

December 11, 2003

**Average Wholesale Price Reform Provisions of the
Medicare Prescription Drug, Improvement, and Modernization Act of 2003**

On December 8, 2003, the President signed into law the conference version of H.R. 1, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the “Act”) into law.¹ The Act provides for sweeping changes to Medicare. This memorandum provides a top-level summary of one of those changes - the Average Wholesale Price reform provisions contained in Title III of the Act.

For covered outpatient drugs administered by a physician,² Medicare currently reimburses at 95 % of the published Average Wholesale Price (“AWP”). Physicians typically obtain Part B drugs from specialty pharmacies and other sources at discounted prices below the published AWP. Pointing in part to this “spread” between AWP and physicians acquisition costs, a 2001 report by the General Accounting Office (“GAO”) and Centers for Medicare and Medicaid Services (“CMS”) claimed that Medicare “overpaid for Part B drugs by over \$1 billion annually.”³

¹ All citations to the Act will be to the text of the bill as reported in the House Conference Report. All new statutory provisions created by this Title will be incorporated into the Social Security Act, codified at 42 U.S.C. § 301, *et seq.*

² Covered physician-administered drugs include some cancer chemotherapy drugs, immunosuppressive drugs following a Medicare-covered organ transplant, erythropoietin for persons with chronic renal failure who are on dialysis, and hemophilia clotting factors.

³ See Committee on Ways and Means, *Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Reimbursement for Part B Drugs, Average Wholesale Price Reform* (November 19, 2003).

Physicians, however, have argued that under the Medicare physician fee schedule, payments for the services associated with administering covered drugs do not fully cover the actual costs of such services. As a result, physicians have often contended that the current reimbursement rates for covered physician-administered drugs are necessary in order to fully reimburse physicians for their costs.

Congress addressed these reimbursement issues in the Act by including provisions intended to reduce Medicare's reimbursement rates for physician-administered prescription drugs while at the same time increasing reimbursement rates for the services associated with administering those drugs. First, the Act revises the method by which Medicare reimburses for covered physician-administered drugs. Second, the Act increases the fee schedule reimbursements to physicians for associated services. The Act also provides for transition payments to physicians in 2004 and 2005 to minimize the disruption caused by the new payment system.⁴

I. Changes to the Drug Reimbursement System

Currently, Medicare reimburses covered physician-administered drugs at 95 % of AWP. Under Section 303 of the Act, beginning in 2005, these drugs will be reimbursed at 106 % of the Average Sales Price ("ASP").⁵

⁴ On August 20, 2003, CMS issued a proposed rule aimed at reducing Medicare costs for drugs covered under Part B. *See* 68 Fed. Reg. 50427 (Aug. 20, 2003). There is some speculation in the trade press that CMS will finalize its rule by the end of the year. It is possible, however, that CMS will have to issue a new proposal in light of the Act.

⁵ H.R. 1 § 303(c)(1), adding new section 1847A to the Social Security Act. The Act draws a slight distinction between multiple source and single source drugs. Multiple source drugs are to be reimbursed at 106 percent of ASP. Single source drugs are to be reimbursed at 106 percent of ASP or 106 percent of wholesale acquisition cost ("WAC"), whichever is less. *Id.*

The Act defines ASP as an average⁶ of the final sales prices to all U.S. purchasers⁷, net of rebates and other discounts.⁸ ASP is to be determined on a quarterly basis, based on sales figures submitted by drug manufacturers.⁹ The Act provides for civil monetary penalties for any manufacturer misrepresentations of ASP data.¹⁰ The Secretary of the Department of Health and Human Services (“the Secretary”) has the authority to adjust the ASP for a drug if the Secretary finds that the ASP does not accurately reflect actual market prices.¹¹

Beginning in 2006, physicians can opt out of the ASP reimbursement system and elect instead to receive stock-replacement drugs through specified Medicare contractors. Starting in 2006, physicians must make an annual election for either the ASP reimbursement system or the drug replacement system.¹² Under the drug replacement system, physicians would obtain the drugs to be administered to their patients from specified Medicare contractors (selected through a competitive bidding system). The Medicare contractors, rather than the physicians, would be reimbursed by Medicare. The

⁶ Computed using included sales divided by the number of units sold.

