REPORT OF THE BOARD OF TRUSTEES

B of T Report 8-I-18

Subject: 340B Drug Discount Program
(Resolution 225-A-18 Resolve 3)

Presented by: Jack Resneck, Jr., MD, Chair

Referred to: Reference Committee B
(Francis P. MacMillan, Jr., MD, Chair)

INTRODUCTION

At the 2018 Annual Meeting of the House of Delegates (HOD), the third resolve of Resolution 225-A-18 was referred for report back at the 2018 Interim Meeting. Resolution 225-A-18, sponsored by American Society of Clinical Oncology (ASCO), asked that our American Medical Association (AMA):

(3) support discontinuing the use of the Disproportionate Share Hospital (DSH) adjustment as a determining measure for 340B program eligibility;

The reference committee heard mixed testimony on this resolve. Testimony was offered that additional research and analysis is needed to assess how to identify the DSH hospitals that should not benefit from 340B program rebates and those that should. The reference committee recommended adopting Resolves 1, 2, and 4, and referral of Resolve 3 for a report back at the 2018 Interim Meeting.

AMA POLICY

Our AMA has an extensive policy that supports increased pharmaceutical drug and biological affordability and policies to ensure patient access to medically necessary prescription medication. However, our AMA does not have specific policy concerning the 340B program other than the HOD adopted resolves of Resolution 225-A-18 (Policy H-110.985, “340B Drug Discount Program”). There is a policy related to rebates which provides that our AMA supports legislation to require generic drug manufacturers to pay an additional rebate to state Medicaid programs if the price of a generic drug rises faster than inflation. (Policy H-110.987, “Pharmaceutical Cost”). Thus, there is support for rebate programs to the extent such programs benefit uninsured patients and patients living on low-incomes. Consistent with the foregoing, AMA policy provides support for the subsidization of prescription drugs for Medicare patients based on means testing (Policy H-330.902, “Subsidizing Prescription Drugs for Elderly Patients”). However, AMA policy also includes support for economic assistance, including coupons (and other discounts), for patients, whether they are enrolled in government health insurance programs, enrolled in commercial insurance plans, or are uninsured (Policy H-125.977, “Non-Formulary Medication and the Medicare Part D Coverage Gap”).
BACKGROUND

The 340B program, which is administered by the U.S. Department of Health and Human Services’ (HHS) Health Resources and Services Administration (HRSA), requires pharmaceutical manufacturers to sell outpatient prescription medication at a discount to covered entities. Congress established the 340B program in order to produce savings for certain safety-net health care providers by allowing them to purchase outpatient drugs at these discounted prices. The U.S. House of Representatives’ report, accompanying the original legislation, stated that these savings would “enable [participating] entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” Pharmaceutical manufacturers are required to enter into an agreement, called a pharmaceutical pricing agreement (PPA), with the HHS Secretary. Under the PPA, the manufacturer agrees to provide front-end discounts on covered outpatient prescription medication purchased by “covered entities.”

The 340B program definition of “covered entity” includes six categories of hospitals: (1) disproportionate share hospitals (DSHs); (2) children’s hospitals; (3) cancer hospitals exempt from the Medicare prospective payment system; (4) sole community hospitals; (5) rural referral centers; and (6) critical access hospitals (CAHs). In addition, to qualify hospitals must be (1) owned or operated by state or local government, (2) a public or private non-profit corporation which is formally granted governmental powers by state or local government, or (3) a private non-profit organization that has a contract with a state or local government to provide care to low-income individuals who do not qualify for Medicaid or Medicare. Also, hospitals must meet payer-mix criteria related to the Medicare DSH program with the exception of CAHs. There are also 11 categories of non-hospital covered entities that are eligible based on receiving federal funding that include: federally qualified health centers (FQHCs); FQHC “look-alikes;” state-operated AIDS drug assistance programs; Ryan White Comprehensive AIDS Resources Emergency Act clinics and programs; tuberculosis, black lung, family planning, and sexually transmitted disease clinics; hemophilia treatment centers; Title X public housing primary care clinics; homeless clinics; urban Indian clinics; and Native Hawaiian health centers. Covered entities may provide drugs purchased through the 340B program to all eligible patients, regardless of a patient’s payer status and whether the drug is intended for self-administration or administration by a clinician. Discounts have been estimated to range from 20-50 percent of the drug’s cost.

