

...BREAKING NEWS...

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## **House and Senate Committees Pass 340B-Related Measures**

The Senate Finance and House Energy and Commerce Committees, which have been asked by Congress to propose roughly \$10 billion in Medicaid and Medicare savings over the next five years, each passed bills this week that could have a major impact on the future of the 340B program.

On October 27, the Energy and Commerce Committee inserted into its Medicaid package a provision that would extend 340B discounts to approximately 75 children's hospitals that are exempt from the Medicare Prospective Payment System (PPS). The measure, which would require these hospitals to meet the same standards as disproportionate share hospitals (DSH) in the program, was introduced by Rep. Paul Gillmor (R-OH) as an amendment and unanimously approved by the Committee.

"All this amendment does is to allow children's hospitals to join other disproportionate share hospitals as covered entities," Gillmor told the committee.

According to Gillmor, this measure would "correct an unintended legislative problem" that prevents these hospitals from participating in the program. The amendment will most likely be identical to H.R. 4036, a bill introduced by Reps. Gillmor and Diana DeGette (D-CO) on October 7.

Just days earlier, the Senate Finance Committee passed its own comprehensive Medicaid bill, which includes provisions that could affect 340B pricing and the methods by which 340B entities bill Medicaid.

In particular, the bill proposes that the Medicaid drug rebate percentage be increased in order to create new savings for the Medicaid program. The rebate percentage is primarily used to determine the size of the rebates that manufacturers must pay to state Medicaid agencies for drugs purchased through the program. However, the percentage is also used by the government and pharmaceutical manufacturers to calculate the 340B prices of covered outpatient drugs.

The committee's bill calls for an increase in the rebate percentage to 17% for both brand name and generic drugs—from 15.1% and 11%, respectively—which could lead to significantly lower 340B prices, especially for generic drugs. The proposal to increase the rebate percentage for generic manufacturers was not included in the committee's original proposal.

The Generic Pharmaceutical Association (GPhA), which represents the manufacturers and distributors of generic drugs, has expressed serious concerns about this proposal and has argued that increasing their rebates to Medicaid could force some companies to withdraw from participating in the Medicaid program. Senator Charles Schumer (D-NY) offered an amendment to block the increase in the rebate percentage for generic manufacturers, but his amendment was rejected by the committee on a party line vote.

In a related measure, the Senate bill also includes a provision that would require manufacturers of brand name drugs to include the price of authorized generic drugs in their brand name drugs' best price calculations. Currently, the law states a manufacturer of a brand name drug may release an "authorized generic" version of the drug after the company's patent is successfully challenged by a generic manufacturer. However, this product is considered to be a generic drug for the purposes of Medicaid rebates, which means that they are not subject to best price. (For more on the authorized generic debate, see *The Monitor*, April 2005.)

With respect to Medicaid billing, both the House and Senate bills include a provision that calls on the Secretary of the Department of Health and Human Services (HHS) to collect information from health care providers on physician-administered drugs in order to "secure rebates for such drugs."

Some in the 340B community have raised concern over this measure in the event that a "physician-administered drug" is interpreted to include drugs purchased through the 340B program. If this happens, manufacturers could be required to give 340B discounts and Medicaid rebates on the same drugs. How this duplicate discount problem would be resolved is unclear.

The House and Senate bills also contain a number of other pharmacy measures, including significant reforms to the Medicaid pharmacy reimbursement system.

Both bills will now be considered in their respective chambers. Once the bills have been approved by the House and Senate, the two committees will have to iron out the differences between the two bills before a final vote later this year.

*The Monitor* will continue to keep you apprised of new developments.