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THE DEFICIT REDUCTION ACT OF 2005: AMENDMENTS TO THE MEDICAID REBATE PROGRAM AND DRUG PAYMENT

The Deficit Reduction Act of 2005 ("DEFRA 2005" or "the Act") was passed by Congress on February 1, 2006 and sent to the White House for the President's signature. The legislation contains several important amendments to the Medicaid Rebate Program. In addition, although major reforms in Medicaid payment for drugs were deleted from the bill, certain changes to the Medicaid Federal Upper Limit ("FUL") provisions are included. Unless otherwise noted, the changes described below will take effect January 1, 2007.

Changes to the Medicaid Rebate Program

Average Manufacturer Price ("AMP") and Best Price ("BP") Reporting: Beginning January 1, 2007, manufacturers are required to report AMPs and BPs to the Centers for Medicare & Medicaid Services ("CMS") on a monthly basis rather than quarterly.[1] Beginning July 1, 2006, CMS will provide to states monthly reports of AMPs

[1] DEFRA 2005, S. 1932, 109th Cong. § 6001(b)(1)(A) (2005). There is a conflict between section 6001(b)(1)(A) and section 6003(a)(1) regarding whether reporting of AMPs and BPs is required to be done on a monthly or quarterly basis. The conference report indicates that monthly reporting was intended. H.R. Rep. No. 109-362, at 256 (2005) (Conf. Rep.). This issue may be addressed in technical corrections to the Act.

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for single source drugs and multiple source drugs.[2] Additionally, CMS will begin publishing AMPs on a website accessible to the public, updated quarterly.[3]

Prompt Pay Discounts: The definition of AMP is amended so that customary prompt pay discounts to wholesalers are no longer deducted in the calculation of AMP.[4] However, the price reports submitted by manufacturers to CMS are to include customary prompt pay discounts extended to wholesalers, in addition to AMP and BP.[5]

Nominal Price Sales: Manufacturers will be required to report quarterly information on sales of Medicaid covered drugs that are made at a nominal price.[6] In addition, the exclusion from BP of nominal prices has been limited so that the exclusion will only apply to sales to the following entities: section 340B covered entities,[7] intermediate care facilities for the mentally retarded, state-owned or operated nursing facilities, and other safety net providers as determined by the Department of Health and Human Services ("DHHS").[8] The nominal price limitations do not apply to nominal drug purchases pursuant to a master agreement with the Department of Veterans Affairs.[9]

Authorized Generics: The definition of BP is amended to include "the lowest price available to any entity for any [single source drug or innovator multiple source drug] of a manufacturer that is sold under a new drug application ["NDA"] approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act."[10] This applies to

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2 Id. § 6001(b)(1)(B).

3 Id.

4 Id. § 6001(c)(1)(C).

5 Id. § 6001(c)(2).

6 Id. § 6001(d)(1).

7 See Public Health Service Act § 340B, 42 U.S.C. § 256b. These are disproportionate share hospitals and certain clinics that receive grants from the Public Health Service.

8 DEFRA 2005 § 6001(d)(2).

9 Id.

10 Id. § 6003(b)(1)(A).

"price[s] available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States."[11] A "special rule" applicable to BP is added to state that "in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under [an NDA] approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, [BP] shall be inclusive of the lowest price for such authorized drug available from the manufacturer during the rebate period to any manufacturer, wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States. . . ."[12] It is clear from this provision that, where a manufacturer sells a generically labeled version of its brand name drug under the same NDA as the brand name drug, sales of the generically labeled drug are included in the BP of the brand name drug. It is also clear that a manufacturer's sales of an authorized generic drug to another company, which subsequently sells to its own customers under the first manufacturer's NDA, are included in the first manufacturer's BP. In the latter case, the statute can also be read as providing that the second company's sales are not included in the first manufacturer's BP. However, the statute is somewhat ambiguous on this point. Interested manufacturers may want to seek clarification from CMS, the implementing agency.

