

Policy Statement on the 340B Drug Pricing Program by the American Society of Clinical Oncology

By American Society of Clinical Oncology

Congress established Section 340B of the Public Health Service Act—commonly referred to as the 340B Drug Pricing Program—in 1992.¹ The 340B Drug Pricing Program requires manufacturers to provide substantial discounts for sales of covered drugs to covered entities as a prerequisite to qualifying for Medicaid reimbursement. Covered hospitals and other covered entities must limit the use of discounted drugs to the outpatient care of individuals who meet the program's definition of a "patient," among other requirements. The 340B Drug Pricing Program is administered by the Office of Pharmacy Affairs within the Health Resources and Services Administration (HRSA) of the US Department of Health and Human Services.²

Currently, there are six types of hospitals that can qualify as covered entities under the 340B Drug Pricing Program on the basis of the hospital's disproportionate share hospital (DSH) adjustment percentage and other factors.³ The DSH adjustment factor is a federal parameter established under Medicare as a proxy to identify hospitals with high levels of uncompensated care. In addition, there are 12 categories of nonhospital providers that can qualify for the 340B program on the basis of their eligibility for federal funding, such as federally qualified health centers.³

The financial implications of the 340B discount can be significant for a health care institution. The discount can substantially reduce the burden on covered entities that provide uncompensated or undercompensated care. In addition, drugs purchased by the covered entity at a discount can be sold to all individuals who meet the program's definition of a "patient." For purposes of the 340B program, a patient is an individual who is treated by a covered entity, regardless of their insurance status, not necessarily an individual who lacks adequate health care coverage. As a practical matter for eligible beneficiaries, this means that for patients who are covered by private insurance or Medicare, a covered entity participating in the 340B Drug Pricing Program can benefit financially from the difference between the discounted cost of the drug and the amount reimbursed by the patient's insurance program. This difference, commonly referred to as the "spread," can be quite significant when aggregated over a large number of patients.

The impacts of the 340B Drug Pricing Program are especially significant in the area of oncology, given the integral role that drug therapies play in the treatment of individuals with cancer. ASCO members deliver oncology care to patients in substantial numbers both inside and outside of 340B settings. In this policy statement, ASCO provides a summary of issues and recommendations related to the 340B program for policymakers to consider from the perspective of profession-

als dedicated to the prevention, diagnosis and treatment of cancer.

Discussion

In considering the future of the 340B Drug Pricing Program, the relevant issues raised by policymakers and various advocates fall into the following general categories:

- Whether the program satisfies the original intent of the legislation.
- Whether the size of the program is appropriate.
- Whether adequate safeguards are in place to ensure appropriate compliance and oversight of the program.
- Whether unique considerations related to cancer care warrant special attention by policymakers.
- These issues are discussed in greater detail below

Does the 340B Drug Pricing Program Satisfy the Original Intent of the Legislation?

Advocates have written extensively regarding whether the current 340B Drug Pricing Program satisfies Congress' initial vision. Advocates supporting the current program frequently cite an excerpt from the legislative history describing the intent to "[s]tretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."^{2,4} These advocates conclude that the 340B program should be interpreted broadly to provide resources through discounts on outpatient drugs to permit covered entities to stretch limited resources and maintain and expand other health care services available to low-income and vulnerable patients.²

In contrast, advocates who favor restraining the size and growth of the 340B Drug Pricing Program typically conclude that the legislative history envisions a more limited role for the program: to primarily provide low-income individuals with access to prescription drugs. Under this view, advocates emphasize the role of this legislation as a technical correction to remedy an unintended consequence of the Medicaid Drug Rebate Program, which since 1990 has required manufacturers to provide the "best price" to state Medicaid programs for prescription drugs.⁴ This requirement inadvertently made it more difficult for hospitals treating high volumes of indigent patients to negotiate favorable drug pricing. To address this problem, drug manufacturers whose drugs are covered under the Medicaid program must enter into a pharmaceutical pricing agreement with the federal government to provide discounts under the terms of the 340B program to be eligible to participate in Medicaid.⁶ In addition, language requiring manufacturers of drugs covered under Medicare Part B to enter into pharmaceutical pricing agreements was added to the law as section 303(i)

