LEGAL CORNER

Medicare Payment for Drugs to Change in 2005

by Susan W. Berson, JD

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) significantly changed how Medicare reimburses for coverage of drugs. Currently, Medicare Part B covers only drugs and biologicals that are *not* self-administered and that are provided "incident to" a physician's service. While chemotherapy and other types of cancer treatments are still covered by Medicare, the MMA has changed how these drugs are reimbursed in 2005 and beyond.

Prior to the MMA, Medicare generally reimbursed covered drugs at a percentage of average wholesale price (AWP). The AWP methodology was intended to represent the average price at which wholesalers sold drugs to their customers based on prices reported by drug manufacturers. However, many viewed this reimbursement method as flawed because of a lack of uniform criteria for establishing or reporting AWP, and the fact that manufacturer and wholesale discounts did not need to be included in the calculation.

So, the Office of the Inspector General (OIG) in the Department of Health and Human Services (HHS) began to look into how drug manufacturers established and reported the AWPs of certain Medicare-covered drugs. The OIG was concerned that Medicare was reimbursing some drugs at amounts higher than what the providers were actually paying for the drugs. Even worse, the OIG believed that, in some cases, drug manufacturers were marketing this "spread" and advising providers of the significant profit they could make by prescribing the specified product. The OIG began to question whether providers might change their prescribing patterns to order the more "profitable" drug—possibly affecting the quality of care.

The response from the provider community was swift and unequivocal: any drug margins were used to cover inadequate practice expense reimbursement. Providers maintained that any "fix" to the current reimbursement system must also include changes to practice expense reimbursement if patient access to care was not to be adversely affected.

Prior to the enactment of the MMA, many steps were taken to correct the flawed AWP methodology, with the Centers for Medicare & Medicaid Services (CMS) moving toward a reimbursement system based on true acquisition costs. But the regulatory process was slow, so Congress made the changes legislatively with the passage of the MMA. Beginning in 2005 for the physician office-setting and in 2006 for the hospital outpatient setting, most drugs and biologicals will be reimbursed using either the average sales price (ASP) methodology or through a competitive acquisition program.

Under ASP, drug payments will equal 106 percent of the applicable price for the drug, subject to appropriate co-insurance amounts. Some drug sales are exempt from the ASP calculation, including sales that are nominal in amount (i.e., drugs that cost $50/encounter or less, which are bundled into their administration payments) and certain sales that are exempt from the Medicaid drug rebate program. A study will be conducted to determine if purchases made by large purchasers, such as pharmacy benefit managers, should also be excluded from the calculation of ASP. In limited circumstances, such as public emergencies, exceptions in ASP pricing will be allowed. On the other hand, all volume discounts, prompt-pay discounts, rebates, free goods, and any other discounts will now be taken into account when calculating the reimbursement amounts for drugs.

To monitor market prices and ensure that drug prices are not manipulated, the OIG will conduct studies to determine the market prices of various drugs and biologicals. A manufacturer that reports a drug price exceeding the market price or average manufacturer's price by a set amount will have its prices disregarded. Additionally, manufacturers must submit information quarterly on drug pricing, units sold, acquisition costs, and nominal sales on all drugs covered under Medicare and Medicaid. Data obtained from group purchasing organizations, physicians, and suppliers may be taken into consideration when determining the accuracy of the information reported by manufacturers.

Apart from ASP, the MMA also requires the HHS Secretary to establish a competitive acquisition program. While certain drugs that do not offer significant cost-savings may be excluded from the program, this program would allow providers to acquire competitively bid drugs and biologicals. The competitive acquisition program would have three requirements:

- Providers must obtain their drugs or biologicals only from a manufacturer or a distributor.
- Providers would need to comply with all requirements set by the Food and Drug Administration regarding safe storage and handling.
- Providers must comply with code of conduct and fraud and abuse rules.

While the provisions contained in the MMA are intended to reduce the cost of many expensive pharmaceutical products—including anti-cancer drugs—the implementation process is complex, and changes may take place over the next two to three years.

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