



U.S. SENATE COMMITTEE ON

Finance

SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN

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For Immediate Release

Wednesday, October 22, 2003

Grassley Works to Prevent Document Destruction, Protect Medicaid Drug Program from Fraud

WASHINGTON — Sen. Chuck Grassley is objecting to a government proposal that he says would make it easier for prescription drug manufacturers to defraud the Medicaid drug rebate program.

The U.S. Department of Health and Human Services has issued a rule for public comment which would allow drug manufacturers to destroy billing records after three years. Grassley formally protested this proposed policy change in a letter sent last week to the HHS Secretary. He said that such a short time frame would severely limit the ability to make a case against wrongdoing because documents including pricing data and other information would no longer be available.

"Instead of making it easier for those defrauding the Medicaid drug rebate program to get away with breaking the law, we should be making it easier to identify and prosecute those who are ripping off the taxpayers and taking away from a program that lower-income beneficiaries depend on," Grassley said.

Grassley said that it may be appropriate to set a definite period of time for record-keeping requirements, but three years is too short of a time frame because of the way the False Claims Act works. Such cases are filed under seal, so even when a False Claims Act case is filed and an investigation is underway, drug manufacturers are not necessarily on notice to suspend the destruction of documents.

Grassley was the Senate author of the 1986 *qui tam* whistleblower amendments to the False Claims Act. Enforcement of the False Claims Act and its whistleblower provisions has returned more than \$10 billion to the U.S. Treasury since 1986.

According to the Centers for Medicare and Medicaid Services, approximately 550 pharmaceutical companies participate in the Medicaid drug rebate program. Forty-nine states and the District of Columbia cover drugs under the program. Arizona does not.

A copy of Grassley's letter to the Secretary of Health and Human Services follows below.

Grassley also referred his concerns to the Justice Department and to the Inspector General for the Department of Health and Human Services.

October 17, 2003

The Honorable Tommy G. Thompson
Secretary
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Thompson:

The purpose of this letter is to express my deep concern regarding a final rule with comment period, published by the Department of Health and Human Services (HHS) in the Federal Register on August 29, 2003. (42 CFR Part 447) Specifically, the final regulation:

- 1.) establishes a recordkeeping requirement for drug manufacturers under the Medicaid drug rebate program;
- 2.) sets forth a three year time limitation during which manufacturers must report changes to average manufacturer price and best price for purposes of reporting data to HHS; and
- 3.) announces the pressing need for codification of fundamental recordkeeping requirements.

Unfortunately, it is my opinion that this regulation has numerous unintended and adverse consequences upon the False Claims Act.

On September 19, 1995, HHS proposed a regulation affecting, among other things, the document retention period for the Medicaid drug rebate program. This proposed regulation was intended to address numerous issues, including manufacturer recordkeeping requirements and price recalculations. Consequently, and based upon that fact, HHS recently decided to extract several portions of that proposed regulation and issue a final rule. Because eight years have passed since the proposed rule, HHS decided to provide interested parties with an additional opportunity to provide comments on the provisions and extended the effective date of the rule from October 1, 2003, to January 1, 2004.

My first and foremost concern is that it appears this new regulation will have a severe and adverse impact upon the False Claims Act and whistleblowers generally. Typically, old billing records, including pricing data and supporting documentation regarding a drug manufacturer's Average Manufacturer Price and Best Price are necessary in cases brought under the False Claims Act. Should this regulation become effective, it will dramatically limit the ability of a whistleblower

to review and rely upon old records to prove liability and/or damages because there will be no records available going back further than three years.

Further complicating this situation is the fact that False Claims Act cases are filed under seal. As a result, even if a False Claims Act case is filed and an investigation is on-going, drug manufacturers may not be on notice to suspend the destruction of documents. This will dramatically affect the ability of a whistleblower to establish a case and will have a concurrent negative affect upon the Department of Justice (DOJ) in those cases in which it intervenes.

At the same time, I recognize the value in establishing a definite period of time for recordkeeping, in cases where none existed before. But, the three year period just does not work, especially when taking the False Claims Act into consideration.

As drafted, this regulation is just plain wrong-headed and should not take effect. Indeed, it is my opinion that HHS should not take any actions that would make it easier for those defrauding the Medicaid drug rebate program to get away with breaking the law. Instead, we should be making it easier to identify and prosecute those who are ripping off the Medicaid drug rebate program, rather than creating an environment where the record retention policies implemented by HHS assist criminals and complicate cases for whistleblowers and Justice Department attorneys.

In addition, it is also likely that this regulation will have an adverse impact on cases currently in the system. Surely, HHS does not want to encourage the destruction of documents by drug manufacturers who are not yet aware of the fact that they are the subject of an unresolved audit or government investigation.

By this letter, I am also advising both DOJ and the HHS, Office of the Inspector General of my concerns. In closing I look forward to receiving a response from you addressing how the concerns outlined in this letter, regarding the impact of 42 CFR Part 447 upon the False Claims Act, will be addressed.

Thank you in advance for your assistance in addressing this critically important issue in the battle against fraud, waste, and abuse in the Medicaid drug rebate program.

Sincerely,

Charles E. Grassley
Chairman

cc:Attorney General John Ashcroft
Dara Corrigan, Office of the Inspector General, HHS