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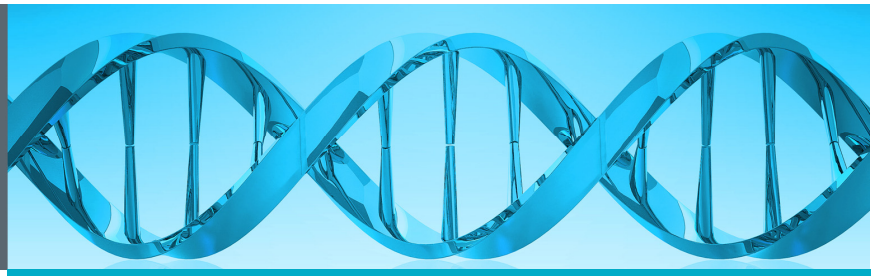

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340B Drug Pricing Program Questioned by Congressional Subcommittee

In this Issue:

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The House Energy & Commerce Health subcommittee held a hearing on the 340B Drug Pricing Program to "review the functionality of the program to ensure it is meeting its intended goals." Hospitals, the pharmaceutical industry, and other program participants must be prepared for changes to the program, as the Health Service Resources Administration (HRSA) intends to issue program guidance later this year. HRSA also intends to issue a Notice of Proposed Rulemaking that will address civil monetary penalties and drug ceiling prices within the 340B program. The Energy & Commerce Committee may revisit HRSA's statutory authority over the 340B program and the hearing is an indication of the committee members' thoughts on the program's administration as well as the committee's oversight role.

Titled "Examining the 340B Drug Pricing Program," the subcommittee hearing included testimony from the Health Resources and Services Administration, the Government Accountability Office and the Department of Health and Human Services Office of the Inspector General.

Committee Chair Rep. Joe Pitt (R-PA) commented during the hearing that greater oversight and transparency of the 340B program is needed to ensure that the program is preserved and is functioning as Congress intended. Created in 1992, the 340B Drug Discount Program requires drug manufacturers that participate in Medicaid to provide discounted outpatient drugs to eligible health care organizations that provide care to uninsured, low -income populations.

Rep. Fred Upton (R-MI), who is the Full Committee Chair, and other Republicans noted that the program had grown significantly since the Affordable Care Act's enactment and that recent findings from the GAO and

OIG are concerning. Republican members of the subcommittee also communicated concern that hospitals could not account for any savings from the program and that the money was being used outside of the intent of the program. Rep. Gene Green (D-TX), the ranking member of the subcommittee, however, expressed that the 340B program is an important safety net to providers and that it helped expand access to care for underserved populations. Rep. Green and Rep. Frank Pallone (D-NJ) did agree, however, that proper oversight of the program is needed if it is to continue to function and support the mission of safety net providers.

Reps. Marsha Blackburn (R-TN) and Renee Ellmers (R-NC) also made opening statements. Blackburn said she was concerned about the accuracy of HRSA's oversight of the 340B program and about HRSA's definition of an eligible 340B patient. Ellmers noted that HRSA does not monitor how 340B entities are using the savings generated by the program and that more transparency is needed for the 340B program to be accountable. No other subcommittee members made opening statements.

Witness Statements

Espinosa testified about the history of the 340B program and how the agency conducts its oversight. For example, she noted that Congress provided HRSA with an additional $6 million in FY 2014 that the agency has used to improve its information technology systems, increase the number of audits, and hire additional auditors and staff to implement new IT investments for expanded program integrity efforts. She also acknowledged the omnibus proposed regulation that HRSA intends to promulgate in 2015. This rule would have established enforceable policy on the definition of a covered entity and a definition of a patient. However, the U.S. District Court for the District of Columbia ruled the agency exceeded its authority. In response, HRSA intends to issue guidance later this year. This guidance will be open for public comment. Cdr. Pedley did not make an opening statement.

Draper testified about GAO's investigation of the 340B program and its recommendations to HRSA on how to improve its oversight. She said that HRSA relied on covered entities to police themselves. In addition, she said the 340B program lacked guidance on key requirements of the program. Specifically, the program lacks a definition of a patient eligible for the program and that the guidance does not establish criteria that hospitals must meet to qualify for the program. Manufacturers also do not have the guidance needed to ensure drugs are distributed equitably to 340B providers and those facilities outside the program.