DISCUSSION

Affordability and access to prescription medication is an area of increased focus by Congress and the Trump Administration. In the past year the 340B program has become the subject of significant scrutiny. A central question posed by a number of stakeholders: do the rapidly increasing number of DSH hospitals eligible for the 340B program discounts provide low-income patients the benefit of the prescription drug rebates that they receive? (Other aspects of the 340B program, addressed by the newly adopted AMA policy concerning the 340B program, have also been flagged including manufacturer and covered entity noncompliance with 340B program requirements and insufficient federal agency authority and resources to provide appropriate oversight.)

The Affordable Care Act increased the size and scope of the 340B program by expanding eligibility to more types of hospitals, such as critical access hospitals and sole community hospitals, and expanded Medicaid eligibility. As a result of the latter, the number of hospitals qualifying as DSH hospitals increased as DSH designation is calculated based on a formula that utilizes the number of Medicaid covered patients that a hospital serves. The number of participating unique covered entities has grown from 3,200 in 2011 to 12,722 in October 2017. The number of hospitals has grown significantly, from 591 in 2005 to 2,479 as of October 2017.
There have also been a number of unintended consequences of the 340B program. A 2015 Avalere study found that hospitals participating in the 340B program were more likely than non-340B hospitals to acquire independent physician practices.\textsuperscript{10} These acquisitions create financial windfalls for hospitals due to the 340B program yet do not necessarily improve affordability for patients. Patient costs and resultant co-pays/co-insurance and deductibles for care in a hospital outpatient department (HOPDs) can be higher than those in physician offices.\textsuperscript{11} (In those instances, patient care in HOPDs is more costly for health insurers too.) Furthermore, some 340B eligible hospitals may have commercial contracts that pay substantially more than the Medicare rate for drugs,\textsuperscript{12} so the profit margin can be multiples of the cost of the drug. Patients may face a 20 percent coinsurance on this higher amount. Yet, hospitals eligible for the 340B program obtain drugs at a substantial discount. The 340B program does not require that the hospital pass the savings to uninsured or underinsured low-income patients. To the extent that the hospital does not pass along the savings, the combined payment by insurer and patient provides profit for the 340B hospital; the additional volume generated when 340B hospitals acquire independent physician practices results in even greater profits. There are also reports that hospital systems have acquired 340B program eligible hospitals in order to purchase drugs for their suburban clinics utilizing the discounts even though such clinics do not serve uninsured or underinsured low-income patients.

There have been several congressional hearings on the 340B program convened by the U.S. Senate’s Health, Education, Labor, and Pension (HELP) Committee as well as the U.S. House of Representatives’ Energy and Commerce (E&C) Committee. Testimony offered by the U.S. Government Accountability Office (GAO),\textsuperscript{13} the HHS Office of the Inspector General (OIG),\textsuperscript{14} and other witnesses included concerns with the 340B program’s: (1) inadequate “patient” definition; (2) eligibility criteria for covered entity; (3) oversight of covered entities and manufacturers; and (4) oversight of the use of contract pharmacies. The lack of program data to assess the extent to which 340B program covered entities are ensuring low-income patients benefit from the rebates and the savings has particularly troubled policymakers and other stakeholders.

In addition to the hearings, over 17 federal bills have been introduced concerning the 340B program in this Congress. A number of the bills would mandate reporting on care provided to low-income individuals and would impose new eligibility requirements for certain categories of covered entities. For example, in December 2017, Representative Larry Buschon (R-IN) introduced H.R. 4710, Protecting Access for Underserved and Safety-net Entities Act (340B PAUSE Act). The bill would impose a moratorium on registration for certain new 340B program hospitals and associated sites. H.R. 4710 would also mandate data collection by covered entities including the number and percentage of insured (by insurer) and uninsured individuals who are dispensed or administered 340B program discounted drugs. In January 2018, Senator Bill Cassidy (R-LA) introduced S. 2312, Helping Ensure Low-income Patients have Access to Care and Treatment Act (HELP Act). The bill would impose a registration moratorium on new non-rural 340B program covered entities and associated sites as well as new eligibility requirements for covered entities. It would also require reports on the level of charity care provided by covered entities. Similarly, in April 2018, Representative Earl Carter (R-GA) introduced H.R. 5598, 340B Optimization Act. The bill would amend the Public Health Service Act to require certain disproportionate share hospital covered entities under the 340B drug discount program submit to HHS reports on low-income utilization rates of outpatient hospital services furnished by such entities.

