

THE 340B DRUG DISCOUNT PROGRAM

A Review and Analysis of the 340B Program

WINTER 2013

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TABLE OF CONTENTS

Executive Summary.....	1
I. Background on the 340B Program.....	7
A. The Genesis and Purpose of the 340B Program	7
B. General 340B Eligibility Criteria	8
C. Specific Criteria for 340B Hospital Eligibility.....	8
D. Ambiguous 340B Eligibility Requirements for Private Nonprofit Hospitals	10
E. The Uncertain Safety Net Status of Some 340B Hospitals.....	11
F. 340B Eligibility and Provision of Uncompensated Care.....	11
G. The Definition of "Patient" Under the 340B Program	11
H. Current Size and Recent Growth of the 340B Program	12
II. 340B Program May Distort Pharmacy and Hospital Markets	17
A. Potential Hospital Market Distortions	17
B. Potential Pharmacy Market Distortions	18
C. The Impact of 340B Incentives on Clinical Decision-Making	19
D. Potential Cost-Shifting to Third-Party Payers Under 340B.....	19
III. The Need for Oversight to Ensure 340B Program Is Consistent with Its Statutory Purpose	21
A. The Potential for Drug Diversion	21
B. The Need for Continued Improvement in General Program Oversight	22
IV. The Role of the 340B Program After Coverage Expansion	23
V. Conclusion.....	25
Appendix	27

Executive Summary

KEY FINDINGS

Congress created the 340B program in 1992 to help uninsured indigent patients gain better access to prescription medicines. To achieve that goal, Congress created a program that requires pharmaceutical manufacturers to provide discounts on outpatient prescription drugs to entities that serve high numbers of uninsured indigent patients. This program, as originated, provided discounts to outpatient facilities for the purpose of sustaining certain services to this population. 340B is important today and going forward for the many patients who are dependent on this program. This white paper examines the history and original intent of the program as well as highlights key findings to help policymakers ensure that the 340B program meets its stated purpose and to provide a roadmap for next steps to be considered.

In addition to making other important observations, this paper also raises questions about whether the 340B program is leading to unintended and potentially harmful consequences for patients. Areas of most concern include the following:

- Concerns that some uninsured indigent patients may not be experiencing direct benefit from the program's existence.
- Anecdotal evidence that clinical decision-making may be skewed by efforts to take advantage of the 340B discount.
- Growing evidence of displacement of non-340B providers who serve a key role in providing patient access to important health care services.

The paper also identifies critical ambiguities in the 340B standards and potential deviations from Congressional intent that, along with limited oversight of the program, have made it difficult to determine whether the program is meeting Congressional goals.

In addition to identifying unintended and potentially harmful consequences for patients, the paper identifies several key findings to help policymakers ensure that the 340B program meets its stated purpose—helping uninsured indigent patients gain better access to prescription medicines. These key findings provide a roadmap for next steps:

- Adequate funding for the Health Resources and Services Administration (HRSA) is needed to ensure it is appropriately resourced to oversee the 340B program in support of the efforts it has already begun.
- Continued oversight of the 340B program is needed to ensure that the program is consistent with its statutory purpose.
- Improved transparency is necessary to help advance the program's goals and ensure that resources are being directly used to reduce drug costs for uninsured indigent patients.
- Full and transparent accounting for all cost-savings derived from the 340B program should be required to ensure that they are used to reduce drug costs for uninsured indigent patients.
- Clearer definition of the term "patient" is needed to ensure that it corresponds to the purpose of the 340B law, particularly given the increased coverage of prescription medicines by commercial insurance, coverage of uninsured persons through the Affordable Care Act and creation of Medicare Part D providing prescription drug insurance to seniors and disabled persons.

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KEY FINDINGS

- Clarification of hospital eligibility criteria to ensure the 340B program is (1) meeting its intended purpose of helping uninsured indigent patients improve access to prescription medicines and (2) does not further expand because more patients are insured and fewer are uninsured.
- 340B guidance should follow formal notice and comment rulemaking under the Administrative Procedures Act in order to

ensure that careful, well-informed decisions are made and that all stakeholders have the opportunity to provide information and perspectives before HRSA policies are finalized.