Maxwell testified about the OIG's audits of the 340B program and the deficiencies in HRSA's oversight of the program. While HRSA has made improvements in response to the OIG's findings, Maxwell said that additional transparency in 340B drug prices is needed and that HRSA's current patient definition does not account for the complexity of contract pharmacy arrangements. This can result in "diversion," which is the dispensing of a 340B-purchased drug to an ineligible patient.

Question and Answer

The following highlights exchanges during the question and answer session.

Rep. Pitts: Pitts asked about using the Disproportionate Share Hospital (DSH) adjustment in determining whether a facility qualified for 340B in light of the expansion of Medicaid under the Affordable Care Act. Draper noted that 340B is an outpatient program and that DSH is an inpatient indicator and is used as a proxy for low-income and uncompensated care. Pitts also asked whether jails and prisons qualify as covered entities. Espinosa said this would be addressed in the forthcoming guidance.

Rep. Green: Green noted that Congress appropriated additional funding to HRSA for program integrity and asked how the money had been spent and if it had resulted in any savings. Espinosa said that HRSA has increased the number of audits and auditors but that it was not able to quantify any savings from the new appropriation at this time because the 340B program does not require covered entities to account for how they spend any savings generated by the program. Green asked about the court ruling and Espinosa explained that HRSA will address in the guidance concerns regarding civil monetary penalties, dispute resolutions, and the covered drug ceiling price. Green also asked if HRSA needs additional funding for oversight of the program and Espinosa noted that the President's budget request sought additional resources for program integrity.

Rep. Shimkus: Shimkus focused his questions on how covered entities are using the savings and questioned why HRSA was not able to determine this. Draper said that the 340B law does not require such accounting and that entities that do track and account savings are required to do so by other statutes. For example, federal qualified health centers are required to account for such information.

Rep. Pallone: Pallone asked what would be covered in the forthcoming guidance. Espinosa said the guidance would address the definition of a patient, hospital eligibility, and contract pharmacies. Pallone also asked how rulemaking differs from guidance and Espinosa said that enforcement mechanisms are stronger in rulemaking.

Rep. Griffith: Griffith was concerned about the length of time HRSA was taking in issuing the guidance and said that it could issue guidance as it solves an issue, such as the definition of a patient, rather than waiting to issue one omnibus guidance. He also said HRSA should be more forthcoming in requesting authority if it is needed. The panelists noted that the 340B program is very complex.

Rep. Castor: Castor asked about the number of audits and whether drug manufacturers were overcharging covered entities. She said the program needed greater transparency. Maxwell said OIG did find some overcharging. Espinosa said that HRSA works to resolve any issues with overcharging and that they typically are the result of a clerical error.

Rep. Long: Long asked when HRSA would share pricing information with Congress. Espinosa said that the agency is working on completing its information technology systems to provide such information. Long also asked if HRSA would share the pricing information with state Medicaid agencies, but the panelists said that new statutory authority would be needed.

Rep. Butterfield: Butterfield expressed his support for the 340B program and said it was vital to ensuring access to care for low-income and uninsured patients.

Rep. Ellmers: Ellmers focused her questions on how covered entities, namely hospitals, use the savings generated by the 340B program. The panelists said that HRSA would like to have greater clarity in this area, but that the program does not require covered entities to report such information.

Rep. Buschon: Buschon asked whether hospitals should "profit" off the 340B program and whether or not HRSA should prescribe to covered entities how any savings should be used. Panelists reiterated that program does not require covered entities to report such information.

Rep. Collins: Collins asked for specifics on how the ceiling prices of a 340B drug is determined. Pedley explained how the formula is defined in law and that the ceiling prices are updated on a quarterly basis. She also

explained how the formula at times created a ceiling price of 1 cent, but that recent changes to the law prevent the ceiling prices from being a negative number.

Rep. Bilirakis: Bilirakis asked how savings from the 340B program are calculated and Pedley explained how the estimate is extrapolated from assuming a 50 percent discount price. He also asked for examples of a covered entity. Pedley said there were about 22 different types.

Be on the lookout for more information later this year as program guidance is issued and changes are finalized.

For More Information

For more information regarding this Update Series, please contact the author, a member of the Polsinelli's Health Care practice, or your Polsinelli attorney.

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**AHLA Connections* and *Modern Healthcare* (June 2014).

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* *Law360*, March 2014
** *The American Lawyer* 2013 and 2014 reports

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