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Advisory

December 2000

HEALTH CARE

HCFA Publishes Long-Awaited Privacy Regulations

The Department of Health and Human Services (HHS) has published the first comprehensive federal regulations covering the privacy of health information. Announced on December 20, 2000, HHS said it believed that the regulations do not go far enough because of limitations in the statute on which they are based. The new regulations are lengthy and complex. Next month's Mintz Levin Health Care Advisory will carry an analysis of the new requirements and their impact on health care providers and others.

Medicaid Drug Rebate Law Celebrates First Decade as Federal Prosecutors Provide First Close Look at Implementation

By Carolyn J. McElroy, Esq.¹

The Medicaid rebate law celebrates its tenth anniversary next month. Designed to give the state Medicaid programs the benefit of the lower drug prices associated with volume purchasing, it has spawned about a dozen similar laws designed to give price concessions to state-funded drug assistance programs. Although state governments now receive about \$3 billion annually in rebates from drug manufacturers, state and federal oversight has been sparse. This situation may be coming to an end, however. The Office of the Inspector General of the Department of Health and Human Services (OIG) said that the federal government would be scrutinizing rebate reporting by companies as part of an overall pharmaceutical reimbursement enforcement initiative. Although the impact that the change of administration in Washington will have on pharmaceutical pricing and reimbursement is yet unknown, it is unlikely that ongoing enforcement initiatives will be affected in the short run.

The Medicaid programs, which are funded in part by the federal government and in part by the states, serve as insurance for the indigent. The states administer the programs under a myriad of state laws and regulations, and with the oversight of the Health Care Financing Administration (HCFA).

Medicaid programs, as a condition of receiving federal funding, are required to provide certain minimum levels of services. Although the federal government does not require that the states provide prescription drug benefits as part of the Medicaid program, each of the state Medicaid programs have elected to do so. Because the pharmaceutical program is not mandated by HCFA, however, the states have

¹ Carolyn J. McElroy joined the Mintz Levin Washington, D.C. office after five years as head of the Maryland Medicaid Fraud Unit in the Office of the Attorney General.

historically exercised relatively independent control over the manner in which drugs are covered by Medicaid funds. Thus, unlike other aspects of the Medicaid program for which HCFA prohibits restrictions on services, states are free to require co-payments, or to place limits on the number of prescriptions that Medicaid will cover.

Prior to the passage of the Medicaid rebate law, many of the states exercised their broad authority over the pharmacy programs by restricting the lists of drugs that Medicaid would cover, often for reasons that appeared to relate more to cost-cutting than to beneficiary needs. The Medicaid rebate law, enacted as a part of the Omnibus Budget Reconciliation Act of 1990² (OBRA 90), represented a means to both give the Medicaid programs some financial relief from escalating drug costs, as well as assuring the manufacturers that their products were welcome in the Medicaid programs. The law requires that a manufacturer give the Medicaid programs the benefit of its best commercial price or a percentage rebate of the state's purchases in return for assurances that all of the manufacturer's products will be reimbursed by Medicaid.³ The vehicle for accomplishing both ends is the Medicaid Rebate Agreement that the manufacturers have entered into with HCFA or, in some cases, directly with the states.

The rebate law is a decade old, and has spawned approximately a dozen copycat state rebate laws for state-funded pharmacy assistance programs. Although the state and federal governments now receive roughly \$3 billion per year in rebates for the Medicaid programs,⁴

oversight of the program's integrity and compliance has been sparse and aimed largely toward ensuring that rebates are paid timely.

This respite from broad-based enforcement action may be short-lived. At a recent conference, a representative of the Office of Counsel to the Inspector General for Health and Human Services told industry representatives that the federal government would be scrutinizing Medicaid rebate reporting as part of an overall joint state and federal pharmaceutical reimbursement enforcement initiative. Philadelphia-based Assistant United States Attorney James G. Sheehan, who is well known for his efforts in prosecuting health care fraud cases, said that his office is actively investigating allegations of fraud and abuse in the rebate program. Moreover, there are both criminal and civil investigations of drug manufacturers being conducted from other United States Attorney's Offices, including Boston and Miami. A number of large drug companies have received subpoenas in connection with these investigations.

How does the Medicaid Rebate Law Work? The Medicaid rebate law requires pharmaceutical manufacturers to pay the state Medicaid programs per-unit rebates equal to the difference between the average price received by the manufacturer from the state, and the "best" price for which the manufacturer sold the drug (but no less than 15.1% of the average price) for sole source or innovator drugs.⁵ An additional rebate is due if the price of a drug rises faster than the Consumer Price Index (CPI). Generic drug manufacturers must rebate 11% of the average received from the sale of their drugs.

Drug manufacturers enter into a rebate agreement with HCFA, and report both the average price and "best" sales price information to the HCFA quarterly. HCFA calculates the rebate amount, and advises the states of the per-unit amount of the rebate they may request from the manufacturer. Pursuant to the Medicaid rebate law, the average and best price information that is reported by the manufacturers is confidential, and the only information available to the states is the net per-unit amount of the rebate.

