

## ONLINE FIRST

# Cost Consequences of the 340B Drug Discount Program

Rena M. Conti, PhD

Peter B. Bach, MD, MAPP

CREATED IN 1992, A LITTLE-KNOWN FEDERAL DRUG discount program called “340B” allowed a handful of hospitals that cared for the poor to obtain drugs for their patients at substantially reduced prices. Today, through a series of expansions, including some enumerated in the Affordable Care Act, numerous other types of entities such as community hospitals and cancer centers that serve both the poor and the well-insured can participate.<sup>1</sup> Between 2009 and 2012 the number of enrolled hospitals doubled, and today the program includes 1679 hospitals, a third of all hospitals in the United States.<sup>2</sup>

The program requires drug manufacturers that participate in the Medicaid drug rebate program to extend substantial discounts on drugs administered in the outpatient setting, including oral drugs that can be distributed through contract pharmacies as well as physician-administered drugs such as those used to treat cancer and diseases of the immune system. The typical discount ranges from 30% to 50% off the drug’s list price.<sup>2,3</sup> Through the expansions of the program in participating hospitals, affiliated outpatient clinics, and outpatient pharmacies, the total cost of program-driven drug discounts has increased from around \$1 billion per year a decade ago to \$6 billion in 2010, and it is projected to reach \$12 billion by 2016.<sup>3</sup>

The original intent of the 340B program was presumably to enable underfinanced care facilities to purchase drugs that would be used for the treatment of medically and financially vulnerable patients they served. The program does not require hospitals to only provide the discounted drugs to patients who are poor and in need, nor does it include a requirement that the savings on drugs be passed on to patients or insurers. Therefore, hospitals can use the discounted drugs with all of their “eligible” patients (except those receiving Medicaid). Regulators define “eligible” patients as those who receive regular medical care at the hospital or its outpatient affiliates; these patients do not need to be poor or uninsured.

When insurers and patients pay for the treatments as if the hospital obtained the drugs at list price rather than at the 340B-based discounted price, the hospital or treating phy-

sician practice can keep the profits generated.<sup>2</sup> Likewise, contract pharmacies can retain the profits they obtain when they dispense discounted drugs to patients who are fully insured. A recent report suggests that a single practicing oncologist can generate about \$1 million in profits for a hospital by obtaining drugs at 340B-discounted prices and using them to treat well-insured patients.<sup>4</sup>

For participating hospitals this windfall comes at a time when state Medicaid agencies have substantially reduced reimbursements and federal support for many hospitals is scheduled to decline beginning in 2014.<sup>5</sup> Pharmaceutical manufacturers have objected to the expansions of a program that generates hospital profits but that might not be directly benefiting the poor.<sup>4</sup> Although no regulatory agency monitors the hospitals’ use of 340B profits, a recent report did find examples of some participating institutions using their 340B profits to fund programs that support or expand access to services.<sup>2</sup>

Fair or not to hospitals or drug manufacturers, the 340B program drives down the acquisition costs of drugs but not their reimbursement. Therefore, it may be having paradoxical effects on the costs of patient care, in particular for patients with cancer, for 3 reasons.

First, the availability of profits from administering expensive cancer drugs is known to alter physician prescribing behavior.<sup>6</sup> This occurs because oncologists practicing in the outpatient setting generate profits from the difference between drug acquisition costs and insurer reimbursement and patient co-payments. For oncologists practicing in 340B-affiliated outpatient clinics, prescribing may shift toward more expensive drugs because profit margins will in general be larger. How great this shift will be is uncertain.

Second, the 340B program creates a widening disparity between noneligible and eligible hospitals and affiliated oncology practices in the profits they are able to obtain from the care of well-insured patients with cancer.<sup>7</sup> This disparity is likely underlying trends toward consolidation and affiliations between community-based oncology practices and 340B-eligible hospitals.<sup>5</sup> This disparity may also lead to shift-

**Author Affiliations:** Section of Hematology/Oncology, Department of Pediatrics, University of Chicago, Chicago, Illinois (Dr Conti); and Health Outcomes Research Group, Memorial Sloan-Kettering Cancer Center, New York, New York (Dr Bach).

**Corresponding Author:** Rena M. Conti, PhD, Section of Hematology/Oncology, Department of Pediatrics, University of Chicago, 5841 S Maryland Ave, Chicago, IL 60637 (rconti@uchicago.edu).

ing of care out of community-based oncology practices and into hospital-based infusion suites. These trends will tend to increase total spending. Cancer care delivered in a hospital-based outpatient infusion suite is typically more expensive than that delivered in a physician's community-based office.<sup>8</sup> Moreover, market consolidation may increase private insurance contracted rates and thus private insurance premiums and other patient costs.<sup>9</sup>

Third, drug manufacturers will likely seek to increase list prices even further to offset revenue losses incurred as a larger number of drug sales become eligible for 340B discounts (and thus fewer drugs are sold at full price). An analogous response was seen when Congress enacted mandatory rebates for the purchase of drugs for Medicaid-eligible patients.<sup>10</sup> The extent to which this is a concern will depend on the ability of hospitals to bargain with manufacturers for lower acquisition prices and the effects of the penalties levied by the Centers for Medicare & Medicaid Services against drug manufacturers when they increase prices to a greater extent than the rise in the consumer price index.

In summary, as currently structured, most of the costs of the program are borne by manufacturers; the financial benefits of the 340B discounts are accruing almost entirely to hospitals, clinics, and physicians; and patients' out-of-pocket costs and total cost of care are being increased.

Could the program be reconfigured to provide support to hospitals serving the most vulnerable patients while eliminating its cost-increasing effects? There are a number of available options. One option would be for hospitals and their affiliated contract pharmacies to be limited to providing the drugs they obtain at 340B discount rates only to those patients who are poor and uninsured. Administratively, this approach would be analogous to the process for Medicaid drug rebates in hospitals and probably most consistent with the original intent of the program. Manufacturers would benefit because the number of drugs sold at a discount would be reduced, and therefore the incentive to inflate prices for new drugs would be reduced. Eligible hospitals and their affiliated physicians would lose a source of profits. Patients and insurers would directly benefit through the elimination of 340B-created incentives to overprescribe expensive drugs and indirectly benefit through a slowdown in con-

solidation of hospitals with community-based clinical centers and physicians.

Alternatively, hospitals and treating physicians could be required to pass on their savings from drug purchases to patients and their insurance providers, including Medicare. This approach would reduce the incentive for overutilization of high-priced drugs and lessen (but not eliminate) competition between outpatient cancer centers for well-insured patients. An intermediate version of this approach is to allow insurers to recoup some 340B profits from hospitals and physicians and pass those profits back to their beneficiaries. Congress would need to empower the Centers for Medicare & Medicaid Services to do the same for the Medicare program.

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