In order to address the lack of data available directly from 340B program hospital covered entities or HRSA vis-à-vis the benefit to low-income patients, the House E&C Committee Chairman Greg Walden (R-OR) and health subcommittee Chairman Michael Burgess (R-TX) requested a report on the topic from the GAO. On June 18, 2018, the GAO issued the report, Drug Discount Program:
Characteristics of Hospitals Participating and Not Participating in the 340B Program. The report found that:

- In 2016, the median amount of charity care provided by all 340B hospitals was similar to the median amount provided by all non-340B hospitals, and the median amount of uncompensated care provided by these 340B hospitals was higher than that provided by their non-340B counterparts. But again, the differences between the 340B and non-340B hospitals varied across the different hospital types. For example, while the median amount of uncompensated care provided by 340B general acute care hospitals (340B DSH) was higher than that of their non-340B counterparts, the median amount provided by 340B CAHs was lower than that of non-340B CAHs.

While the report provides additional needed analysis and data, more information is needed concerning the program's implementation and benefit to low-income patients. To ensure the 340B program covered entity criteria aligns with the goal of ensuring low-income patients are able to access affordable treatments, at least one national medical specialty society has recommended that Congress establish new metrics that such entities must meet that are objective, universal, verifiable, and align program eligibility with the care provided by the covered entity to indigent and underserved individuals. Consistent with the foregoing, alternative eligibility measures could be calculated by analyzing the amount of charity care provided by hospitals in the outpatient setting. Ultimately, eligibility should be designed to qualify entities based on the amount of care delivered to underserved populations in outpatient settings. This would dovetail with new AMA policy to work with policymakers to establish 340B program eligibility for all physician practices demonstrating a commitment to serving low-income and underserved patients, new covered entity criteria should promote participation by institutions and practices of all sizes in all settings. To advance this goal, ASCO has convened an expert workgroup to develop recommendations for a revised eligibility formula in order to appropriately capture the level of outpatient charity care provided by hospitals, as well as standalone community practices. ASCO will provide policymakers and other stakeholders with the recommendations during the current congressional session.

CONCLUSION

The significant growth of the 340B program, particularly among DSH hospitals, should align with newly adopted HOD policy concerning 340B program and related AMA policies. Specifically, the program should promote access to affordable prescription drugs by low-income patients receiving care from 340B program covered entities. In addition, our AMA should engage with national medical specialty societies to leverage expertise and align recommendations to federal policymakers.

RECOMMENDATIONS

In light of these considerations, your Board of Trustees recommends that the following recommendations be adopted in lieu of the third resolve Resolution 225-A-18 and the remainder of this report be filed:

1. That our American Medical Association support a revised 340B drug discount program covered entity eligibility formula, which appropriately captures the level of outpatient charity care provided by hospitals, as well as standalone community practices. (New HOD Policy)
2. Our AMA will confer with national medical specialty societies on providing policymakers with specific recommended covered entity criteria for the 340B drug discount program. (Directive to Take Action)

Fiscal Note: Less than $5000

REFERENCES

1 Section 340B of the Public Health Service Act, codified at 42 U.S.C. § 256b.
3 42 U.S.C. § 256b(a)(4)(A)–(K)
4 Id.
5 Id.
6 Id.
9 Id.
11 An Avalere report on Cost of Cancer Care stated that its “risk-adjusted results suggest that treatment for patients receiving chemotherapy in a HOPD costs on average 24 percent more than treatment received in a physician’s office.” Available from http://www.communityoncology.org/pdfs/avalere-cost-of-cancer-care-study.pdf