



U.S. SENATE COMMITTEE ON

# Finance

SENATOR CHUCK GRASSLEY, OF IOWA - CHAIRMAN

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For Immediate Release

Wednesday, Jan. 7, 2004

Grassley Praises Decision to Prevent Document Destruction,  
Protect Medicaid Drug Program from Fraud, Help Whistleblowers

WASHINGTON -- Sen. Chuck Grassley, chairman of the Committee on Finance, is praising the reversal of a government proposal that would have made it easier for prescription drug manufacturers to defraud the Medicaid drug rebate program and more difficult for whistleblowers to bring cases.

Last year, the U.S. Department of Health and Human Services issued a rule for public comment that would have allowed drug manufacturers to destroy billing records after a mere three years. Grassley formally protested this proposed policy change in a letter sent last October to the HHS secretary. He said such a short time frame would have severely limited the ability to make a case against wrongdoers because documents including pricing data and other information would no longer be available.

Now, the agency is removing the three-year record-keeping requirement and replacing it with a 10-year record-keeping requirement. In addition, HHS proposed that manufacturers must retain records beyond the 10-year period if the records are the subject of an audit or a government investigation.

“This is the right course of action,” Grassley said. “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.”

In a letter to HHS this week, Grassley praised the decision to extend the record-keeping period. He asked for clarification of whether the agency intends to make the 10-year period permanent.

Grassley said it may be appropriate to set a definite time period 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 under way, 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 this week to the Secretary of Health and Human Services follows below.

January 6, 2004

Via mail and telefax (202) 690-7380

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

Dear Secretary Thompson,

I was delighted to see that the Department of Health and Human Services (HHS) in its proposed rule, noticed today in the Federal Register (42 CFR Part 447), agreed to modify materially a final rule that established, among other things, a new, 10-year record keeping requirement for drug manufacturers under the Medicaid Drug Rebate Program.

In the original rule, HHS set forth a three-year time limitation during which manufacturers were to report changes to average manufacturer price and best price for purposes of reporting data to HHS. I strongly opposed that provision in a letter to you dated October 17, 2003, because it would have had a severe and adverse impact upon the False Claims Act, whistleblowers and related anti-fraud provisions.

Today, I see that HHS is removing the three-year record-keeping requirement and replacing it with a 10-year record-keeping requirement. In addition, HHS proposed that manufacturers must retain records beyond the 10-year period if the records are the subject of an audit or a government investigation.

There is one remaining issue that I would appreciate your addressing. The interim final rule with comment period that was published today sets forth a sunset provision in the Background Section. In essence, it provides that the record retention requirements will be in effect until December 31, 2004, about one year from now, or when HHS publishes a final record-keeping requirement in the Federal Register. At the same time, the Proposed Rule, also published today, states that the HHS proposes that the 10-year record-keeping requirement be effective **without a sunset date provision** (emphasis added). Could you please explain the interaction of these two provisions? I would appreciate a response to this matter by February 2, 2004.

In closing, I wish to again thank you for your assistance and should you have any questions, please do not hesitate to contact me.

Sincerely,

Charles E. Grassley  
Chairman

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