

## **Association of Community Cancer Centers Position Paper on the 340B Drug Discount Program**

October 2013

The Association of Community Cancer Centers (ACCC) is an institution-based membership organization with members in all 50 states and in all sites of service. ACCC's membership encompasses private practices and hospitals—academic and community-based—both for-profit and not-for-profit. Given this diversity in membership, ACCC is uniquely qualified to share its position on the 340B Drug Discount Program and its future.

In 1992, Congress created the 340B Drug Discount Program to reduce outpatient drug costs for certain types of healthcare facilities that treated a high proportion of uninsured or underinsured patients. The law requires pharmaceutical manufacturers to give discounted rates on drugs to qualifying hospitals or clinics, otherwise known as qualified entities. Congress expanded the program as part of the Affordable Care Act of 2010, allowing more healthcare facilities to qualify.

### **1. The 340B Drug Discount Program Allows Providers to Offer More Services to the Uninsured, Underinsured, and Medicaid Patient Populations**

The program has grown significantly since its inception, with large increases in participation occurring over the past five years. According to the Health Resources and Services Administration (HRSA), the government agency with oversight of the program, there are more than 1,600 hospitals enrolled in the 340B Program. In addition, those hospitals have contracted with over 25,000 neighborhood pharmacies to dispense these discounted drugs.

According to the law, the discounted drugs can be used with any patient being treated in the outpatient department of the covered entity. It does not restrict usage to those patients without insurance or on Medicaid or otherwise underinsured. That means that even patients with private insurance may be getting drugs purchased through the discount program. This practice significantly increases the quantity of drugs bought and billed through the 340B Program.

In cancer care, hospitals treat most of the underinsured, uninsured, and Medicaid patient populations. Increased savings from drugs purchased through the 340B Program allow hospitals to reinvest those savings in programs for these patients.

In some cases, the discounts allow hospitals to continue to treat patients who cannot afford their treatments; in other cases, the savings have allowed hospitals to open free clinics in underserved areas where patients might otherwise not have timely access to medical care. Altering the 340B Program may force changes to these types of offerings.

## **2. Clearer Regulations Must Be Promulgated to Ensure the Long-Term Viability of the 340B Program.**

While the 340B Program has helped providers care for traditionally underserved populations, ACCC believes that in order for the program to be sustainable in the future, HRSA must promulgate regulations that offer clear, coherent, and relevant direction.

Providers have expressed frustration that lack of clarity in the rules and regulations around the 340B Program has made the program unnecessarily difficult from an implementation and compliance standpoint. At the same time, pharmaceutical industry participants in the 340B Program have expressed concerns about the scope of the program expanding beyond its original intent.

ACCC supports HRSA reviewing the definitions currently in place throughout the 340B Program and making alterations, where the agency sees fit, in order to set the program on the course for long-term viability. This includes the definitions of “patient,” “outpatient department,” and “covered entity.”

Should this clarification process alter the program in any meaningful way, ACCC suggests that HRSA implement the change over an extended period of time, e.g., three to five years, to ensure compliance with any revised rules.

Overall, ACCC has been supportive of the intent of the 340B Program and, indeed, many ACCC members currently participate in it. We recognize that making the changes recommended in this paper, such as reviewing and possibly altering the definitions contained within the 340B Program, may lead to significant changes within the program. However, we feel that for the program to continue successfully into the future, changes need to be made that are in line with the original intent of Congress when it created the program in 1992.

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