Conclusion: Because of the potentially serious consequences that could evolve from these and other findings, Congress should conduct a thorough examination of the 340B program to ensure it is meeting its original goals.

Congress created the 340B program in 1992 to help uninsured indigent patients gain better access to prescription drugs. To achieve that goal, Congress created a program intended to reduce outpatient drug costs for certain types of health care facilities serving large numbers of uninsured indigent patients. Accordingly, the law requires pharmaceutical manufacturers to give statutorily specified discounts for drugs dispensed to outpatients of qualifying entities, or Medicaid cannot cover the manufacturer's drugs.¹ Qualifying hospitals or clinics are known as 340B entities or "covered entities."

The 340B law's legislative history makes clear that the intent of the 340B program is to help uninsured indigent patients by giving covered entities that serve high numbers of uninsured indigent patients access to discounts for outpatient drugs.² Today, however, it is unclear whether this goal is being met, even as the program continues to grow dramatically. Evidence suggests that the program has departed significantly from its statutory foundation. There also is little concrete evidence of how and whether benefits of the 340B program are reaching the intended beneficiaries of the program—namely uninsured indigent patients. Moreover, in some instances, the 340B program may skew patient care due to financial incentives that flow to the covered entities, but may not reach patients.

By any measure, the program has expanded significantly over the years. From 2005 to 2011, the number of

hospitals participating in the 340B program nearly tripled (growing from 591 to 1,673), and the number of hospital sites (separate locations of a given hospital that participate in 340B) nearly quadrupled (growing from 1,233 to 4,426).³ Today, about one-third of all U.S. hospitals participate in the 340B program.⁴ Overall, the number of covered entity sites that participate in the program has nearly doubled in the past 10 years, from 8,605 in 2001 to 16,572 in 2011.⁵ An analysis performed by Avalere Health estimated that under the 340B program, covered entities currently receive annual discounts of \$2 billion on brand-name drugs alone.⁶ Moreover, rapid 340B growth is projected to continue in future years: the Berkeley Research Group, for instance, estimates that 340B drug purchases will double from \$6 billion annually in 2010 to \$12 billion annually by 2016.⁷

These figures raise critical questions about the growth of the 340B program, how the program has evolved, and whether the changes that have occurred over the years are consistent with Congress' intent in creating the program.

Analyses have pinpointed no single factor that explains the 340B program's growth. Instead, it appears that a combination of incentives and opportunities have been key drivers for a 340B expansion that may not align with Congressional intent, and in fact may encourage use of the program for insured patients, with no guarantee that the program benefits uninsured indigent patients. More-

¹42 U.S.C. § 1396r-8(a)(1), (a)(5).

²H.R. Rep. No. 102-384 (II) (1992).

³Government Accountability Office, Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement (Washington, DC: GAO, September 2011), 27–28 (hereafter referred to as GAO 340B report).

⁴Avalere Health analyzed 340B enrollment data as of April 2012 and estimated the number of all hospitals in the United States (excluding psychiatric, rehabilitation, and long-term care hospitals) using the FY 2009 Medicare cost report data. See also GAO 340B report, 20, 29, 34.

⁵GAO 340B report, 8.

⁶Avalere Health analysis of FY 2008 Medicare cost report data.

⁷Berkeley Research Group, PowerPoint presentation given at the 8th Annual Oncology Economics Summit, La Jolla, CA, Feb. 21–22, 2012, 6.

over, there are indications that the program may have unintended consequences, including the displacement of non-340B providers who also serve a key role in increasing patient access to important health care services. Two decades after the program's creation, insufficient guidance is available regarding how the program should operate. As a result, there are significant questions about whether the program is meeting its goals and whether it creates unintended consequences for patients, providers, and other stakeholders. This paper examines those questions.

