In late December and early January, states started receiving millions of dollars in reimbursements owed to them after Bayer Corp. and GlaxoSmithKline (GSK) agreed last April to pay more than $344 million to settle Medicaid fraud charges.

California received the largest settlement—$14.4 million from Bayer.

The largest settlement check that GSK paid to a state was $5.7 million to New York.

More than $2.3 million from the nearly $5 million that North Carolina recovered from Bayer and GSK will fund public schools in the state, said Noelle Talley, spokesperson for the North Carolina Attorney General’s Office.

A state law requires that civil penalties recovered by North Carolina from settlements, like those from Bayer and GSK, are set aside to help fund schools, she said.

The remaining portion will go back to the state’s Medicaid program.

The settlements—the nation’s largest ever involving Medicaid fraud—were triggered by a whistleblower lawsuit filed under the False Claims Act by George Couto, a former manager at Bayer, who died before the drug companies settled.

Couto’s estate received about $34 million for his contribution in bringing information forward and assisting the government in making its case against the company, according to the U.S. Attorney’s Office in Boston, which handled the investigation.

Bayer and GSK were caught hiding their lowest prices from Medicaid by selling relabeled products to health maintenance organization (HMO) giant Kaiser Permanente Medical Care Program at “deeply discounted prices,” and concealing the scheme from the government.

Manufacturers are required to pay rebates to state Medicaid programs based on the difference between a drug’s average manufacturer price (AMP) and the best price offered to private-sector purchasers, with a minimum rebate of 15.2% of AMP.

The settlements are also the first effort to recoup losses to 340B-covered entities. Drug manufacturers are required to enter into a contract with the government to provide certain pricing concessions to 340B-covered entities based on the same pricing data and variables that are used to calculate Medicaid rebate amounts. When Medicaid rebates are underpaid, 340B-covered entities are overcharged for their drugs.

According to the settlement agreements, Bayer and GSK were required to submit a report to the Department of Health and Human Services Office of Inspector General (OIG) within 10 business days of completion of reimbursement to 340B-covered entities “that includes sufficient information and documentation” as to whether the drug companies correctly calculated the overcharges and fully reimbursed each entity.

OIG spokesperson Judy Holtz referred all questions about the settlements to the Justice Department.

Susan G. Winkler, deputy chief of the health care fraud unit for the U.S. Attorney’s Office in Boston, said that “both entities submitted the required reports.”

Ted Slafsky, director of the Public Hospital Pharmacy Coalition, said a survey of his organization’s membership of safety net providers has found that “most of those who were supposed to have received a check have received it by now.”

However, he said, “it is difficult to determine whether our members who have received checks received the correct amount because the government and the pharmaceutical industry will not provide actual amounts of the overcharges.”

Slafsky said there was some confusion about receipt of the checks because “some of the checks were mailed to the wrong location” and, although the checks included the statement, “In Full Satisfaction of 2003 Federal Settlement, Subject to the Terms of the Federal Settlement Agreement” as required by the settlement agreements, there was “no reference to the 340B program” on the checks.

“We are confident that the process for ensuring accurate refunds in future settlements will be improved,” Slafsky said.

Other Medicaid fraud settlements—Tap Pharmaceuticals, $875 million in 2001; Pfizer, $49 million in 2002; AstraZeneca, $355 million in 2003; and a separate Bayer settlement of $14 million in 2001—did not include agreements to repay amounts overcharged to 340B-covered entities.

A March 2001 report by OIG found that seven drug companies had excluded sales to repackagers from their best-price calculations, including sales to three HMOs.

In March 2003, OIG reported that five manufacturers of 11 prescription drugs had overcharged 340B-covered entities $6.1 million for sales occurring from October 1998 through September 1999.

But the government kept secret the identities of the drug companies investigated for the two reports.

Mary Kahn, spokesperson for the Centers for Medicare & Medicaid Services (CMS), said that CMS “will be going back to each of these manufacturers and do a recalculation based on the actual best prices and request that those companies pay the full rebates.”

The Health Resources and Services Administration—the agency that oversees the 340B program—is “working with the Department of Justice (DOJ) and [OIG] to recover 340B overcharges from the drug companies,” an agency spokesperson said. “We are committed to recovering these overcharges; however, the DOJ and OIG have the lead in pursuing this matter.”

—Donna Young