

Expect Big Change in Drug Pricing System

by

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HIGHLIGHT: As medication grows in importance, settlements of DOJ fraud and abuse probes could produce a new structure.

THE STRUCTURE of pharmaceutical pricing in the United States will change significantly in the near future even without new legislation, with substantial effects on drug research and development, marketing, reimbursement and coverage. The recent, intense focus on pharmaceutical pricing levels by the current administration and state legislators, federal and state enforcement and drug purchasing officials, managed care entities, private antitrust litigants, politicians and the media virtually ensures that fundamental changes will be made.

Most immediately, however, significant changes in the structure of pharmaceutical pricing can be expected from the likely forthcoming settlements of several Department of Justice health care fraud and abuse investigations of the pricing, reimbursement and promotional practices of pharmaceutical companies.

These anticipated settlements can also be expected to affect the continuing debate on and resolution of other pharmaceutical pricing-related issues, including the type and scope of the extension of any Medicare benefits to senior citizens, legislation regarding the reimportation of drugs, and the market exclusivity granted to pioneer pharmaceuticals by both the patent laws and the federal Food, Drug and Cosmetic Act. n1

n1 21 U.S.C. 301, 355(c).

The growing use of pharmaceuticals in health care, the continued development of important new medications and the desire among policymakers and others both to control the cost of government drug purchasing and to expand government drug reimbursement programs, have led to immense focus on the current structure of pharmaceutical pricing. n2

n2 See, e.g., Report to the President from the Department of Health and Human Services. Prescription Drug Coverage, Spending, Utilization, and Prices (April 2000), at www.aspe.hhs.gov/health/reports/drugstudy.

The concern about drug pricing is not new. n3 For several decades, the federal government has been aware that, for at least some drug products being purchased through Medicare and Medicaid, the government has been reimbursing for their use at higher prices than the actual acquisition cost to private parties, physicians and others. Despite this knowledge, until recently there has been little

political interest or consensus in redesigning the drug reimbursement framework under Medicare and Medicaid.

n3 See, e.g., Office of Inspector General, Department of Health and Human Services, "Use of Average Wholesale Prices in Reimbursing Pharmacies Participating in Medicaid Prescription Drug Program" (Oct. 1989). There are almost yearly reports by OIG on this issue and its impact on the Medicare and Medicaid programs.

The principal controversy continually has centered on the proper method for drug reimbursement - whether it should be based on acquisition cost or some artificial pricing construct, such as average wholesale price (AWP). n4 The AWP has been used in the pharmaceutical industry to represent a baseline suggested wholesale price, and has been routinely published by pharmaceutical companies as well as by independent reporting services, such as Medispan and the Blue Book, now both compiled by First Data-bank (FDB).

n4 AWP is described in one reference as the published suggested wholesale price of a drug. See National Pharmaceutical Council, *Pharmaceutical Benefits Under State Medical Assistance Programs*, at E-5 (1999).

Both pricing methods were incorporated into federal and state reimbursement law, and the Health Care Financing Administration (HCFA) had the authority to reimburse Medicare claims based on either estimated acquisition cost (EAC) or AWP. However, the artificial construct, the AWP, generally became the default price because it was too difficult administratively for HCFA to determine and verify the actual acquisition prices of hundreds of thousands of pharmacy and physician purchasers across the country.

Reimbursing based on AWP

Notwithstanding its administrative ease, however, using a pricing construct did not allow the government to respond effectively to the changing health care market, which, beginning in the early 1990s, became subject to increasing downward pressure on the cost of all products and services, including drugs, as a result of the rise of managed care. In 1997, as a result of the Balanced Budget Act, Congress modified HCFA's authority and mandated that HCFA reimburse physicians for covered drugs under Medicare based on only 95% of the AWP, thereby ensuring that the reimbursement framework would remain fundamentally unchanged and would continue to be unresponsive to market forces. n5 Since 1997, the administration has repeatedly attempted to reduce payments for drugs reimbursed through Medicare, with only limited success. n6

n5 P.L. 105-33, *42 U.S.C. 1395u(o)*.

n6 See letter dated May 31, 2000, from Donna E. Shalala, secretary of Health and Human Services, to Tom Bliley, R- Va., chairman, Commerce Committee, House of Representatives (detailing administration efforts to reduce Medicare payments during 1997-2000) (Shalala Letter), at [com-
notes.house.gov/cchea/hearings/106.nsf.main](http://com-
notes.house.gov/cchea/hearings/106.nsf.main).

