will have seven days to decide whether the drug meets the definition of a "multiple source drug" subject to the upper reimbursement limit described above.[17]

In addition, the Secretary will be required to compare on a yearly basis the national retail sales price data with the pricing data provided by the states for the 50 most widely prescribed drugs. This information, compiled in the form of performance rankings, will be submitted to Congress and to the states.[18]

Beginning January 1, 2006, for single source drugs that are physician administered and beginning January 1, 2008, for the 20 physician administered multiple source drugs with the highest dollar volume of administrations under the Medicaid program (as determined by the Secretary), the states must collect and submit utilization data and coding information in order to obtain federal reimbursement.[19] The Secretary may, however, delay the requirements to prevent hardship to states that need additional time to implement the reporting system.[20]

IV. Implications for Children's Hospitals

Finally, the DRA amends the Medicaid rebate statute to include certain qualifying children's hospitals within the definition of a "covered entity" for purposes of the rebate program, effective February 8, 2006.[21] Sales to these children's hospitals are therefore exempt from best price determinations. Importantly, despite Congress's apparent intent to the contrary, the DRA does not amend the definition of a "covered entity" under the 340B program, which allows certain health care providers access to discounted prices for prescription drugs.[22] Therefore, although sales to these qualifying children's hospitals are exempt from best price determinations, these hospitals are not eligible for 340B pricing, even though the title of the DRA provision suggests that they are.

[15] § 6001(e).
[16] *Id.*
[17] *Id.*
[18] *Id.*
[19] § 6002.
[20] § 6002(a).
[21] § 6004.
[22] 42 U.S.C. § 256b(a)(4).

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This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

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