Medicare Part D: An Uncertain Prescription for Reducing Drug Pricing Fraud

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On January 1, 2006, the federal government began Medicare Part D as a drug benefit plan with the stated goal of providing seniors with affordable prescription drugs.1 By some estimates, Medicare Part D is projected to cost $678 billion dollars over the first 10 years and $8.1 trillion dollars over the next 75 years.2 Healthcare fraud may add an additional 5% to these cost projections. In 2004, the federal government lost about $20 billion dollars to healthcare fraud.3 Medicare Part D creates a lucrative market for the pharmaceutical industry and a lucrative target for drug pricing fraud to induce improper overpayments of drug benefits by the federal government.

Medicare Part D requires the federal government to contract with private entities as sponsors of approved Part D prescription drug plans. Most Part D sponsors are managed care organizations (“MCOs”), such as Blue Cross/Blue Shield, which then contract with pharmacy benefit managers (“PBMs”), such as Medco Health Solutions, Inc., to provide pharmacy benefit services such as mail order service and access to retail pharmacies. A PBM’s main purpose is to control a MCO’s costs through negotiated discounts from pharmaceutical manufacturers and reduced reimbursement rates from retail pharmacies.

To increase market share and revenues, pharmaceutical manufacturers bargain with PBMs to place their drugs on PBM drug formularies, to market their drugs, and to switch prescriptions to their drugs. In return, the pharmaceutical manufacturers provide PBMs some form of remuneration (for example, a rebate). In some cases, pharmaceutical manufacturers have been accused of artificially inflating their drugs’ list price (published as the “Average Wholesale Price”) to help PBMs earn hidden fees from MCOs. MCOs reimburse the PBMs based on the list price, and the PBMs retain any difference between that list price and the actual cost charged to the PBMs by the drug maker.

In the context of Medicare Part D, the federal government has deemed such actions to be fraud and requires Part D plan sponsors to take certain actions that will allow the federal government to achieve better drug prices and reduce program costs. Unfortunately, Medicare Part D’s untested measures will probably fail to adequately meet the government’s objectives.

Medicare Part D requires prescription drug plan sponsors to disclose all negotiated discounts (i.e. rebates, subsidies, remuneration) to the federal government and to pass along the savings to the government and beneficiaries.4 The sponsors must disclose the

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2 Julie Appleby and Richard Wolf, Medicare Cost Projections Drop, USA TODAY, Feb 3, 2006, at 4A.
costs actually paid (net of discounts, chargebacks, and average percentage rebates) by the sponsors to retail pharmacies and pharmaceutical manufacturers.\footnote{42 U.S.C. § 1395w-115 (2003); 42 C.F.R. § 423.322 (2005).} This cost information is required to insure that the federal government does not overpay (in the form of direct subsidies and reinsurance) sponsors for the drug benefit. In addition, the government has the right to audit the sponsors’ financial statements and records to insure compliance with these requirements.\footnote{Id.} Unfortunately, the government cannot guarantee the integrity of the data received by the sponsors. In most cases, PBMs will participate as sponsors or contract with sponsors to manage a Part D prescription drug plan. Given their long-standing relations and practices with pharmaceutical manufacturers and retail pharmacies, PBMs are in a position to conceal or otherwise alter accurate cost and pricing information.

Medicare Part D requires sponsors to develop drug formularies through a competent pharmacy and therapeutic committee (“PTC”) that makes formulary decisions based on accepted scientific evidence, recognized standards of practice, and therapeutic safety and efficacy.\footnote{42 C.F.R. § 423.120(b) (2005).} By this requirement, the federal government seeks to severely limit, if not eliminate, the undue influence and undisclosed remuneration from pharmaceutical manufacturers in the formulary process. The federal government supports legitimate discounts by pharmaceutical manufacturers for placement on a formulary provided that their drugs meet the underlying requirements and the discounts are disclosed and passed along as previously discussed. Unfortunately, the federal regulation requires that only one physician and one pharmacist who serve on the PTC be independent and free of conflict with sponsors and pharmaceutical manufacturers. The sponsors otherwise remain free to load PTCs with experienced members prepared to make favorable formulary decisions on behalf of pharmaceutical manufacturers in return for concealed remuneration to the sponsors.

Medicare Part D requires sponsors to create and maintain programs to control fraud, abuse, and waste.\footnote{42 U.S.C. § 1395w-104(b)(3); 42 C.F.R. § 423.504(b)(4) (2005).} Through these programs, the sponsors should readily prevent, identify, or correct the incidence of fraud such as a failure to disclose and/or share remuneration with the federal government. In effect, this regulation permits sponsors to police themselves and allows them voluntarily to withhold reporting fraud to the federal government. As a result, the federal government may never discover the incidence of fraud or, much less, recover the losses to the government. The government has taken this voluntary approach before. In 2003, the U.S. Department of Health and Human Services (“HHS”) provided the pharmaceutical manufacturers with guidance on creating and maintaining an effective compliance program to insure the integrity of pricing data relied upon by the federal government for drug benefit plans and to prevent illegal remuneration to the pharmaceutical industry, including PBMs and retail pharmacies.\footnote{68 Fed. Reg. 23731 (May 5, 2003).} This guidance is not mandatory and thus lacks any force in combating the fraudulent practices of pharmaceutical manufacturers.
Medicare Part D requires prescription drug plan sponsors’ chief executive officer, chief financial officer, or designee, to certify claims, cost, and pricing data to the federal government.10 Far from absolute, these certifications are based on the corporate officers’ best knowledge, information and belief, which leaves open a potential release from any liability. Taking advantage of this loophole, corporate officers may attempt to insulate themselves from any potential liability. Nonetheless, this provision makes corporate officers good targets for criminal investigations and prosecutions for healthcare fraud.

Faced with these challenges, the federal government should consider a few additional steps in combating drug pricing fraud and reducing overall costs of the Medicare Part D program. First, the PTC should consist only of experienced physicians and pharmacists free of any conflicts of interest with any PBM, MCO, or pharmaceutical manufacturer. Second, the federal government should make HHS’ Compliance Program Guidance for Pharmaceutical Manufacturers mandatory with requirements to disclose all drug cost and pricing information (private and government) to the federal government. Third, Part D plan sponsors should be required to report suspected or confirmed incidents of fraud and disclose all drug cost and pricing information (private and government) to the federal government. Fourth, all participating retail pharmacies should be required to disclose drug cost and pricing information (private and government) to the federal government. Fifth, a central government database should be established to collect drug cost and pricing information, including pricing information for all state Medicaid programs and the U. S. Department of Veterans Affairs.

Even with these measures, detecting drug pricing fraud may be difficult given the long-standing practice in the pharmaceutical industry. Pharmaceutical manufacturers have well-established relations with the largest retail pharmacies, MCOs, and PBMs. Pharmaceutical manufacturers will devise new and more creative methods to conceal the remuneration provided to Medicare Part D sponsors and retail pharmacies. Ultimately, the federal government will continue to rely on whistleblowers (i.e. qui tam suits) to bring incidents of fraud to its attention. When that occurs, the federal government should seek criminal prosecution of the sponsors’ and pharmaceutical manufacturers’ corporate officers.

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