



## Safety Net Hospitals for Pharmaceutical Access

---

### 340B Provisions in the New Health Care Reform Law

The health care reform bill that was signed into law by President Obama on March 23 contains provisions that have a significant impact on the 340B drug discount program and its participants. Several hundred new covered entities will be eligible for outpatient discounts and hospitals will benefit from greater transparency within HRSA's administration of 340B, improvements to the program's integrity, and the possibility of an increase in the 340B discount rate.

The following is a summary of the major provisions of health care reform that will affect the 340B program and its covered entities. Be advised that although these provisions have been signed into law, HRSA has indicated that will take some time before these changes to the 340B program are fully in place. SNHPA will provide regular updates on the implementation process within HRSA.

**New 340B covered entities.** The new law expands 340B eligibility to free-standing children's hospitals, free-standing cancer hospitals, and critical access hospitals (CAHs) in the outpatient setting. In addition, sole community hospitals (SCHs) and rural referral centers (RRCs) now require a Medicare DSH adjustment percentage of 8 percent to qualify for outpatient 340B discounts, while the minimum percentage for other hospitals currently eligible for the discount will remain at 11.75 percent. Fewer than 100 SCHs and RRFs fall between the 8 and 11.75 percent levels. Critical access hospitals (those in remote areas with fewer than 25 beds) will not have to meet an indigent care standard. Like current 340B enrollees, a newly eligible entity will have to be either a public or private nonprofit hospital with a contract with state or local government to serve the indigent.

While children's hospitals were recently added to the program under a new federal guideline, this legislation adds the children's hospitals and the other facilities to the list of covered entities under the Public Health Service Act, which entitles them all to benefits such as access to nominally priced drugs and voluntary inpatient discounts. However, certain "orphan drugs" will be ineligible for 340B discounts for these new covered entities. Drug manufacturers must continue to provide 340B discounts for orphan drugs for existing covered entities such as DSH hospitals. SNHPA and other organizations are working to repeal the orphan drug exemption for new entities.

Eleven free-standing cancer hospitals that are exempt from the Medicare prospective payment system are now potentially eligible for the 340B program. However, since they will have to meet the same indigency requirements as DSH and children's hospitals (a Medicare DSH adjustment of 11.75 percent or greater), it is unclear how many will actually qualify.

**Likely increase in 340B discounts.** The new law increases the mandatory Medicaid drug rebate percentage on brand name drugs from 15.1 percent to 23.1 percent of average manufacturers price (AMP), with the exception of clotting factor and pediatric drugs. The rebates on these drugs will increase to 17.1 percent of AMP. The rebate percentages for generic drugs will increase from 11 percent to 13 percent of AMP. We hope this will result in a significant increase in the 340B discount percentage since the 340B price is tied to the Medicaid rebate. Although AMP is also expected to increase due to a change in the formula, SNHPA is hopeful that the overall 340B discount should rise for your hospital, resulting in significant savings for your institution.

**Protects 340B providers when billing Medicaid managed care.** Manufacturers are protected under federal law from having to give both 340B discounts and Medicaid rebates on the same drugs. The prohibition against duplicate discounts generally means that covered

entities must pass their 340B discounts to Medicaid, by billing their 340B drugs at actual acquisition, to compensate states for the loss of the rebate they otherwise would have been able to collect if the drugs had not been purchased through 340B. However, because drugs covered and paid for by Medicaid managed care organizations (MCOs) are not subject to rebates under the Medicaid drug rebate program, covered entities have been able to bill and collect more favorable reimbursement for their Medicaid MCO drugs.

This important revenue source was placed at risk under health care reform as a result of a bill extending the Medicaid rebate to drugs paid for by Medicaid MCOs. 340B provider groups worked hard to convince Congress to exempt 340B drugs from the expansion of the rebate program to protect the Medicaid MCO revenue source for 340B pharmacies. They were successful. Their requested exemption language was incorporated into the legislation.

**Helps seniors in the Medicare Part D donut hole.** The budget reconciliation bill passed along with the health care reform law helps Part D prescription drug plan beneficiaries in the coverage "donut hole" by increasing the 50 percent discount for brand-name drugs that manufacturers had already agreed to pay under an agreement with the White House to 75 percent for both brand-name and generic drugs. The remaining 25 percent of drug costs in the donut hole would be picked up by the beneficiaries. Beneficiaries will receive a \$250 check towards Medicare prescription drug costs they incur in the coverage gap in 2010.

#### **Calls for Government Accounting Office study on 340B program.**

During the markup of the health reform bill in the Senate Health, Education, Labor and Pensions (HELP) Committee, amendments that would have blocked the 340B program's expansion were drafted, including one to sunset the entire program for some 340B providers. Sen. Orrin Hatch (R-Utah) introduced an amendment that would have delayed any expansion of 340B until the Government Accounting Office (GAO) completed a study to determine whether such an expansion was necessary once health care reform was implemented. A compromise between Hatch and the HELP Committee leadership was struck and the committee agreed to go forward with the GAO study with the expansion provisions remaining in the legislation. The health care reform law requests that the GAO study be completed within 18 months and address the following questions:

- Whether the 340B program should be expanded since it is anticipated that the millions of individuals who are uninsured as of the date of the law's enactment will have health care coverage once the law is implemented.
- Whether mandatory sales of certain products by the 340B program could hinder patients' access to those therapies through any provider.
- Whether income from the 340B program is being used by 340B covered entities to further the program's objectives.

SNHPA will be reaching out to the GAO and will be working hard to make sure that the 340B hospital perspective is heard. SNHPA believes that expanding 340B is an essential component of health care reform, improving access and quality of care for patients at a minimal cost to the drug industry.

#### **New integrity provisions for manufacturers and covered entities:**

- **Availability of 340B prices.** The new law will require that 340B covered entities have access through the Office of Pharmacy Affairs (OPA) Web site to the actual 340B ceiling prices verified by the Secretary of Health and Human Services (HHS).

- **New integrity provisions for manufacturers and covered entities.** HHS is required to develop a system to ensure accurate pricing by manufacturers under the program. The government is also required to perform spot checks of manufacturer sales transactions and inquire into the cause of pricing discrepancies, and ensure corrective action. As to covered entities, they will be required to annually update their contact information on the OPA Web site. In addition, the Secretary is required to develop more detailed guidance on billing Medicaid. Covered entities will be subject to fines if they have engaged in knowing and intentional violations such as drug diversion.
- **Improved Dispute Resolution Process.** HHS is required within 180 days of the new law's enactment to issue regulations that will establish a formal dispute resolution process for covered entities that have been overcharged by drug manufacturers. HHS is required to set deadlines to ensure disputes will be resolved in a timely manner and that establish procedures that will allow covered entities access to information from manufacturers and third parties that will demonstrate the merits of their claims. Manufacturers will also be entitled to use this new process in disputes filed against covered entities.
- **Mandatory credit or refund process.** The new law requires the HHS Secretary to establish procedures for manufacturers to issue refunds to covered entities and to oversee those refunds when there is an overcharge. Manufacturers will be required to explain to the Secretary why and how the overcharge occurred and how refunds are calculated and will be issued.

For further information, please contact SNHPA's Director of Government Relations Rob Recklaus at [rob.recklaus@snhpa.org](mailto:rob.recklaus@snhpa.org) or at (202)552-5852.