



U.S. SENATE COMMITTEE ON

Finance

SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN

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Grassley: Federal officials must get control of Medicaid drug rebate program

WASHINGTON – Sen. Chuck Grassley said today that the federal government needs to take a much more aggressive role in controlling Medicaid spending on prescription drugs by making sure that states get the full rebate they're entitled to through the Medicaid drug rebate program.

Grassley made his comments in response to a new report of the Government Accountability Office, which he requested along with Rep. Henry Waxman. The report found that the Center for Medicare and Medicaid Services – which administers the federal Medicaid program – was negligent in making sure that drug prices and, in turn, Medicaid drug rebates were determined in an accurate way.

“For the last ten years, federal officials have left the program vulnerable to tremendous waste, fraud and abuse,” Grassley said. “Administrators need to move quickly to update the way these prices are determined to prevent taxpayers from being shortchanged hundreds of millions, and possibly billions, of tax dollars.”

Drug manufacturers pay rebates to states based on prices and financial concessions manufacturers make available to entities that purchase their drugs. Today's GAO report said that the Medicaid drug rebate program does not incorporate payments negotiated by pharmacy benefit managers on behalf of third-party payers, in particular, and that affects the amount of the rebate payments made to states.

A separate report issued last November by Taxpayers Against Fraud said that \$535 million in federal dollars and \$413 million in state dollars had been recovered through whistleblower cases against drug manufacturers in Medicaid drug pricing fraud cases from 2001 to 2003. Additional settlements are expected, according to the report, because approximately 100 whistleblower cases remain under seal and involve allegations against over 200 drug manufacturers.

Grassley said that the whistleblower provisions of the False Claims Act are proving to be a valuable weapon in protecting the Medicaid program against fraud by drug makers, but “no time should be wasted by CMS in bringing its own methods up to date and preventing this waste of resources for such an important health care program.”

The new GAO report is titled “Medicaid Drug Rebate Program. Inadequate Oversight

Raises Concerns about Rebates Paid to States.” Its reference number is GAO-05-102. It can be accessed today at www.gao.gov. Grassley delivered the following remarks in a floor statement today.

Floor Statement of U.S. Sen. Chuck Grassley of Iowa
Chairman, Senate Committee on Finance
GAO Report on Medicaid Drug Rebate Program
Monday, March 7, 2005

Mr. President, I am taking this opportunity to talk about the mess we have in the Medicaid program. A mess that does not properly account for billions of taxpayer dollars. First, allow me to remind everyone about a report released last summer by the Government Accountability Office (GAO). That report on Medicaid Program Integrity found that Medicaid’s size and diversity made it vulnerable to fraud, waste and abuse. Further, the GAO found that the Centers for Medicare & Medicaid Services (CMS) allocated only \$26,000 and only eight employees to work on Medicaid program integrity.

As I said at the time, it does not make sense for CMS to invest so little in federal oversight when so many federal taxpayer dollars are at stake. If one considers that Medicaid has surpassed Medicare as the single largest government health program in the United States, it makes no sense at all. The Congressional Budget Office projects the federal share of total Medicaid payments for FY 2005 at greater than \$183 billion. Medicaid’s vulnerability to fraud, waste and abuse have also ranked it on the GAO’s list of high-risk programs for the past two years.

The Medicaid program continues to pay too much for prescription drugs. CMS estimated that Medicaid expenditures for prescription drugs in CY 2003 totaled more than \$31 billion, triple the \$9.4 billion spent in 1994. Each year drug companies pay approximately \$6 billion in rebates.

Today, the GAO released a damning report on Medicaid drug spending. Congress established the Medicaid drug rebate program in 1990 to help control spending on drugs. Note that the word choice and intent here was control not out of control. It should come as no surprise that the GAO’s report shows that the drug program has been and continues to be badly mismanaged.

The report— requested by Congressman Waxman and me—identified fundamental problems in the program. The mismanagement has been bi-partisan and has spanned multiple administrations. According to the GAO, it is a program virtually without regulation. CMS has been sitting on draft regulations since 1995—a decade ago.

It is also a program virtually without oversight. The GAO found that the Office of Inspector General has issued only four audit reports on drug-company reported prices since the inception of the program. Of course, the OIG says in its defense that its efforts have been hampered by unclear CMS program guidance and a lack of documentation by drug companies. According to the GAO, even when the OIG has managed to identify problems related to the drug companies’ reported prices and methodologies for price reporting, CMS has not done much of

anything to resolve them.

The drug rebate program is governed by a contractual agreement between the states and each drug company that wants to participate in Medicaid. One of the things that boggles the mind is that this contract allows drug companies to rely upon quote—"reasonable assumptions"—unquote.

Each drug company may craft its own "assumptions" as long as they are consistent with the "intent" of the law. Consequently, because drug companies can pick their own methods, they in effect set their own prices and the amount of rebates they pay.

According to the GAO, quote—"CMS does not generally review the methods and underlying assumptions that [drug companies] use to determine [the reported prices], even though these methods and assumptions can have a substantial effect on rebates"—unquote. Furthermore, quoting the GAO again—"CMS sometimes identifies price reporting errors . . . but does not follow up with [drug companies] to verify that errors have been corrected"—unquote. In sum, the GAO report confirms that neither CMS nor the OIG know the extent to which Medicaid overpays for prescription drugs because the program lacks effective management and oversight. A worse state of affairs is not likely. Drug companies have been profiting for the past fifteen years on Medicaid drug pricing. We are dealing with a system that unnecessarily costs taxpayers untold hundreds of millions, if not billions of dollars annually. The Medicaid drug rebate program is quite simply a mess—a Medicaid mess.

I urge my colleagues to consider this GAO report and its recommendations.