

Federal Drug Discount and Compliance Monitor

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...**BREAKING NEWS...**
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Finance Committee Chairman Criticizes Oversight of 340B Program *Letter Recommends Creation of HRSA-CMS Interagency Task Force*

Citing “systemic problems” in the 340B program, Senate Finance Committee Chairman Charles Grassley (R-IA) has issued letters to Health and Human Services (HHS) Secretary Michael Leavitt and Health Resources and Services Administration (HRSA) Administrator Elizabeth Duke calling for more vigilant enforcement of the 340B law and improvements to program oversight.

The letters, dated September 1 and recently made available to the public, are critical of the agencies’ response to reports and recommendations articulated by the HHS Office of Inspector General (OIG) over the last year. According to Senator Grassley, HRSA has not adequately fulfilled its pledge to pursue refunds from manufacturers that have overcharged covered entities, nor has HHS provided the Office of Pharmacy Affairs (OPA) with the necessary tools to ensure that future violations of the program do not occur.

“As chairman of the [Finance] Committee, I am concerned that HRSA has neither fully addressed the OIG’s recommendations related to problems identified in the 340B program nor made substantial progress toward implementing its comprehensive plan,” the letters state.

In his five-page letter to Administrator Duke, Senator Grassley asks HRSA to respond to specific questions regarding the agency’s efforts to recover refunds from five manufacturers that were found by OIG to have overcharged 340B entities for 11 drugs during fiscal year 1999. In particular, the letter requests detailed information on how each manufacturer has responded to HRSA’s requests for refunds, as well as copies of all correspondence between HRSA and the affected manufacturers.

HRSA first identified the manufacturers from the OIG study in September 2004 after receiving a letter from Senator Grassley requesting an update on HRSA’s efforts to address the report’s findings (*The Monitor*, July 2004). At the time, HRSA stated that it had asked the manufacturers to determine the extent of the overcharges and develop a “corrective action plan” for reimbursing the affected 340B entities. However, according to Senator Grassley, the manufacturers have not yet issued the appropriate refunds or informed HRSA that they intend to do so.

In addition to addressing HRSA's efforts to enforce the 340B law, Chairman Grassley also makes a number of recommendations aimed at improving the long-term administration of the program. For instance, Senator Grassley's letters encourage HRSA to ensure that OPA is granted access to 340B ceiling price data. Since September 1, 2004, the agency has not been able to verify 340B pricing because HRSA did not reach an agreement with the Centers for Medicare and Medicaid Services (CMS) for fiscal year 2005 that would allow OPA to acquire the necessary data.

"It is disturbing that the agency responsible for ensuring that drug companies charge appropriate 340B prices lacks the pricing data to monitor the program," the letter states.

(The Monitor has learned that HRSA and CMS reached a deal yesterday that will allow OPA to verify pricing data through December 31, 2005. However, there is no agreement between HRSA and CMS beyond that point.)

Senator Grassley's letters are also critical of HHS's oversight of 340B Pharmaceutical Pricing Agreements (PPA), which are executed by manufacturers when they agree to participate in the program. According to the Senator, not all drug companies have signed PPAs, which is a requirement for manufacturers that wish to have their drugs covered by the Medicaid program. Furthermore, the letters argue that HHS should not allow manufacturers to pick and choose which of their drugs are subject to 340B or refuse to offer 340B pricing due to "product shortages."

"Drug companies should not be dictating the terms of their PPAs with the Secretary at the expense of taxpayers," the letter states. Furthermore, Senator Grassley's letter to Administrator Duke asks that HRSA state whether the agency is aware of any drug companies that have not signed PPAs and articulate its policy for addressing situations in which manufacturers do not make certain products available to covered entities.

In his letter to Secretary Leavitt, Senator Grassley also expresses concern that there is no mechanism in place to ensure that 340B providers are routinely credited in cases where drug companies have recalculated their best price figures and provided refunds to the Medicaid program. Senator Grassley's letter calls for the creation of a HRSA-CMS task force that would allow the agencies to work more closely on this and other 340B enforcement matters. The letter further suggests that the task force regularly meet with 340B stakeholders including drug manufacturers and 340B covered entities.

The letters request that both Secretary Leavitt and Administrator Duke respond to the Senator's comments by October 3. "It is absolutely essential that the Federal government prove itself capable of enforcing the requirements of its existing drug programs in an efficient and timely manner," the letter to Secretary Leavitt states. "Further delay in pursuing these matters is unjust to the American taxpayers who ultimately fund the public hospitals and other government-supported providers entitled to 340B discounts."

The October issue of The Monitor will address the letters in further detail.