

## HEALTH LAW UPDATE

May 13, 2010

### HEALTH REFORM

#### 340B Program Changes

Historically, the 340B drug pricing program has allowed certain hospitals and federal grantees and federally-qualified health center look-alikes to purchase outpatient drugs at heavily discounted prices. The Patient Protection and Affordable Care Act and Health Care and Education Reconciliation Act of 2010 (collectively, the Reform Legislation), expanded the types of hospitals and entities eligible to participate in the program. Newly-eligible providers should evaluate their current outpatient operations to determine if participation in the 340B program would be advantageous for them and to ascertain whether they need to take any action to be eligible to participate.

Under the Reform Legislation, PPS-excluded children's and cancer hospitals may participate in the 340B program for outpatient drugs, if they would have had a DSH hospital payment adjustment percentage of greater than 11.75 percent (if they were otherwise a PPS hospital). Similarly, rural referral centers and sole community hospitals are eligible for 340B program participation if they would have had a DSH payment adjusted percentage greater than eight percent. Also, critical access hospitals may participate in the 340B program, but they are not required to meet a minimum DSH payment adjustment percentage. Orphan drugs, as defined under § 526 of the Federal Food, Drug and Cosmetic Act, are not eligible for 340B discount pricing for the newly-eligible types of organizations. Additional information on 340B criteria may be accessed through the [Health Resources and Services Administration \(HRSA\) website](#).

Newly-eligible providers can participate in 340B discounts effective as of January 1, 2010 but enrollment will not occur until the Health Resources and Services Administration's (HRSA) Office of Pharmacy Affairs has produced guidance and enrollment material for the new provider types. While it is unclear whether retroactive 340B discounts will be available for covered outpatient drugs purchased between January 1 and a provider's actual enrollment date, the Office of Pharmacy Affairs has permitted retroactive discounts for newly-eligible provider types in the past. As a result, newly-eligible providers should establish eligibility as quickly as possible to take advantage of the potential for retroactive discounts.

The most significant change for children's hospitals and cancer hospitals may involve changes to their outpatient drug purchasing methodology as they may not purchase their 340B covered outpatient drugs through a group purchasing organization (GPO). The GPO purchasing limitation, however, is not applicable to rural referral centers, sole community hospitals or critical access hospitals. Also providers should retain documentation to demonstrate that covered outpatient drugs for which they intend to seek retroactive 340B discounts were not submitted for Medicaid rebates.

With the expansion of the 340B program, Congress has included new compliance requirements and penalties for 340B violations. The Reform Legislation imposes new penalties on covered entities for knowingly and intentionally reselling 340B drugs to individuals who are not patients of the provider and requires that the providers

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regularly update their 340B eligibility information on HRSA's website. In addition, HHS is required to verify the accuracy of information submitted by providers and develop a standardized system to identify 340B eligible providers to facilitate 340B transactions.

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