of the Medicare Prescription Drug Improvement and Modernization Act of 2003.⁷

To the extent that the 340B Drug Pricing Program exists to benefit vulnerable patient populations, there is insufficient evidence to ensure that the program is achieving these objectives to the fullest extent possible. As discussed in greater detail below, concerns regarding whether and how the 340B program is achieving its goals are accentuated by the rapid growth of the program and consulting activity to assist hospitals in maximizing revenue under the program, the passive role adopted by the federal government in regulating this area, and a general lack of attention by policymakers to the impacts of the program on outpatient oncology care.

Is the Size of the 340B Drug Pricing Program Appropriate?

By any objective measure, the size of the 340B Drug Pricing Program has increased significantly over recent years. The original legislative history makes reference to approximately 90 hospitals being eligible.⁴ In 2005, there were 591 hospitals participating in the 340B Drug Pricing Program. This number increased to 1,673 by 2011, representing almost one-third of all hospitals in the United States.⁸ The total number of covered entity sites (including but not limited to hospitals) has undergone similar growth. The total number of covered entity sites nearly doubled in size between 2001 and 2011, increasing from 8,605 to 16,572.⁸

Some commenters have criticized the fact that the 340B Drug Pricing Program has grown significantly in large part on the basis of a parameter that is calculated on the basis of inpatient care (the DSH adjustment percentage) to determine eligibility for the outpatient 340B Drug Pricing Program. The concern arises from the fact that a measure of inpatient services is used to define eligibility for a program involving outpatient drug prescriptions. This has resulted in a common perception that the growth rate of the program is unrelated to the utilization of prescription drug therapies to assist vulnerable, low-income populations. This is because the DSH adjustment percentage focuses on inpatient care that may or may not reflect the patient population obtaining outpatient prescription drug therapies from an entity participating in the 340B Drug Pricing Program.

To qualify for the 340B Drug Pricing Program, hospitals, children's hospitals, free-standing cancer hospitals, rural referral centers, critical access hospitals, and sole community hospitals must exceed the statutory threshold for the DSH adjustment percentage.³ The formula is calculated on the basis of Medicaid inpatient days and Medicare Supplemental Security Income inpatient days, such that if the total number of Medicaid inpatient stays increases for an institution, the DSH adjustment percentage increases.⁹ There is an emphasis on inpatient stays under this formula, and there is no consideration in the formula regarding whether prescriptions filled under the 340B Drug Pricing Program are for individuals who are low income, uninsured, underinsured, or otherwise vulnerable under our health care system.

The expansion of the size of the 340B Drug Pricing Program has also been the product of ongoing policy changes made by both Congress and HRSA. On several occasions, Congress has expanded the categories of hospitals and other providers that are eligible to become covered entities under the program, such as through the Deficit Reduction Act of 2005 and the Affordable Care Act.

Another factor contributing to the expansion of the 340B Drug Pricing Program has been the expanded use of contract pharmacies. Contract pharmacy arrangements are used by 340B entities to distribute drugs at sites other than the 340B-covered site. When HRSA promulgated implementing contract pharmacy guidance in 1996, HRSA only allowed covered entities without an on-site pharmacy to enter into contract pharmacy arrangements.¹⁰

More recently, HRSA issued revised guidance in 2010 that allowed for significant expansion of the use of contract pharmacy arrangements. The 2010 guidance allows 340B-covered entities to create multiple contract pharmacy arrangements that permit them to achieve a higher percentage of prescriptions filled through affiliated contract pharmacies. This development has been praised by some as a means to improve patient access to drug therapies and criticized by others as a way for 340B entities to leverage the spread between the cost of 340B drugs and the reimbursement rates provided by various insurance plans. In the initial year after release of the guidance in April 2010, the number of contract pharmacy arrangements under the 340B Drug Pricing Program grew from 2,646 to 6,915, an increase of 161%. The Office of Pharmacy Affairs has projected that the number of contract pharmacies will exceed 11,500 in 2013.¹²