⁷ The Act excepts certain sales from inclusion in the computation of ASP, including (a) sales exempt from inclusion in the determination of “best price” under section 1927(c)(1)(C)(i) of the Social Security Act, and (b) “such sales as the Secretary identifies as sales to an entity that are merely nominal in amount.” H.R. 1 § 303(c)(1), adding new section 1847A to the Social Security Act.

⁸ Rebates and discounts include “volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks and rebates (other than rebates under section 1927).” For years after 2004, the Secretary may include “other price concessions . . . that would result in a reduction of the cost to the purchaser.” *Id.*

⁹ H.R. 1 § 303(c)(1), adding new § 1847A to the Social Security Act.

¹⁰ *Id.*

¹¹ *Id.*

¹² *Id.* at § 303(c)(1), adding new § 1847B to the Social Security Act.

contractors would also be responsible for collecting the 20 % co-insurance premiums owed by beneficiaries,¹³ thus relieving physicians of the risk of non-payment by patients.

As a means of transitioning to the ASP reimbursement system, for drugs furnished in 2004, Medicare will reimburse at 85 % of AWP (determined as of April 1, 2003).¹⁴ The Secretary has limited discretion to adjust this percentage for specific drugs based on information provided by the manufacturer within a specified timeframe. In no event, however, may the Secretary adjust the percentage below 80 %.¹⁵

II. Fee Schedule Increases

Section 303(a) of the Act also includes several provisions intended to increase the fee schedule payments made to physicians. In an effort to compensate physicians for their true costs in administering these drugs, the Act:

1. Directs CMS to use a survey submitted by a qualified physician specialty organization (likely the American Society of Clinical Oncologists) to calculate practice expenses;¹⁶
2. Directs CMS to use data regarding oncology nursing salaries from the American Society of Clinical Oncologists study (if such data is contained in the survey);¹⁷
3. Directs CMS “promptly” to evaluate existing drug administration codes, taking into account levels of complexity and resource consumption. The Act exempts any revisions from budget neutrality requirements;¹⁸

¹³ *Id.*

¹⁴ H.R. 1 § 303(b)(2), amending Social Security Act § 1842(o). A few specified exceptions are made for certain drugs (including, among others, certain infusion drugs administered through durable medical equipment, certain vaccines, and drugs that were not available for payment as of April 1, 2003). These drugs continue to be reimbursed at 95 percent of AWP in 2004 or, in some cases, beyond. *Id.* at §§ 303(b)(1) & (2).

¹⁵ H.R. 1 § 303(b)(2).

¹⁶ H.R. 1 § 303(a)(1)(B), amending Social Security Act § 1848(c)(2).

¹⁷ *Id.*

4. Directs CMS to use supplemental survey data including expenses for drug administration in calculating practice expenses if such surveys are submitted in a timely manner;¹⁹ and
5. Directs the Medicare Payment Advisory Committee (“MedPAC”) to review any payment changes made under the Act. MedPAC is required to report to the Secretary and to Congress by January 2006 for items and services furnished by oncologists and by January 2007 for other affected specialties. These reports may include recommendations for further adjustments in payments.²⁰

In order to provide for a transition to the new payment system, the Act provides for transitional payments to physicians in 2004 and 2005.²¹ Such payments will be made as an adjustment to the payments that would otherwise be made to physicians in those years. For 2004, the adjustment amounts to 32 % of the payment that would otherwise be made. In 2005, the adjustment amounts to three percent of the payment that would otherwise be made.

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.* at § 303(a)(5).

²¹ *Id.* at § 303(a)(4).

We are continuing to analyze the implications of this sweeping new legislation and will be following closely as CMS issues regulations and takes other actions necessary to implement the AWP reforms and fee schedule revisions. If you would like further information about the implications of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 or other aspects of the Medicare provisions of the Social Security Act, please contact:

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