States seeking to collect rebates for state-funded pharmacy assistance programs do so in a variety of ways. Some states⁶ require that the same price information be reported to the states under separate rebate agreements designed to service state-funded pharmacy assistance programs, while other state programs seek to use the amount of the Medicaid rebate as a basis for estimating rebates due for the state-funded programs. In Vermont, the state extended its Medicaid program coverage to seniors and low-income citizens after receiving a waiver from HCFA, thus essentially gaining rebate pricing benefits for non-Medicaid sales.⁷

Where is the Government's Enforcement Focus? The government and the states are likely to concentrate on the following issues involving the reporting of best price and the additional or CPI rebate amount:

Are free goods, rebates, discounts, signing bonuses and other significant inducements tied to product sales taken into consideration when calculating best price? The Medicaid Rebate Agreement⁸ states that "best prices shall be inclusive

² 2 U.S.C. 1396r-8.

³ The states may still exercise some restrictions on the formulary, but the limits are expressly defined in the statute. For example, the states are not required to cover drugs intended to induce weight loss.

⁴ Returning approximately 15% of the amounts spent by Medicaid on pharmaceutical products.

⁵ The categories of sole source and innovator drugs include biological products and patented drugs or "brand" drugs which are the first to reach the market. An innovator product must continue to pay rebates using this formula even after there are generic equivalents on the market.

⁶ Including most notably California, New York and Pennsylvania.

⁷ The Pharmaceutical Research and Manufacturers of America (PhaRMA) recently filed suit to overturn the waiver, asserting that HCFA did not have the authority to force manufacturers to rebate amounts for the non-Medicaid beneficiaries.

⁸ <http://www.hcfa.gov/medicaid/drug8.htm>

of cash discounts, free goods, volume discounts, and rebates.” It requires manufacturers to adjust the best price previously reported if a subsequent event (*e.g.*, the customer earns an additional discount by meeting purchase quotas) reduces the net price. If there is a single discount given in connection with a sale of several products (a “bundled” sale), the discount should be applied proportionately to the dollar value of the units of each drug sold under the bundled arrangement. There are, however, no regulations and little guidance on how to calculate best price in the context of a multi-level, multiple product transaction. Because the lack of guidance will make it difficult for the government to challenge any good faith methodology used to value and apportion free goods and discounts, enforcement efforts will likely focus on cases where the manufacturer either wholly failed to account for a discount, or took an extreme approach to valuation or apportionment.

Are educational, clinical and research grants mere price concessions? Assistant United States Attorney Sheehan claims that kickback and rebate cases involving grant funds are “in the pipeline.”⁹ To examine these allegations, the government is likely to look beyond the language of the contract and evaluate the intent behind the transaction. Was the receipt of grant funds tied to the purchase of products or to an exclusivity agreement? Was the expenditure beneficial to the interests of the company, *e.g.*, a bona fide clinical trial? Did the customer treat this money as a reduction in the net price of the product in its inventory documents? Did the grant spur overutilization of the product?

Are nominally priced goods that may be excluded when calculating “best price” simply free goods in disguise? While free goods must be included in the best price calculation, prices that are “nominal,” *i.e.*, less than 10% of the average manufacturer’s sales price, need not be included.¹⁰ Enforcement efforts are expected to concentrate on bundled sales to commer-

cial customers that include nominally priced goods.

May bulk sales to HMOs, PBMs, or retail chains be excluded from best price reporting under the “repackaging” exemption? Products that are sold for repackaging are exempt from inclusion in best price reporting. The law and the Rebate Agreement, however, are largely silent as to the definition of “repackaging.” The results of a recent OIG inquiry into sales to HMOs suggests that the OIG expects the repackager to vend the product using its own labeler code in order for the sale to qualify for the repackaging exemption. While FDA regulations do require that a repackager obtain its own labeler code, HMOs, PBMs and retail chain pharmacies sometimes rebottle product into smaller-sized bottles and incorporate the original manufacturer’s labeler code into the NDC. The OIG apparently takes the position that these transactions do not qualify for the repackaging exemption.

If a new version of a pharmaceutical product is released, must the manufacturer transfer the base quarter from the old version for purposes of calculating the CPI rebate? The OIG has indicated that it is actively looking for evidence of fraud in this area. However, absent direct evidence of intent to evade paying the rebate, the OIG will have a near-impossible task proving that manufacturers have the obligation to carry over base price histories between different versions of a drug product. The law hinges the obligation to pay an additional rebate on the “average manufacturer price for the dosage form and strength of the drug” (*emphasis supplied*), and the base price is measured with reference to the date a product receives FDA approval. Therefore, assuming that a new product in an existing line is different enough to require a separate FDA approval, both the law and the Rebate Agreement appear to mandate a new base price for purposes of computing the additional rebate.