In the near future, the expansion of Medicaid under the Affordable Care Act could significantly increase the number of hospitals that qualify for the 340B Drug Pricing Program. This is the direct result of the use of the DSH adjustment percentage to determine eligibility for various types of hospitals, as discussed above. As the number of Medicaid enrollees increases, the number of hospitals meeting the DSH adjustment percentage is likely to increase. Given that the states are split on whether to expand Medicaid coverage under the Affordable Care Act, there may be uneven effects under the 340B Drug Pricing Program from state-to-state.

Are Adequate Safeguards in Place to Ensure Appropriate Compliance and Oversight of the 340B Drug Pricing Program?

Over the years, stakeholders have noted that the 340B program's oversight standards make it particularly susceptible to confusion, misinterpretation, and abuse. Covered entities are required to avoid diversion of covered outpatient drugs and ensure that they are billing in a manner that avoids the application of duplicative discounts. In 2011, the Government Accountability Office (GAO) reported that the 340B program lacked sufficient oversight. The report identified self-policing as the primary means of compliance enforcement, and noted that at the time of the GAO's examination, HRSA had never conducted an audit of covered entities or drug manufacturers.⁸

Subsequently, HRSA has taken steps over the past 2 years to initiate oversight and compliance activities, and Congress directed HRSA to implement additional oversight and program integrity provisions under the Affordable Care Act. The Affordable Care Act requires, for example, that the Secretary of Health and Human Services establish improvements in the compliance system that will guarantee accuracy and transparency in determining the 340B ceiling price, establish refund procedures for overcharges by manufacturers, create a mechanism to track rebates and other discounts and ensure appropriate credits and refunds where applicable, establish a selective auditing system, and impose a civil monetary penalties for noncompliance.

The Affordable Care Act also altered compliance activities for covered entities, requiring the development of a mechanism for covered entities to update their information and a verification system to ensure accuracy of the information provided. Under these requirements, HRSA must also develop detailed guidance that describes methodologies and options for billing Medicaid for drugs.

Many of the difficulties in ensuring compliance with the 340B Drug Pricing Program could be addressed through agency action to clarify ambiguous regulatory guidance with respect to key definitions. An entity may only provide covered outpatient drugs to individuals who meet the definition of a patient that HRSA finalized in a 1996 guidance document.¹³ Since its release, the definition of whether a person is a patient of the covered entity has proven to be an ambiguous concept for drug manufacturers and covered entities alike.¹⁴ Because this definition is central to ensuring that a covered entity remains compliant with the diversion prohibitions of 340B, stakeholders on both sides argue that HRSA should update and clarify the outdated 1996 definition. Some argue that this ambiguity may contribute to program growth by allowing covered entities to divert drugs to patients in ways that are inconsistent with the intent underlying this program.

The Office of Pharmacy Affairs released a proposal that would have updated the definition of a 340B patient in 2007, by revising the definition to strengthen its requirements. The proposal would have required covered entities to own, control, maintain, and possess patient records that document services leading to the use or prescription of a 340B drug rather than merely maintaining patient records. The proposal also would have eliminated the language that allowed providers who were not employed or providing health care services under contract with the covered entity from writing 340B prescriptions. Finally, the proposal would have mandated that an individual must receive outpatient services resulting in use or prescription of a 340B drug from a provider employed or under contract with the covered entity.¹⁵

HRSA never finalized the proposed 2007 patient definition. Today, covered entities operate under the 1996 patient definition for the purposes of their diversion compliance. Stakeholders on both sides agree that the failure to establish a clear and actionable patient definition creates substantial confusion and compliance problems. This ambiguity continues to contribute to the overarching problems in 340B oversight and enforce-

ment. Absent clear guidelines, HRSA and the manufacturers are significantly disadvantaged in conducting audits to verify that drugs purchased at a 340B discount have not been improperly diverted.

