

Title VI – Improving Access to Innovative Medical Therapies

Subtitle A—Biologics Price Competition and Innovation

[POLICY UNDER DISCUSSION]

Subtitle B—More Affordable Medicines for Children and Underserved Communities

Sec. 611. Expanded Participation in 340B Program

Current Law

Section 340B of the Public Health Service Act (PHSA), established under Section 602 of the Veterans Health Care Act of 1992 (P.L. 102-585), requires pharmaceutical drug manufacturers that participate in the Medicaid drug rebate program, to enter into a pharmaceutical pricing agreement (PPA). Under PPAs manufacturers agree to provide discounts on covered outpatient drugs purchased by specified government public health facilities, called covered entities. The Health Resources and Services Administration (HRSA) is the federal agency that administers the 340B program. HRSA lists approximately 13,000 covered entity sites in a program participation database. According to HRSA, there are also 800 pharmaceutical manufacturers that participate in the 340B program. Covered entities include hospitals owned or operated by state or local government and serve a higher percentage of Medicaid beneficiaries. Other 340B covered entities are federal grantees such as federally qualified community health centers (FQHCs), FQHC look-alikes, family planning clinics, AIDS drug assistance programs, and a number of other public health organizations identified in the PHSA.

Participating covered entities receive discounts on all covered outpatient drugs. The 340B discount is the average manufacturer price (AMP) reduced by a minimum rebate percentage of 15.1 percent for brand name prescription drugs and 11 percent for generic and over-the-counter drugs.

Proposed Law

This provision would expand the covered entities that could qualify to receive discounted prices under the 340B Program. The new entities would include (1) children's hospitals excluded from the Medicare prospective payment system but who would otherwise meet existing 340B hospital requirements, (2) critical access hospitals, and (3) rural referral centers or sole community hospitals (these entities must have a disproportionate share adjustment (DSH) percentage of at least 8%). The provision would also expand discounts available to participating hospitals to inpatient drugs. Further, the hospitals that participate in the 340B program would be permitted to participate in group purchasing arrangements for inpatient drugs. However, the prohibition on

hospitals also participating in outpatient drug group purchasing agreements would remain. The Secretary would be authorized to create exceptions to the group purchasing participation for a hospital's purchasing of outpatient drugs. These exceptions would include (1) outpatient drugs unavailable due to supply shortages, (2) outpatient drugs when generic drugs are available at lower prices, (3) exceptions that help reduce the administrative burdens of managing 340B drug inventories and uncovered products (as long as duplicate discounts occur or a drug diversion problem results). As determined by the Secretary, hospitals would be required within 90 days after filing their Medicare cost reports to issue a credit to the state Medicaid program for inpatient drugs provided to Medicaid beneficiaries. These changes would take effect on January 1, 2010 and apply to drugs purchased on or after that date.

The calculation of 340B prescription drug discounts would be unchanged, except in the case when a covered drug is not distributed to the retail pharmacy class of trade. In this situation, the average manufacturer price would be defined as the average price paid to the manufacturer for the drug by US wholesalers for distribution to the acute care class of trade, after deducting for prompt pay discounts. The Secretary would establish a mechanism for collecting information from manufacturers on prices paid by the acute care class of trade to wholesalers.

Sec. 612. Improvements to 340B Program Integrity

Current Law

There are a number of provisions in Section 340B to ensure compliance with statutory and program rules. Under Section 340B covered entities are prohibited from reselling or transferring drugs to other organizations or patients of programs other than the covered entity. HRSA has published regulations defining a 340B patient, but not yet issued a final rule. In addition, covered entities are prohibited from receiving multiple discounts for the same product, such as a Medicaid rebate and a 340B discount. Manufacturers are permitted to audit the records of covered entities if they suspect product diversion is taking place and there are criminal penalties for intentional drug diversion.

Proposed Law

The Secretary would develop systems to improve program integrity activities for manufacturers and covered entities, as well as administrative procedures to resolve disputes.

Prescription Drug Manufacturers. The Secretary would be responsible for developing a system to verify the accuracy of manufacturers' ceiling prices. The system would include the following features (1) the development of appropriate standards and methodology to calculate ceiling prices, (2) a regular comparison of ceiling prices with quarterly pricing data submitted by manufacturers, (3) spot checking sales transactions to covered entities, (4) investigating pricing discrepancies by manufacturers and requiring manufacturers to take appropriate action. In addition, the system would have a number of other features. It would establish procedures for manufacturers to follow in issuing refunds to covered entities for overcharges. It would allow Internet access of the Health and Human Services website to the applicable ceiling price information in a secure way (i.e., through the use of mechanisms like password protection) to assure the protection of privileged pricing data. The system would include a mechanism so that

the Secretary is aware of rebates and other manufacturer discounts provided to other than 340B purchasers. If such discounts or rebates have the effect of lowering the applicable ceiling price an appropriate credit would be issued for 340B purchasers. The system would establish procedures for selective auditing of manufacturers and wholesalers; and the imposition of civil money penalties on manufacturers and wholesalers when pricing violations are discovered.

Covered Entities. The Secretary also would develop procedures and systems to help ensure covered entities compliance with program rules in order to prevent the diversion and violation of duplicate discount provisions and other requirements. The following features would be included in the program integrity program. The improvements would (a) enable covered entities to update their program participation information over the internet, (b) provide for detailed guidance so that covered entities can better avoid duplicate discounts when billing covered drugs to state Medicaid agencies, (c) establish a single standardized identification system so that covered entity sites can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered drugs, including the chargeback processing for such drugs, (d) imposing sanctions on a covered entity for program violations.

Dispute Resolution. The Secretary also would be responsible for developing an administrative dispute resolution process. This process would address covered entity overpayment claims as well as manufacturer claims of drug diversion or claims against covered entities for obtaining double discounts. The dispute resolution process shall identify a decision making body or individual, as well as administrative requirements, such as: time frames, deadlines, and documentation required to support claims. The administrative resolution of claims shall be a final agency decision and shall be binding on the parties, unless invalidated by an appropriate court.

There is an authorization for appropriation such as may be necessary to carry out these program integrity activities beginning in fiscal year 2010 and for succeeding years.