HB 2385 A -A8, -A9, -A10, -A11 STAFF MEASURE SUMMARY

Senate Committee On Health Care

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Meeting Dates: 5/6, 5/8, 5/13

WHAT THE MEASURE DOES:

The measure makes it an unlawful trade practice for drug manufacturers to take specified actions that limit or interfere with a pharmacy's ability to acquire or dispense 340B drugs.

Detailed Summary:

- Prohibits a drug manufacturer or entity operating on manufacturer's behalf from
  - denying, restricting, prohibiting, or otherwise interfering with the acquisition of a 340B drug by pharmacy that has contracted with a covered entity to dispense 340B drugs unless the acquisition is prohibited by the United States Department of Health and Human Services (HHS).
  - requiring a covered entity to submit utilization review data as a condition for the acquisition of a 340B drug unless such data submission is required by HHS.

House Vote: Passed. Ayes, 37; Nays, 18.

Fiscal impact: Fiscal impact issued.

Revenue impact: No revenue impact.

ISSUES DISCUSSED:

EFFECT OF AMENDMENT:

-A8 Allows the State Board of Pharmacy to impose a civil penalty of up to $5,000 per day on a manufacturer that violates provisions of the measure.

-A9 Defines "entity" for purposes of the measure as a federally-qualified health center as defined in 42 U.S.C. 256b(a)(4)(A)."

-A10 Requires covered entities to determine the difference between total payments received for all 340B drugs and the total acquisition cost, and to utilize 95 percent of that difference to decrease the out-of-pocket costs for people whose household income does not exceed 400 percent of federal poverty guidelines.

-A11 Requires covered entities to report to the Department of Consumer and Business Services annually. Report must include drug acquisition costs, payments received, and itemized reporting on efforts to lower out-of-pocket costs for individuals, including by implementing a sliding fee scale.

BACKGROUND:

In 1990, Congress created the Medicaid drug rebate program to lower the cost of pharmaceutical drugs purchased by state Medicaid program. The program requires drug manufacturers to enter into a rebate agreement with Department of Health and Human Services as a prerequisite for having coverage of a drug by Medicaid and Medicare Part B. Under the program, drug manufacturers must pay rebates to state Medicaid programs that are based on the manufacturer's "best price" for the drug.

In 1992, the cost relief provided by the Medicaid drug rebate program was extended to safety-net providers through the passage of Section 340B of the Public Health Service Act. Under 340B, drug manufacturers give front-end discounts on specified outpatient drugs purchased by "covered entities," which includes federally qualified health centers and other specified programs and entities that serve vulnerable populations.

House Bill 2385 A makes it an unlawful trade practice for drug manufacturers to take specified actions that limit or interfere with a pharmacy's ability to acquire or dispense 340B drugs.