Key concerns include:

- **The Definition and Interpretation of a 340B "Patient":** The law prohibits diverting drugs purchased at 340B discounts to individuals who are not "patients" of the covered entity. However, the lack of a clear definition regarding who qualifies as a "patient" of a 340B-participating covered entity has led many entities to use the program broadly for *insured* individuals, at a profit, with no formal guarantee or evidence that the discount flows to the patient. Moreover, as noted by the Health Resources and Services Administration (HRSA) and the U.S. Government Accountability Office (GAO), current practices raise concerns that "some covered entities may be broadly interpreting the definition [of patient] to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus, for whom the entity is serving an administrative function and does not actually have the responsibility for care."⁸ This incentive to maximize opportunities for arbitrage from insured patients (i.e., to gain revenue by charging insurers higher rates for drugs than their acquisition costs under 340B) raises critical questions about: (1) whether and how the 340B program benefits uninsured indigent patients, and (2) the potential unintended consequences for non-340B providers. As the health system landscape undergoes rapid transformation, this issue is of particular concern: in the absence of any 340B program requirement that facilities provide savings directly to patients, the potential arises for 340B entities to obtain

revenue from the program simply by using 340B-discounted *drugs* for insured patients and billing insurers at rates that exceed the drugs' acquisition cost.

- **The Metrics Used to Qualify Some 340B Entities:** The metrics used to qualify 340B hospitals may not be calibrated to ensure proper identification of those safety net facilities that serve large numbers of uninsured patients. To date there is no empirical evidence demonstrating that these criteria adequately distinguish the types of facilities Congress intended to capture. In fact, analysis by Congress' Medicare Payment Advisory Commission (MedPAC) found little relationship between a key eligibility criterion for 340B hospitals, the disproportionate share hospital (DSH) adjustment percentage, and the amount of uncompensated care provided by such facilities.⁹ Additionally, a recent GAO report notes that due to a lack of program guidance and oversight, certain types of hospitals that "provide a small amount of care to low-income individuals not eligible for Medicare or Medicaid could claim 340B discounts."¹⁰
- **Expected Expansion in the 340B Program:** Paradoxically, 340B expansion will also be driven by the growth of insurance coverage for outpatient drugs, which has become more common since Congress created the 340B program in 1992.¹¹ In 2006, for example, the Medicare program added a broad prescription drug benefit. In addition, 340B eligibility will likely increase starting in 2014 as a direct result of more low-income people becoming Medicaid eligible under the Patient Protection and Affordable Care Act (ACA). Under the hospital eligibility provisions in the 340B law, a hospital is more likely to be 340B eligible the more Medicaid patients it serves.¹² This means that even as the ACA reduces the number of people who are uninsured by expanding Medicaid eligibility, the number of 340B-eligible hospitals is expected to increase.¹⁴ The GAO similarly observed that the growth in hospital 340B participation that has occurred in recent years may be due partly to state-level expansions in Medicaid eligibility that predate the ACA.¹⁵

⁸GAO 340B report, 23.

⁹Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy (Washington, DC: MedPAC, March 2007), 50.

¹⁰GAO 340B report, 23.

¹¹According to the GAO, "As more people gain insurance coverage under PPACA, covered entities may serve more patients with private insurance and Medicaid, which may affect the extent to which they generate 340B revenue." (GAO 340B report, 16).

¹²42 U.S.C. § 256b(a)(4)(L)(ii).

¹³GAO 340B report, 23.

¹⁴*Ibid.*, 29, 34.

¹⁵*Ibid.*, 27 and footnote 62.

- **Insufficient Regulation and Guidance to Ensure Benefits Flow to Uninsured Patients, and No Analysis of the Effect on Non-340B Providers:** In the past, insufficient oversight of the 340B program, in the absence of guidance fleshing out key requirements in the law, has permitted unsupervised 340B expansion. For example:

- Subregulatory (i.e., without notice and comment rulemaking) guidance issued in 1996 that allows outpatient facilities deemed to be “integral parts” of 340B hospitals to participate in the 340B program has also driven program growth, with little evidence that participation reduces the burden on uninsured patients.

