



Safety Net Hospitals for Pharmaceutical Access

S. 1376 – 340B Program Improvement and Integrity Act of 2007 Summary

I. Section 1 - Title

II. Section 2 - Expansion of Covered Entities Receiving Discount Prices

-In addition to clarifying the status of Children's Hospitals as 340B covered entities, the legislation would add the following new entities as facilities potentially eligible for the 340B program: Critical Access Hospitals, Sole Community Hospitals, Rural Referral Centers.

-Sole Community Hospitals and Rural Referral Centers qualified to enroll as 340B covered entities would be required to meet the following eligibility requirements: (1) A DSH adjustment percentage of no less than 8%, and (2) public or non-profit status and, if a private non-profit facility, under contract with state or local government to provide care to indigent patients. Critical Access Hospitals would also be subject to the criteria listed in (2) above.

-The Secretary of Health & Human Services would be directed to establish reasonable exceptions to the existing prohibition against 340B entity participation in group purchasing arrangements for covered outpatient drugs.

III. Section 3 – Extension of 340B Discounts to Inpatient Drugs

-340B discounts would be extended to the inpatient setting for all covered drugs.

-A credit would be given to the Medicaid Program by the covered entity for a portion of the savings derived from 340B discounts in the inpatient setting. This would be applicable to both brand name and generic covered drugs. This section establishes a formula to calculate the credit to Medicaid. The fundamentals of the formula are as follows:

Brand name drugs

Hospital annual inpatient drug spend on Medicaid patients X AMP adjustment % X 15.1% = Medicaid credit

Generic drugs

Hospital annual inpatient drug spend on Medicaid patients X AMP adjustment % X 11% = Medicaid credit

*Secretary of HHS will calculate average manufacturer price (AMP) adjustment % because only HHS has access to AMP at this time

* 15.1% = Medicaid rebate % for brand name drugs

* 11% = Medicaid rebate % for generic drugs

IV. Section 4 – Improvements to 340B Program Integrity

-The Act would establish measures to improve overall administration and enforcement of the 340B Program. The Secretary of HHS would be directed to implement various measures to ensure compliance by both manufacturers and covered entities with 340B program rules and standards. The Secretary would also be directed to establish a dispute resolution process to address instances of overcharges for 340B covered drugs.

V. Section 5 – Other Improvements

-Allow use of multiple contract pharmacies on the part of covered entities.

-Direct the Secretary of HHS to establish procedures to ensure coordination between the Centers for Medicare & Medicaid Services (CMS) and the Health Resources & Services Administration (HRSA) on matters concerning administration of the 340B program.

-Have as effective date of January 1, 2008.

VI. Section 6 – Conforming Amendments

-Cites conforming amendments to the Social Security Act.

-Defines terminology

-Contains various provisions amending sections of the 340B statute and the Social Security Act that would otherwise “freeze” the law in its form as of November 1992, and makes clear that the provisions of the bill improving and enhancing the 340B program are intended to take effect notwithstanding any such provisions of law.