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1ST DISTRICT, ILLINOIS

340B Program Improvement and Integrity Act of 2007

"I believe that the 340B Program Improvement and Integrity Act of 2007 will allow hospitals who are serving our constituents—particularly the poorest, the uninsured, and the elderly to cut costs and serve more people."

What is 340B?

•The 340B Drug Discount program was created through the Veterans Health Care Act of 1992, P.L. 102-585.

•Congress established the program to limit the costs of outpatient drugs paid by safety net hospitals, community health centers, and other health care providers that serve a high proportion of indigent individuals, in order to enable such facilities to achieve savings on pharmaceuticals that will help them stretch their limited resources available for indigent care.

•The law requires pharmaceutical manufacturers participating in the Medicaid and Medicare Part B programs to provide discounts on covered outpatient drugs purchased by "covered entities" that meet statutorily defined criteria.

•The statute prohibits a covered entity from "diverting" 340B drugs – that is, from reselling or otherwise transferring drugs purchased at 340B discounted prices to anyone who is not a patient of the covered entity.

Who currently participates in the 340B program?

•Approximately 12,000 safety net providers qualify for reduced priced drugs under 340B.

If passed, the 340B Drug Expansion Program would extend drug discounts for inpatient and outpatient drugs to approximately 14,000additional safety net providers.

What does the 340B Program Improvement and Integrity Act of 2007 do?

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- 340B program discounts, currently available only on outpatient drugs, would be extended to covered drugs used in the inpatient setting as well.
- Additional, new covered entities would be potentially eligible for the 340B program, including: critical access hospitals, sole community hospitals, rural referral centers, Medicare-dependent hospitals, maternal & child health centers, mental health & substance abuse centers. The bill also clarifies that Children's Hospitals are able to enroll in the program if they meet defined, statutory criteria.
- The Secretary of Health & Human Services (HHS) would be directed to establish reasonable exceptions to an existing prohibition against 340B entity participation in group purchasing arrangements for covered outpatient drugs.
- Covered entities would be authorized to use multiple contract pharmacies and supplement in-house pharmacies with contract pharmacies.

Auditing and compliance enforcement authorities and procedures would be expanded in order to enhance and improve overall 340B program integrity and more effectively to prevent drug diversion and other forms of program abuse.

How will the bill improve program integrity?

- The Secretary will provide covered entities with access to applicable ceiling prices for covered drugs though the HHS website, in a secure form protected through the use of passwords or similar security devices.
- The Secretary of HHS would be directed to implement various, new measures to ensure compliance by both manufacturers and covered entities with 340B program rules and standards.
- Manufacturers and covered entities that knowingly and intentionally violate program rules and requirements would be subject to sanctions that may include monetary penalties.

The Secretary would be directed to establish an administrative process through which covered entities could pursue claims that they have been overcharged for drugs purchased under the 340B program.

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- The price a manufacturer charges to a 340B covered entity for a drug can be no greater than the 340B ceiling price calculated under a statutory formula that is based on the drug's Average Manufacturer Price (AMP) and the amount of the Medicaid rebate that the drug's manufacturer must pay a State when the drug is used for outpatient treatment of a Medicaid recipient..
- The Average Manufacturer Price is the average price paid by wholesalers for a drug when it is purchased for distribution in the retail class of trade. A Medicaid rebate is an amount that the law requires a drug manufacturer to reimburse to a State Medicaid program when Medicaid has covered the cost of an outpatient drug used in treatment of a Medicaid recipient. Under the Medicaid Drug Rebate program, manufacturers pay quarterly rebates to States for drugs billed to Medicaid.
- The 340B ceiling price is ordinarily significantly less than the price at which non-federal providers can purchase a drug, as well as less than the reimbursement available for the drug under insurance plans that cover costs of pharmaceuticals for non-indigent individuals.

Because the 340B discount price cannot exceed a statutory ceiling price, but has no lower limit, 340B covered entities can negotiate even deeper discounts on drugs.