- Subregulatory guidance was issued in March 2010 allowing covered entities to provide 340B drugs through an unlimited number of outside entities (“contract pharmacies”). The guidance included no geographic proximity requirement (even in cases where the entity has its own in-house pharmacy), raising questions about whether and to what extent the program may adversely affect competing non-340B pharmacies. According to the GAO, by July 2011 there were more than 7,000 contract pharmacy arrangements (and an unknown number of contract pharmacies) in the 340B program.¹⁶

- **A Potential Distorting Effect of the Program on Hospital and Pharmacy Markets:** There is some evidence suggesting that 340B expansion may have other adverse consequences that Congress did not envision when it created the program. As stated by the GAO, “As the number of covered entities enrolled in the 340B program increases and more drugs are purchased at 340B prices, there is the potential for unintended consequences, such as cost-shifting to other parts of the health care system.”¹⁷ Moreover, the more entities that become 340B eligible and elect to take advantage of the program’s benefits, the more difficult it may become for non-340B providers to compete. Non-340B providers—including community pharma-

cies and oncologists that are not 340B eligible—may be displaced because they must pay more to purchase drugs than competing 340B covered entities do.

- **Potential Implications for Patient Care:** Another unintended consequence of the program is that 340B covered entities may have a financial incentive to alter patient care pathways so that individuals who would otherwise receive inpatient care are treated on an outpatient basis, allowing the drugs used in treatment to be purchased at 340B-discounted prices.

- **Importance of Continued 340B Oversight to Ensure the Program Is Consistent with Congressional Intent:** A September 2011 GAO report found that past oversight of the program was inadequate. The report recommended that HRSA improve its oversight of the 340B program by verifying the eligibility of facilities applying to enroll as well as the continued eligibility of enrolled entities; monitoring compliance of covered entities with the requirement that 340B drugs be dispensed only to eligible patients treated in outpatient settings; and ensuring that manufacturers are offering 340B drugs to 340B entities at or below the statutorily mandated ceiling price.

Since the publication of the GAO report, HRSA has taken many steps to improve oversight of the 340B program. In February 2012, for example, HRSA issued a letter announcing its plans to conduct selective and targeted audits of covered entities in fiscal year 2012.¹⁸ The audit initiative has advanced since that time: HRSA has now announced its completion of 51 audits¹⁹ and has also issued guidance promising to make audit results publicly available on its website when the audits are completed. Likewise, HRSA launched a new initiative to recertify entities in the 340B program in an effort to improve program integrity and compliance.²⁰ Further, HRSA issued two May 23, 2012 guidance documents, one outlining its position on 340B eligibility of accountable care organizations, and the other clarifying its previous nondiscrimination guidance. Both documents are important to clarifying program rules and promoting program integrity.²¹

¹⁶*Ibid.*, 27 and footnote 61.

¹⁷*Ibid.*, 34.

¹⁸See letter to 340B program participants from Administrator Mary Wakefield, February 10, 2012, at <http://www.hrsa.gov/opa/programrequirements/policyreleases/programintegrity021012.pdf>.

¹⁹According to a HRSA official speaking at a recent conference, as of September 12, 2012, 51 audits of covered entities had been completed.

²⁰77 Fed. Reg. 33226 (June 5, 2012).

²¹Health Resources and Services Administration, 340B Drug Pricing Program Notice, Release No. 2012.2, Clarification of Covered Entity Eligibility Within Accountable Care Organizations, May 23, 2012; Health Resources and Services Administration, 340B Drug Pricing Program Notice, Release No. 2011-1.1, Clarification of Non-Discrimination Policy, May 23, 2012.