The Benefits of a Self-Assessment to Identify Potentially Risky Practices

The lack of regulatory activity in the Medicaid rebate arena makes it seem less necessary to devote resources to compliance efforts. This is a dangerous assumption in an industry where false claims and even criminal initiatives are not infrequently the vehicles by which the government first clearly communicates its expectations of health care providers. If an ounce of prevention was worth a pound of cure before the revitalization of the False Claims Act, that same ounce is certainly worth a few tons of remedial efforts in the age of whistleblowers and multimillion dollar settlements.

It may be helpful to assess your compliance quotient by performing a self-assessment of your company’s practices and comparing the results with Medicaid “Best Price” (BP) and “Average Manufacturer’s Price” (AMP) reporting requirements. The first step in any such assessment is to collect and review the information used to report price information to the government, and to ask the following questions.

- What sales were included and what sales were excluded from the AMP price reporting? AMP price reporting requirements dictate that the manufacturer exclude sales to Public Health Service customers from the calculation of average manufacturer’s price. Manufacturers are required to identify the end-user correctly even when the product is sold through a wholesaler. Are existing reporting systems effective? Are the appropriate sales included and excluded from this reporting?
- Manufacturers are entitled to and should deduct chargebacks and discounts from AMP reporting. Are the amounts deducted appropriate, or do reductions include amounts that are attributable to other products or administrative costs? If so, are the deductions reasonable and appropriate under the law and

⁹ See OIG Special Fraud Alert, August 23, 1994, and OIG opinion letter dated July 17, 2000 (<http://oig.hhs.gov/ak/prebate.htm>)

¹⁰ This provision was intended to allow manufacturers to continue the practice of providing drugs to charitable organizations for token payments.

the Medicaid Rebate Agreement? Manufacturers have been known to overpay rebates because allowable deductions from AMP are missed; look for errors in the system that affect both ends of the process.

- For BP reporting, identify the invoices used to define “best” price. Were all appropriate classes of trade included in the collection of price data? For the customers involved, were the invoices reflective of the actual net price? Were there additional chargebacks, discounts or free goods offered to those customers in connection with the contracts for that product—or for other contracts with the same customer? If yes, is it conceivable that the government could prove the discounts were tied to the purchase of the product in question? (Be sure to audit both the rebate department and the marketing department in this self-audit.)
- Are there agreements for grants, signing bonuses, expensive training programs or marketing subsidies, contracts for goods and services, or other financial ties between the manufacturer and the customers who are deemed to be—or might be—the customer to whom the “best price” is given? Have you written off any sales debts for, or engaged in any charitable efforts with, this customer? If so, what efforts have been made to assess the impact of the incentives on the price of the product at issue? Have the legal and/or compliance departments reviewed the issues?
- Is there a mechanism in place to ensure that rebates or incentives that are not realized until the end of the reporting quarter are properly meas-

ured and applied to prior quarters—and are the changes reported to HCFA as required?

- Are the calculations themselves correct?
- Is there an adequate system to ensure that marketing decisions affecting AMP or BP are communicated to the rebate department, and aligned with the appropriate invoices? Are broad-based marketing incentives regularly reviewed by the legal department and/or compliance for rebate and anti-kickback implications *before* the transaction is closed?

It seems clear that government expectations, consumer needs and pressures, current industry marketing systems, and rising pharmaceutical costs have embarked on a collision course. HCFA needs to define the terms of the rebate and reimbursement laws, and is expected to do so—either alone or with the help of the proposed General Accounting Office inquiry and Congress—in the context of a debate over Medicare prescription coverage. In the meantime, focused compliance efforts and legal counsel may be the most effective medicine against an unwelcome outcome from the government’s announced initiative.

Congress Amends OSHA’s Bloodborne Pathogens Standard

Congress has passed and President Clinton has signed a law designed to reduce the incidence of needle-stick injuries among health care workers. The Needlestick Safety and Prevention Act (the “Act”) is designed to help the over 600,000 health care workers who

receive needlestick injuries annually. The Act, enacted in November and effective immediately, substantially modifies OSHA’s Bloodborne Pathogens Standard (29 C.F.R. § 1910.1030) to ensure more widespread use of safer medical devices to prevent needlesticks. Among other things, the amended standard requires employers to:

1. Consider and implement new technologies designed to minimize occupational exposure to bloodborne pathogens as part of their annual review of their Exposure Control Plan. Importantly, employers are now required to not only solicit the input of potentially exposed employees in the identification, evaluation and selection of such new technologies and engineering controls, but also document such solicitation in the Exposure Control Plan.
2. Maintain a Sharp Injury Log for the recording of “percutaneous injuries from contaminated sharps” in addition to other required logs. The Sharp Injury Log, which must protect the privacy and confidentiality of the injured employee, must record (a) the type and brand of device involved in the incident; (b) the department or work area where the exposure incident occurred; and (c) an explanation of how the incident occurred.

Like all OSHA logs and records, the Sharp Injury Logs must be retained for a period of five (5) years. Although aimed principally at employers in the health care field, the legislation applies to all employers. OSHA is expected to publish detailed regulations implementing the Act by May 6, 2001.

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