Legal Opinion Letter

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# MEDICARE DRUG REIMBURSEMENT REFORM PRESENTS CHALLENGES AND OPPORTUNITIES

by
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In the debate preceding Congress' passage of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") and subsequent discussion of its implementation, public and media attention focused largely on how it expands federal Medicare coverage of prescription drugs for certain seniors. Largely overlooked, but no less significant to patients, providers, and pharmaceutical manufacturers, were the law's changes to the process of reimbursement for so-called "Part B"-covered drugs. As the changes move forward, some in the medical community are voicing serious concern over the new reimbursement scheme, calling for delay in implementation or even major congressional surgery. Medicare is one of the government's most complex programs, and complications and inequities will be inevitable when imposing reform. Such challenges, however, do not require major alterations, and policy makers should exercise great caution in any actions they take regarding Part B drug reimbursement.

It is especially important for policy makers to recall the long, tortured history of drug reimbursement under the old Part B system which initiated the current changes. Part B of the Medicare law covers reimbursement for drugs administered incident to physicians' services, such as chemotherapy and vaccinations. This payment system utilized a process that relied upon the "Average Wholesale Price" ("AWP") of a drug, a term that appeared nowhere in any federal statute or regulation and was determined through the use of pricing lists compiled by private publishers. Drug companies, federal regulators, and medical providers have always acknowledged that AWP was merely a "sticker" price, and, much like automobiles' MSRP, represent more than the actual price most doctors would pay. Some have mused that AWP stood for "Ain't What's Paid." *Medicare Changes May Lead Florida Doctors to Abandon Chemotherapy Business*, ST. PETERSBURG TIMES, May 17, 2004. Consequently, Medicare over-reimbursed doctors for the drugs it covered. Federal officials acknowledged, however, that such overpayment made up for the under-reimbursement of doctors' in-patient services, such as administering chemotherapy, in which the covered drugs were used. *See, e.g.*, letter from Nancy-Ann DeParle, Admin. of HCFA, to Members of Congress, dated Sept. 8, 2000. The system was wasteful and detrimental to patients, who had to shoulder higher co-payments and potential shifts in their treatment because of it.

The vagaries of the AWP system, and Congress' inaction, also gave rise to a cottage industry of plaintiffs' lawyers, federal health regulators, and state attorneys general accusing drug companies of "fraudulent" price reporting and illegally "inflating" the AWP. While no charges have been proven in court, the pressure of lawsuits and investigations has transferred over $1 billion in settlements, resources that could otherwise have been devoted to research and development. *See* Bagely, Bentivoglio & Maxwell, *Accurate Drug Reporting: A Modest Proposal*, Washington Legal Foundation LEGAL BACKGROUNDER, Oct. 17, 2003. The financial lure is apparently so strong that despite the change in the law, Wisconsin recently sued twenty drug companies for "inflated" wholesale prices. *State v. Abbott*, Wis. Cir. Ct., filed June 3, 2004. While these legal actions may generate revenue for states and trial lawyers, and headlines for regulators, they did

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nothing to prescribe policy changes for the broken AWP system, and offered false hope to doctors and their patients.

Last year, Congress finally took action and imposed a far more rational system of reimbursement for drugs and services to take effect in 2005, one based on the average sales price ("ASP") that reflects discounts and rebates. Beginning in 2006, Medicare intends to allow doctors to choose between 106% of the ASP or reimbursement based on prices established through competitive bidding. In order to address concerns over the need for Medicare to sufficiently cover the costs of office services such as chemotherapy, Congress, using data from oncologists, increased reimbursements for such services at the same time they are bringing the payment system for the drugs more in line with the market. The extra 6% added onto ASP accounts for services reimbursement. For 2004, such payments are increased by 32%.

The Centers for Medicaid and Medicare Services (CMS), which will be responsible for implementing this part of the MMA, has no experience with either ASP or competitive bidding as a means of reimbursing doctors under Part B, so there are still important details to be worked out. The fact that CMS will be using an "average" price suggests that some purchasers will pay higher than average, some lower. This may differ based upon geographical location and the purchasing power of some buyers, such as hospitals, versus others. It is possible that some doctors' reimbursement won't cover the combined cost of the drugs and their administration. Some doctors will certainly miss the higher revenues that artificially inflated Medicare reimbursements brought them under AWP.

Care providers and their advocates are already raising concerns related to the impending changes in reimbursement, even though much is still not known about repayment rates and prices. This past February, one cancer doctors' group called on Congress to freeze Medicare reimbursement payments at 2004 rates for the first two years of the MMA's implementation (2005 and 2006). American Society of Clinical Oncologists ("ASCO") Press Release, Feb. 18, 2004. Some doctors went so far as to send alarming letters to their patients spelling out possible (though at the moment still very speculative) disruptions in and reduced quality of cancer care thanks to MMA reform. Gardiner Harris, *New Payment System Spurs Talk of Return to Hospital Care and Old Drugs*, N.Y. TIMES, Mar. 11, 2004. ASCO distanced itself from these actions in a March 18, 2004 letter to *The Times*, and another group of doctors found these "scare tactics" to be "dangerous" and unproductive. *The 4 R's of Cancer Care Policy*, LegisLink Action Update, U.S. Oncology, June 17, 2004. Additionally, doctors' allies in Congress sent letters to CMS Administrator Mark McClellan demanding projected reimbursement payments for 2005 based on first quarter average Plan B drug sales data, and urging Congress to "take action" if the data reveals a "deleterious reduction in payment rates."

Just as cancer advocates are right to distance themselves from some doctors' inappropriate scare tactics, they are also correct in the need for good data and more information on how the reimbursement process is going to work. CMS recently issued a proposed 2005 fee schedule for physician reimbursement under Part B of Medicare, which, not surprisingly, projected reduced payments under the new ASP scheme. Center for Medicare and Medicaid Services, *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule for Calendar Year 2005* (CMS-1429-P), available at http://www.cms.hhs.gov/regulations/pfs/2005/1429p.asp. This announcement has provided more fodder for those seeking to alter the current MMA plans. In addition, more new information may be arriving soon from the General Accountability Office, which has indicated to a House of Representatives committee that a preliminary report on the effect of the Part B changes is imminent. *Analysis on Drug Reimbursement Changes Could be Out This Summer, House Aide Says*, HEALTH LAW RPT. (BNA), Apr. 22, 2004 at 605.

As this debate progresses, it is important for policy makers to remember that on its best day, AWP, and the efforts to alter it through litigation and enforcement actions, were still worse than what ASP could ever be on its worst day. The changes being implemented are highly complex, and rough spots and inequities will arise. Possible adjustments and changes, as *The New York Times* editorialized, must be "driven by data, not emotion." N.Y. TIMES, Mar. 22, 2004. CMS and Congress should closely monitor the implementation process, and be prepared to propose and support reasonable modifications to rates and processes to ensure access to quality care. No one involved in the system, especially patients relying on Medicare, benefits from any action which will either delay the move towards market based pricing, or turn the clock back to the perverse AWP system.

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