Among other key initiatives, HRSA has started working with pharmaceutical manufacturers in their efforts to audit covered entities. HRSA has reviewed audit workplans from a small number of manufacturers, and reported at a recent conference that it is working collaboratively with the manufacturers to finalize the workplans. In recent months, HRSA has appeared at conferences attended by both 340B covered entities and pharmaceutical manufacturers, and has signaled its overall intent to implement integrity-related initiatives in numerous ways. HRSA's efforts to ensure program integrity must be sustained and expanded: the agency has indicated that since no new resources are available, it will have to cut costs elsewhere, such as by making timing adjustments to its enrollment practices.²² The agency's new direction and its commitment to integrity and collaboration has been welcomed by stakeholders who share these objectives.

The Role of 340B After Coverage Expansion. Starting in 2014, the number of uninsured Americans is expected to decrease with the expansion in insurance coverage under the ACA. According to the most recent estimates of the Congressional Budget Office, there will be an estimated 29 million nonelderly Americans remaining uninsured in 2019, about 9 percent of the population.²³ At the same time, HRSA expects 340B provider enrollment to continue to grow at historical rates. This raises questions about the program's continuing to meet its original goals, and its viability in the future. Opportunities may exist to recalibrate the 340B program so that its benefits are better targeted to the uninsured, indigent patients whom Congress sought to help when it created the program two decades ago.

²²Additionally, HRSA has expressed the need for user fees to finance additional integrity efforts, and has also indicated that the program needs regulations.

²³Congressional Budget Office estimate of uninsured, at www.cbo.gov/sites/default/files/cbofiles/attachments/43472-07-24-2012-CoverageEstimates.pdf; U.S. Census Bureau population projections, at <http://www.census.gov/population/projections/>.

I. Background on the 340B Program

Congress created the 340B program in 1992 to offer uninsured indigent patients better access to prescription drugs by helping certain facilities serving large numbers of uninsured, low-income patients purchase outpatient drugs at discounted prices.²⁴ The legislative history makes clear that Congress intended the program to help such patients gain better access to medicines.²⁵ To that end, the law requires biopharmaceutical manufacturers to offer discounts to select federal grantee and certain other entities (collectively known as “340B covered entities” or “covered entities”), or their drugs cannot be covered by Medicaid.²⁶ The discounts are based on a statutory cap on participating manufacturers’ prices to covered entities for outpatient drugs (“the 340B ceiling price”).²⁷ The ceiling price formula is based in part on the federal rebate under the Medicaid rebate program.

The law also requires covered entities to meet certain eligibility and other criteria. Covered entities that participate in the program must fit within one of the statute’s eligibility categories, register with the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA),²⁸ and abide by certain other requirements, outlined below.

First, the 340B law’s “diversion prohibition” forbids covered entities from reselling or otherwise transferring discounted drugs purchased under 340B to anyone but their own patients, or from using 340B drugs in an inpatient setting.²⁹ Second, “duplicate discounts” are not permitted; that is, manufacturers cannot be billed for Medicaid re-

bates on drugs purchased at a 340B discount.³⁰ Third, the law requires covered entities to permit HRSA and manufacturers to audit records directly pertinent to compliance with the diversion and double-discounting prohibitions.³¹

HRSA allows covered entities to dispense 340B drugs to their patients through in-house pharmacies or through outside pharmacies with which they contract. Until recently, HRSA only permitted covered entities lacking an in-house pharmacy to use a contract pharmacy (and permitted those entities to use only one contract pharmacy site).

A. The Genesis and Purpose of the 340B Program

Congress created the 340B program to help federal grantees and true safety net hospitals serving low-income uninsured patients by reinstating the deep discounts that manufacturers had voluntarily provided to these facilities before enactment of the 1990 Medicaid drug rebate statute. Before the Medicaid rebate program was established, prescription drug manufacturers voluntarily offered significant discounts to a host of entities serving needy patient populations. However, the Medicaid drug rebate statute failed to exempt these discounts from the Medicaid “best price” provision, a factor that may have impacted manufacturers’ voluntary discounts due to its potential market-wide effects. Congress responded by exempting discounts to these facilities and re-establishing the discounts federal grantees and certain hospital entities serving uninsured indigent patients had been receiving before enactment of the Medicaid rebate statute, explaining that:

²⁴The 340B program was enacted under the Veterans Health Care Act of 1992 (Public Law 102-585), codified as Section 340B of the Public Health Service Act (42 U.S.C. § 256b).