Significant ambiguity also exists regarding whether certain private nonprofit hospitals are qualified entities. To qualify as a covered entity, a hospital must have a DSH percentage of more than 11.75%, refrain from purchasing covered outpatient drugs and supplies from a group purchasing organization or other similar group purchasing arrangement, and meet the government control test. The government control test ensures that an entity has some connection to serving the public. The statute prescribes three pathways to meet the government control test:

1. A hospital may be owned or operated by a unit of state or local governments.
2. A hospital may be a public or private nonprofit corporation formally granted governmental powers by a unit of state or local government.
3. A hospital may be a private nonprofit hospital with a contract with a state or local government to provide health care services to low-income individuals who are not entitled to benefits under Medicare or Medicaid.³

Shortcomings in the guidance regarding how a private, nonprofit hospital can meet these three requirements for 340B participation may also have contributed to the significant growth of the program. The GAO focused on the weakness of guidance in this area in its 2011 report, stating that the weakness could cause outcomes that “may not be what the agency intended”^{8(p23)}; HRSA updated its guidance clarifying the second and third criteria in March 2013.¹⁶ However, these clarifications have not resolved all of the concerns about the lack of guidance regarding how private nonprofit hospitals can meet the requirements for 340B participation. Some concerns in this area involve reports of the following types of activity:

- Hospitals may qualify for 340B on the basis of emergency department and acute care utilization, while sending uninsured patients elsewhere for outpatient care. Sending the uninsured population elsewhere for outpatient care maximizes the proportion of outpatient drugs that a covered entity can dispense and receive the spread between the discounted rate and the amount paid by insurance.
- Hospitals may expand their funding under the 340B Drug Pricing Program by expanding outpatient services in high-income area rather than pursuing underserved markets.

Do Unique Considerations Related to Oncology Care Warrant Special Attention by Policymakers?

As the size and scope of the 340B Drug Pricing Program has grown over the past few years, concerns have been raised regarding whether there are unintended, adverse impacts in the area of oncology. Cancer care is fundamentally different than many other areas of medicine because of the prominent role that drug therapies play in anticancer treatment regimens.

Although community-based physician oncology practices have been recognized as a cost-effective model for providing access points for the care of vulnerable individuals with cancer, outpatient oncology practices cannot qualify as standalone entities for the 340B Drug Pricing Program, and an ongoing trend has emerged in which hospitals are purchasing physician oncology practices.¹⁷ Some of this acquisition activity can be attributed to efforts to build hospital networks or accountable care organizations. However, in the case of oncology care, hospitals have an added incentive to purchase provider practices in an effort to expand the patient base for cancer drugs that qualify for the 340B program. In this context, the acquisition of oncology practices by 340B institutions may have the potential of unintended, market-distorting consequences by creating an uneven practice reimbursement environment favoring the survival of a 340B practice over a non-340B practice; by maintaining a practice that might otherwise have shuttered its doors; and by creating higher out-of-pocket costs for the patient community.

Further, the primary source of direct funding for the 340B Drug Pricing Program is drug manufacturers, rather than taxpayers or consumers. However, as the size of the program increases, there is a potential concern that the discounts achieved under the 340B Drug Pricing Program could be offset by increases in pricing for consumers in other settings.

Recommendations

ASCO members are devoted to ensuring that all Americans have meaningful access to the services necessary to prevent, diagnose, and treat cancer. To this end, we provide the following recommendations to help ensure that the 340B Drug Pricing Program achieves its full potential to achieve the original intent of promoting timely access to health care services for uninsured, underinsured, and low-income Americans regardless of the setting of care. To this end, we urge Congress, HRSA, and other policymakers to adopt the following recommendations.