Recognizing the inability to modify legislatively the reimbursement framework, and in response to a qui tam action in Florida, DOJ, in conjunction with the Office of Inspector General (OIG) of the Department of Health and Human Services, began in 1997 to investigate the pharmaceutical pricing practices of 20 large pharmaceutical companies, as to whether they violated the False Claims Act and/or the federal anti-kickback statute. n7 At the same time, because many states also use the AWP for Medicaid reimbursement, state Medicaid fraud control officials began investigating prices they paid and rebates they received from pharmaceutical companies under state Medicaid programs.

n7 See, generally, David S. McCloud and Laura McGinley, "U.S., States, Bayer Start Settlement Talks," Wall St. J., May 10, 2000, at A-3; Andrew Zajac and Laurie Cohen, "Tapping Medicare Bonanza, A Prescription for Profit," Chicago Tribune, May 23, 1999, at 1; Bill Alpert, "A Drug Bust in the Making? Probing an Alleged Pricing Scam, Feds Demand Data From Big Firms." Barron's, Oct. 27, 1997.

However, unlike the federal reimbursement system, which is limited now to the use of the AWP, the regulatory framework for Medicaid reimbursement also references the EAC. n8 This greater regulatory flexibility allowed the states to devise a creative process to restructure the reimbursement system for drugs, without conducting either administrative rulemaking or enforcement actions. The states' Medicaid fraud control officials persuaded their Medicaid price reporting contractor, FDB, to adopt new procedures to determine the AWP by surveying the wholesale market to obtain the prices that are actually paid by various wholesale purchasers to acquire drugs.

n8 42 C.F.R. 447.332(b).

FDB will then establish a new reference price, now called the market average wholesale price (MAWP), for reimbursement of drugs. The states expect the new MAWP to begin to reflect the changes in actual market prices for drugs and allow them to reimburse consistent with these prices, unlike the AWP, which is, arguably, only a suggested wholesale price. New MAWPs for approximately 50 drug substances, representing about 400 new drug codes, have been established by FDB for state officials and also provided by HCFA to Medicare carriers for use in Medicare reimbursement, effective Oct. 10. n9 Consequently, wholesale purchasers of drugs, such as pharmacies and physicians, have begun to receive significantly lower reimbursement for these products. The savings to the government may be substantial. n10

n9 See letter dated Feb. 16, 2000, from Patrick E. Lupinetti. State of New York, Office of the Attorney General, Medicaid Fraud Control Unit, to Medicaid pharmacy directors. See F-D-C Reports (Pink Sheet) at 4 (April 10, 2000).

n10 See Shalala Letter, supra n. 6 (predicting \$2.9 billion savings to Medicare alone).

In response to these actions, one manufacturer and its pharmacy unit has sued the Medicaid fraud control units for allegedly "improperly usurping the rate-making authority" of state Medicaid agencies through these new reimbursement procedures. n11

n11 Alpha Therapeutic Corp. v. Terry, President of the National Association of Medicaid Fraud Control Units, No. 1:00CV01947 (D.D.C. filed Aug. 11, 2000).

Consent decrees

In addition, it is likely that the state and federal governments will formalize this new price reporting system through broad consent decrees with the pharmaceutical company defendants involved in the investigation. n12 If these types of settlements are entered, they will create an additional mechanism for governmental monitoring and control of drug prices, with respect to both federal and state governments and third party payors, which often follow government reimbursement rates.

n12 See McCloud and McGinley, supra. n. 7. noting that federal and state officials have begun such settlement discussions with Bayer A. G. in one of these health care qui tam actions.

Moreover, such settlements likely will significantly modify the way pharmaceutical companies promote their products to wholesalers, pharmacies, physicians and others, who will be searching for

different ways to recapture reduced profits from lowered reimbursement rates. As a result, pharmaceutical companies likely will begin to receive requests for the provision of other types of economic value to purchasers -- for example, patient compliance and disease management programs, medical education and disease screenings.

This restructuring of the drug pricing framework also can be expected to affect significantly the continuing debate on other pharmaceutical pricing-related issues, including the type and scope of legislative extension of Medicare drug benefits to senior citizens, and legislative efforts to allow the reimportation of drugs produced in the United States and sold overseas for lower prices than in this country. n13

n13 The various bills on reimportation of drugs have been criticized by the FDA, which has warned that the bills may jeopardize drug safety. See F-D-C Reports (Pink Sheet) at 3 (July 31, 2000).