²⁵H.R. Rep. No. 102-384 (II) (1992). For example, according to the U.S. House of Representatives report that accompanied the legislation creating the 340B program, “The Committee bill also provides protection from drug price increases to specified Federally-funded clinics and public hospitals that provide *direct clinical care to large numbers of uninsured Americans*” (emphasis added). *Id.*, at 12.

²⁶42 U.S.C. § 1396r-8(a)(1), (a)(5).

²⁷42 U.S.C. § 256b(a)(1). The law exempts orphan drugs sold to certain covered entities from these ceiling price requirements. *Id.*, § 256b(e).

²⁸The 340B program is administered by the Office of Pharmacy Affairs, HRSA, which lies within the Department of Health and Human Services.

²⁹42 U.S.C. § 256b(a)(5)(B).

³⁰*Id.*, § 256b(a)(5)(A).

³¹*Id.*, § 256b(a)(5)(C).

Like the prices charged to the [Department of Veterans Affairs], prices charged to these “covered entities” would be exempt from the calculation of the Medicaid “best price” for purposes of determining the Medicaid rebate. The Committee expects that this exemption will remove any disincentive that the Medicaid [drug] rebate program creates to discourage manufacturers from providing substantial voluntary or negotiated discounts to these clinics, programs, and hospitals. ... In addition, manufacturers, as a condition of receiving Federal Medicaid matching funds on their covered outpatient drugs, would have to enter into an agreement with the Secretary of HHS to provide price reductions ... to these “covered entities” on covered outpatient drugs.³²

Congress explained that the legislation “provides protection from drug price increases to specified Federally-funded clinics and public hospitals that provide direct clinical care to *large numbers of uninsured Americans*” [emphasis added].³³ Referring to one of the 340B hospital eligibility categories, the legislative history similarly stated that the 340B program was meant to allow participation by a private nonprofit hospital that contracts to care for “low-income individuals who are not eligible for Medicaid or Medicare”—i.e., who are uninsured—but not by a private nonprofit hospital with “a minor contract to provide indigent care which represents an insignificant portion of its operating revenues.”³⁴

B. General 340B Eligibility Criteria

Eligibility for the 340B program is defined in the 340B law.³⁵ Entities generally become eligible by receiving one of 10 types of federal grants or by being one of six hospital types meeting specified standards. The federal grantees typically include clinics that offer primary and preventive services to indigent and uninsured patients. Hospitals do not qualify for the program based on receipt of a federal grant; instead, the statute requires hospitals to meet certain requirements, detailed below, which are generally intended to target hospitals that provide care to the medically underserved. To partici-

pate in the 340B program, eligible entities must register with HRSA and be approved.

The following types of organizations may register with HRSA and become “covered entities”:

- Certain disproportionate share hospitals (DSHs), children’s hospitals, cancer hospitals, critical access hospitals, sole community hospitals, and rural referral centers
- Federally qualified health centers and “look-alikes”
- Family planning and sexually transmitted disease clinics
- Ryan White Care Act grantees
- State-operated AIDS drug assistance programs
- Comprehensive hemophilia diagnostic treatment centers
- Black lung and tuberculosis clinics
- Urban Indian clinics
- Native Hawaiian health centers

Subregulatory guidance issued by HRSA allows certain outpatient facilities of a 340B hospital to participate in the program if they qualify as an “integral” part of the hospital (meaning they must be listed as reimbursable on the hospital’s Medicare cost report).³⁶ This has led to a proliferation of new sites that participate in the program and to significant growth, generating some controversy over whether these new sites are permitted by the 340B law and are consistent with its intent.