In addition, the definition of AMP is amended such that the AMP for a drug for which "a manufacturer . . . approves, allows, or otherwise permits any drug of the manufacturer to be sold under [an NDA] approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act" will be "inclusive of the average price paid for such drug by wholesalers for drugs distributed to the retail pharmacy class of trade."[13]

AMP Regulations: No later than June 1, 2006, the Inspector General of DHHS is required to review the requirements for the calculation of AMP and recommend changes to such requirements.[14] DEFRA 2005 sets a deadline of July 1, 2007 for DHHS to promulgate a regulation that "clarifies the requirements for, and the manner in which, [AMPs] are determined. . . ."[15]

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11 42 U.S.C. § 1396r-8(c)(1)(C)(i) (emphasis added).

12 DEFRA 2005 § 6003(b)(1)(B) (emphasis added).

13 Id. § 6003(b)(2).

14 Id. § 6001(c)(3)(A).

15 Id. § 6001(c)(3)(B).

Physician-Administered Drugs: DEFRA 2005 includes a provision to encourage states to capture physician-administered drugs under the Rebate Program. In order to secure rebates for such drugs (and as a condition of receiving Medicaid payment), states are required to submit certain utilization data and coding (e.g., J-codes and NDC numbers) to DHHS.[16] For single source physician-administered drugs administered after January 1, 2006, states are required to provide for the collection and submission of utilization data and coding for drugs specified by DHHS. For multiple source physician-administered drugs, the Secretary is required to publish a list of the twenty such drugs with the highest dollar volume under the Medicaid Program no later than January 1, 2007.[17] For drugs on this list that are administered after January 1, 2008, the state is required to provide for the collection and submission of utilization data and coding for drugs specified by DHHS.[18]

Changes in Medicaid Payment for Drugs

Federal Upper Limit: The FUL on reimbursement for multiple source drugs has been changed from 150 percent of the published price of the lowest cost generic drug to 250 percent of the AMP of the lowest cost generic drug.[19] In addition, FULs will apply to multiple source drugs for which the Food and Drug Administration has rated two or more products to be therapeutically and pharmaceutically equivalent, rather than three as before.[20]

Retail Survey Prices: DEFRA 2005 permits the Secretary of DHHS to contract with a vendor for the determination of retail survey prices for covered outpatient drugs that represent a nationwide average of consumer purchase prices for such drugs.[21] This information will be provided to states in a monthly basis.[22] Additionally, each state shall provide an annual report to DHHS that includes payment rates under the state plan for

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16 Id. § 6002.

17 Id.

18 Id.

19 Id. § 6001(a)(2).

20 Id. § 6001(a)(1).

21 Id. § 6001(e).

22 Id.

covered outpatient drugs, dispensing fees paid under such plan, and utilization rates for noninnovator multiple source drugs under such plan.[23] The Secretary is required, on an annual basis, to compare the national retail sales price data with data for each state for the fifty most widely prescribed drugs.[24]

Changes to the § 340B Drug Discount Program

Certain children's hospitals were added to the list of "covered entities" that may have access to § 340B discounted prices.[25] This provision is effective for drugs purchased on or after the date of enactment.

Incentives to States Regarding False Claims Acts Cases

DEFRA 2005 also includes provisions related to false claims recoveries. First, states are encouraged to enact state false claims statutes. If a state has in effect a law relating to false or fraudulent claims that provides for qui tam actions and meets other specified requirements, the federal medical assistance percentage for any amounts recovered under a state action brought under such a law will be decreased by ten percentage points.[26] Second, any entity that receives annual payments under a Medicaid state plan of at least $5,000,000 must, as a condition of receiving such payments, establish written policies for employees, contractors, and agents that provide detailed information regarding the federal and state false claims laws, including remedies and whistleblower protections.[27]

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If you have any questions, please contact Michelle L. Butler at 202/737-7551 or Alan M. Kirschenbaum at 202/737-4283.

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23 Id.

24 Id.

25 Id. § 6004(a).

26 Id. § 6032(a).

27 Id. § 6033(a).