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Congressional Subcommittee Calls for More Transparency in 340B

Members of Congress from both parties raised serious concerns yesterday over the Health Resources and Services Administration's (HRSA) oversight of the 340B drug discount program during the first hearing on the program ever convened by Congress.

The hearing, held before the House Energy and Commerce Subcommittee on Oversight and Investigations, focused to a substantial degree on the need for transparency of manufacturer ceiling price information and the authority of the Department of Health and Human Services (HHS) to ensure compliance with the program.

Under the current system, HRSA independently calculates the 340B ceiling prices for all covered drugs using data provided by the Centers for Medicare and Medicaid Services (CMS). Manufacturers, meanwhile, are responsible for calculating their own ceiling prices and using these prices in the marketplace.

One topic raised during the hearing, was whether HRSA has the authority to require participating manufacturers to submit their ceiling price information to the agency so that HRSA staff can determine whether covered entities are receiving the correct prices.

Democratic members Bart Stupak (D-MI), Diana DeGette (D-CO), and Jay Inslee (D-WA) asked the subcommittee's witnesses why HRSA does not compare manufacturer pricing information to its own calculations.

HRSA Deputy Administrator Dennis Williams testified that his agency is restricted by law from comparing manufacturer prices to the government's calculations unless that information is submitted on a voluntary basis.

Williams' interpretation differed from that of HHS Deputy Inspector General Stuart Wright and Public Hospital Pharmacy Coalition (PHPC) General Counsel William von Oehsen, both of whom stated that HRSA does have the authority to require submission of this information and that doing so would greatly improve the integrity and efficiency of the program.

Specifically, von Oehsen pointed out that the standard pharmaceutical pricing agreement (PPA) between participating manufacturers and the government expressly describes manufacturers' responsibilities to include affording HHS reasonable access to manufacturer records that are relevant to a manufacturer's compliance with the terms of the Agreement, and that records of ceiling prices plainly fall into this category.

Subcommittee members also expressed concern that covered entities do not have access to manufacturer ceiling prices and are therefore unable to determine whether they are paying the correct prices for their pharmaceuticals.

“It is nonsensical that covered entities do not have access to the ceiling prices,” said Subcommittee Chairman Ed Whitfield (R-KY).

Whitfield praised drug manufacturer GlaxoSmithKline for agreeing to voluntarily submit its ceiling price information to covered entities that participate in the 340B Prime Vendor Program (PVP). In October, GlaxoSmithKline entered into an agreement with HRSA and PVP under which the company will allow PVP members to access its entire 340B pricing file through a password-protected section of the PVP website.

“It is the right thing to do because it increases transparency,” Whitfield said, adding that he is hopeful that other manufacturers will follow suit and cooperate with HRSA.

David Brown, Director of Government Contracts and Pricing Programs at GlaxoSmithKline, said that the company decided to share this information because “the benefits to the 340B entities outweighed the risks [to GlaxoSmithKline].”

PVP Senior Director Chris Hatwig told the subcommittee that GlaxoSmithKline’s price file has been accessed 792 times by participating entities during the two months following the announcement of the agreement.

Another topic discussed during the hearing was HRSA’s lack of civil and monetary penalties for program violators. In his testimony, Wright observed that the only recourse currently available to HHS is to remove manufacturers from both the 340B and Medicaid drug rebate programs.

“This remedy is so extreme that it limits the likelihood that it will be used,” Wright said in prepared testimony. “Terminating a manufacturer’s participation is an exceptionally severe sanction, given the effect that terminating a manufacturer would have on access to medications for the millions of Medicaid and 340B beneficiaries.”

Stupak pressed Williams on this issue and was particularly critical of HRSA’s failure to obtain refunds to providers from four manufacturers that were identified by OIG in 2003 as having overcharged 340B entities by \$6.1 million during fiscal year 1999.

“Our primary job is to work within the current legislative context,” said Williams, adding that HRSA would prefer to implement other program improvements before asking Congress for new authority to impose intermediate penalties as alternatives to the sanction of terminating Medicaid rebate and 340B agreements.

At the conclusion of the hearing, Chairman Whitfield said that the subcommittee plans to hold a second hearing on the 340B program next year upon the release of an OIG report that is expected to include specific findings on whether 340B entities are being overcharged for their drugs.