C. Specific Criteria for 340B Hospital Eligibility

The eligibility criteria for each category of 340B hospital are fully detailed in the Appendix of this paper. Two criteria are common to most of the hospital categories: (1) the requirement for a “disproportionate share hospital (DSH) adjustment percentage” above a specified level; and (2) the requirement that the hospital (a) be owned or operated by a state or local government; (b) be a private nonprofit hospital “formally granted governmental powers” by a state or local government; or (c) be a private nonprofit hospital with a contract with a state or local government to provide care to low-income individuals who are not eligible for Medicare or Medicaid.³⁷

³²U.S. House of Representatives Report accompanying H.R. Rep. 102-384 (II) (1992),12.

³³*Ibid.*

³⁴*Ibid.*, 14.2542 U.S.C. § 1396r-8(a)(1), (a)(5).

³⁵42 U.S.C. §256B (Public Health Service Act §340B).

³⁶59 Fed. Reg. 47884 (Sept. 19, 1994).

³⁷42 U.S.C. §256(a)(4)(L)-(O).

1. The Medicare DSH Adjustment Percentage

All 340B-eligible hospitals except critical access hospitals must have a Medicare DSH adjustment percentage either greater than 11.75 percent (for DSH hospitals, children's hospitals and cancer hospitals) or greater than or equal to 8 percent (for rural referral centers and sole community hospitals). The DSH adjustment percentage determines whether hospitals receive enhanced payments under Medicare's Inpatient Prospective Payment System. It was not specifically designed for 340B eligibility purposes, and does not measure the percentage of uninsured patients a hospital serves or the level of uncompensated care it provides.³⁸

The DSH adjustment percentage is based on the "DSH patient percentage," which equals the sum of two ratios that each reflect particular groups that are low-income but *insured*: (1) inpatient days for Medicare patients with Supplemental Security Income, as a percentage of all Medicare inpatient days; and (2) inpatient days for Medicaid patients without Medicare, as a percentage of all inpatient days. As noted by the Government Accountability Office (GAO), because the DSH adjustment percentage also is not correlated with charity care, questions have been raised as to whether the DSH adjustment percentage is an appropriate metric on which to base 340B eligibility.³⁹ When the Centers for Medicare and Medicaid Services alters or redefines elements of this calculation, it may have a profound impact on the 340B program.

Congress' Medicare Payment Advisory Commission (MedPAC) has analyzed the DSH adjustment percentage to determine whether hospitals with higher DSH payments had patients who were more costly to treat and/or were providing higher levels of uncompensated care. MedPAC analyzed these issues because Medicare's DSH payments originally were premised on the theory that lower-income patients were more costly to treat, and therefore hospitals required additional payments to treat these patients; but over time many observers shifted to arguing that DSH payments were subsidizing hospitals for uncompensated care.⁴⁰

MedPAC found little connection between hospitals' DSH adjustment percentages and whether they had either high-cost patients or a high percentage of uninsured patients, concluding:

.....
"We found a weak relationship between hospitals' costs per discharge and their share of low-income patients [as measured by the disproportionate share patient percentage]. Many have viewed the DSH adjustment as helping hospitals with their uncompensated care rather than offsetting the cost impact of treating low-income patients. However, *we found little evidence of a relationship between the DSH payments hospitals receive and the amount of uncompensated care they provide.*"⁴¹
.....

Another limitation of the DSH adjustment percentage is that it depends on the sum of two ratios that both relate exclusively to *inpatient* care, even though the 340B program only involves outpatient drugs. Hospitals may therefore qualify for the 340B program based in part on a DSH adjustment percentage that does not reflect their outpatient populations.

2. Shortcomings of the DSH Adjustment Percentage as a 340B Eligibility Criterion

Because Congress established the 340B program to benefit uninsured indigent people, 340B eligibility criteria should reflect the share of uncompensated care⁴² a hospital provides to outpatients (similar to the new Medicare DSH payment formula introduced by the Patient Protection and Affordable Care Act [ACA]).