Recommendation 1. When considering the future of the 340B Drug Pricing program, policymakers should focus on how to best meet the original intent of the program to provide resources and incentives to deliver high-quality care for uninsured, underinsured, and low-income patients. With this goal in mind, HRSA, Congress, and other policymakers should promote transparency and accountability under the 340B Drug Pricing Program by requiring 340B-covered entities to provide, on an annual basis, a full, comprehensive accounting of the amount of 340B savings and the percentage of the savings reinvested into caring for the uninsured, underinsured and Medicaid patients. A number of stakeholders have commented on whether and how the current state of the 340B Drug Pricing Program meets Congress' original and ongoing intent to serve the needs of these patients, and these considerations are highly relevant for improving the program and its reputation.

Recommendation 2. Policymakers should consider policy changes consistent with the original intent of the program and that take into account the changing demographics of oncology care. By any measure, the 340B Drug Pricing Program has undergone tremen-

dous growth since its inception more than two decades ago. There are valid concerns that there may be unintended adverse consequences from some types of growth in the program. To address these concerns, policymakers should adopt several safeguards. First, Congress should discontinue the use of the DSH adjustment percentage or other parameters derived from inpatient data as a means for determining eligibility for the 340B Drug Pricing Program, which involves access to outpatient drug therapies, and replace it with a formula that takes into account the percentage of underinsured and uninsured patients treated in the outpatient setting. This will improve the accountability for the program and address concerns that some entities could profit from the 340B Drug Pricing Program without a commitment to providing outpatient drugs to vulnerable populations. Second, HRSA and Congress should expedite efforts to refine and clarify the definitions of relevant terms and criteria as described below.

Recommendation 3. Issue guidance to clarify relevant definitions and provide funding for key oversight activities related to the 340B Drug Pricing Program. There are significant ambiguities and gaps in the regulatory definitions that underlie the administration of 340B. Congress and HRSA should expedite efforts to define and clarify the term "patient" and other important criteria under the 340B Drug Pricing Program. Such clarification is necessary to promote the goals of the program and permit meaningful oversight. Congress did not provide any funding for administration of compliance efforts under the 340B program until 2009. Although we applaud efforts by HRSA to update the guidance regarding hospital eligibility in March 2013, additional clarity is still necessary involving several fundamental aspects of the program. Cancer care professionals and the institutions they serve should not be subject to audits or other regulatory compliance activities that are based on confusing and ambiguous standards like the current "patient" definition. Both Congress and HRSA should take steps to clarify ambiguous aspects of the 340B program, and HRSA should be provided with the appropriate level of funding and staffing to engage in the necessary oversight activities. There needs to be consistent and effective oversight and audit activities that promote adherence to clear definitions and guidance. Only in this way can policymakers ensure that the 340B Drug Pricing Program is conducted in a fair and efficient manner.

Recommendation 4. Policymakers should place special emphasis on understanding and responding to any adverse impacts that the 340B Drug Pricing program may have on patient access to high-quality oncology care. The impacts—both intended and unintended—of the program are profound in cancer care because of the integral role that drug therapies continue to play in anticancer treatment regimens. The 340B program provides additional resources that health care institutions can deploy to promote quality, value, and access to oncology care and other patient services. In considering the ideal future policies for the 340B Drug Pricing Program, policymakers should consider whether and how the recent and current expansion of the program affects patient access to care through the availability of community-based physician oncology practices. Policymakers

should be cognizant that the existence of such practices increases both patient access and choice, and that there may be additional unintended consequences of their closure or acquisition. Uncontrolled expansion of any program is probably undesirable; however, the 340B program could be modified and better targeted to truly needy patients by appropriately identifying any entities that serve such patients. Integral to any such change is the need for more thoughtful qualification standards based on the characteristics of the outpatient population, standards that would accurately capture the demographics of the patient population being served. As Congress and other policy-makers consider the future of this program, emphasis should be placed on determining what clarifications, safeguards, and pol-

icy changes are necessary to promote quality, value, and access for individuals with cancer and other serious diseases.

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Author's Disclosures of Potential Conflicts of Interest

The author indicated no potential conflicts of interest.

DOI: 10.1200/JOP.2014.001432; published online ahead of print at jop.ascopubs.org on April 15, 2014.

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