Enforcement actions

This forthcoming restructuring of the pharmaceutical pricing framework also will be affected by the current government and private actions against pharmaceutical companies regarding their efforts to protect market exclusivity. The Federal Trade Commission (FTC), for example, has pursued, together with 33 states, antitrust litigation against Mylan Laboratories, challenging as anti-competitive a supply arrangement that resulted in substantial price rises for generic drugs. The FTC recently announced a \$147 million settlement of its action and those of the states, the largest antitrust penalty settlement ever reached by that agency. n14

n14 See 79 Antitrust & Trade Reg. Rep. (BNA) 55 (July 21, 2000).

The FTC also recently announced a settlement with Abbott Laboratories and a generic drug company concerning an allegedly anti-competitive agreement in which the pioneer company paid the generic to delay marketing, in the context of an ongoing patent dispute. n15 A similar action by the FTC, against the predecessor company to Aventis, has not been settled, and the FTC has filed an antitrust complaint alleging an anti-competitive agreement to delay the introduction of a generic version of the pioneer company's drug. n16

n15 In re Abbott Laboratories, FTC File No. 98-0395 (March 16, 2000) (proposed consent order).

n16 In re Hoechst Marion Roussel Inc., FTC No. 9293 (March 16, 2000) (FTC administrative complaint).

In addition to these government health care and antitrust enforcement actions, there have been numerous recent private antitrust challenges to efforts by pioneer pharmaceutical companies to protect their market exclusivity for drugs. In recent months, for example, a trial court has held that an agreement between a pioneer manufacturer and a competitor to refrain from marketing a generic version of the drug in the context of a patent dispute constituted a per se violation of the antitrust laws. n17

n17 *In re Cardizem CD Antitrust Litig., 2000-1 Trade Cas. (CCH) P72, 941 (E.D. Mich. 2000).*

Although some courts have ruled that defendants in similar antitrust actions were immune from antitrust challenge because the injury arose from government action n18 or because the plaintiffs lacked standing, n19 other courts have allowed antitrust challenges to proceed against pioneer companies for activities to protect their marketing exclusivity, notwithstanding allegations of lack of standing based on the indirect-purchaser status of consumers. n20

n18 See *Bristol-Myers Squibb Co. v. Immunex Corp.*, 2000-1 Trade Cas. (CCH) P72, 875 (D.N.J. 2000).

n19 See *Andrx Pharmaceuticals Inc. v. Friedman*, 2000-1 Trade Cas. (CCH) P72, 869 (D.D.C. 2000).

n20 *In re Warfarin Sodium Antitrust Litig.*, 2000-1 Trade Cas. (CCH) P 72, 932 (3d Cir. 2000).

Finally, various federal legislative efforts to extend prescription drug benefits for senior citizens and to revise import policies to allow reimportation of drugs manufactured in the United States, and state legislation to control drug price levels and to require rebate agreements with manufacturers (such as that recently enacted by Maine n21) also may affect pharmaceutical company pricing practices. Concern regarding the potential effect of such state legislation has led to an industry challenge to the constitutionality of the Maine statute. n22

n21 For a brief description of the new Maine drug pricing statute, see F-D-C Reports (Pink Sheet) at 8 (May 15, 2000). One manufacturer, SmithKline, has announced that, as a result of the legislation, it will stop selling prescription drugs to wholesalers in Maine. See Rachel Zimmerman and Laura Johannes, "SmithKline Move in Maine Signals Battle Over Prices." *Wall St. J.*, Aug. 7, 2000, at B-6.

n22 See John Hechinger and Ron Winslow, "Drug Makers Sue Maine to Overturn Drug Pricing Law." *Wall St. J.*, Aug 14, 2000, at B-8.

These current government enforcement actions and potential legislative initiatives thus can be expected to fundamentally restructure pharmaceutical pricing in the United States in the near future. This restructuring will have substantial effects on the pharmaceutical industry, including the potential to further stimulate industry consolidation, to reduce or redirect research and development efforts in view of the reduced financial incentives that would be available to the industry, and to redirect and alter the industry's marketing efforts -- including its direct-to-consumer advertising activities, which have increased substantially during the past few years. n23 It is crucial, therefore, for practitioners to be aware of these numerous enforcement actions and legislative initiatives in order to effectively assist pharmaceutical companies in making the transition to a new pricing framework.

n23 See F-D-C Reports (Pink Sheet) at 11 (June 19, 2000), noting the increasing congressional focus on direct-to-consumer advertising as a way to control drug expenditures.

GRAPHIC: Picture, no caption, STEVE ANSUL