Currently, over half of hospitals in the United States receive DSH payments. As noted by the National Association of Public Hospitals and Health Systems, a safety net hospital "cannot be distinguished by the fact that it receives DSH payments because 64 percent of all hospitals receive Medicare DSH payments."⁴³

Moreover, using the DSH adjustment percentage as a 340B eligibility criterion is problematic because

³⁸Numerous studies link uncompensated care to uninsured; see, for example, *Insuring America's Health: Principles and Recommendations*, National Academies Institute of Medicine, January 2004, at <http://iom.edu/Reports/2004/Insuring-Americas-Health-Principles-and-Recommendations.aspx>; or *Caring for the Uninsured in Massachusetts: What Does It Cost, Who Pays and What Would Full Coverage Add to Medical Spending?* (Washington, DC: Urban Institute, November 2004), available at http://bluecrossfoundation.org/foundationroot/en_US/documents/roadmapReport.pdf.

³⁹See GAO 340B report, 29.

⁴⁰Medicare Payment Advisory Commission, Report to the Congress: Medicare Payment Policy (Washington, DC: MedPAC, March 2007), 70.

⁴¹*Ibid.*, 50. Emphasis added.

⁴²Some measures of uncompensated care have limitations because they include bad debt as well as charity care.

⁴³"What is a Safety Net Hospital?" National Association of Public Hospitals and Health Systems, www.naph.org/Main-Menu-Category/Our-Work/Safety-Net-Financing/what-is-a-safety-net-hospital.aspx?FT=.pdf.

the DSH adjustment percentage can be expected to increase as Medicaid coverage expands under the ACA. As the GAO noted, the number of 340B-eligible hospitals may increase due to the ACA's Medicaid expansion, because the DSH adjustment percentage increases with the number of Medicaid patients served by a hospital.⁴⁴ Consequently, as more people become insured under Medicaid, more hospitals would become 340B eligible. The Berkeley Research Group has estimated that in 2014, 342 hospitals, representing an estimated \$1.2 billion in increased 340B sales, may become newly eligible as a result of Medicaid expansion.⁴⁵

While the ACA provided for payment adjustments to DSH hospitals to reflect the share of uncompensated care they provide,⁴⁶ it did not make corresponding changes to the 340B program's hospital eligibility criteria. Paradoxically, the 340B program is thus likely to expand as the number of uninsured individuals declines, reinforcing the concern that the DSH adjustment percentage is not an appropriate measure to determine whether a hospital is eligible to receive 340B discounts.

D. Ambiguous 340B Eligibility Requirements for Private Nonprofit Hospitals

All 340B-eligible hospitals must be (1) "owned or operated by a unit of State or local government"; (2) a public or private nonprofit hospital "formally granted governmental powers by a unit of State or local government"; or (3) 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 [Medicare or Medicaid eligible]."⁴⁷

While the first of these criteria seems straightforward, the second and third criteria are more vague, and HRSA has issued very little guidance on their exact meaning, making it difficult to determine whether private nonprofit hospitals in the program meet these eligibility requirements. According to the GAO, "HRSA has not issued guidance specifying the criteria under which hospitals that are not publicly owned or operated can qualify for the 340B program."⁴⁸

In connection with the second criterion, HRSA issued a FAQ response on its website, as follows:

A DSH is said to be "formally granted governmental powers" when the State formally delegates to the DSH a type of power(s) usually exercised by the State, for the purpose of providing health care services to the medically indigent. ... Whether ... a DSH meets eligibility for 340B based on "formally granted governmental powers" will be evaluated by OPA on a case-by-case basis.⁴⁹

To date, HRSA has not built on this FAQ response by specifying the types of uniquely "governmental" powers that might be granted to a private nonprofit hospital. And HRSA has not provided any guidance at all on the third criterion, requiring an entity to have a contract with a state or local government to provide services to low-income individuals not entitled to Medicare or Medicaid.

Without interpretive guidance to help private nonprofit hospitals understand what arrangements will or will not satisfy the second and third criteria, it is difficult to determine whether these provisions are being used in accordance with their intent. According to the GAO, "For the second requirement, HRSA requires a state or local government official and a hospital executive to certify that a contract exists to meet the requirement, but does not require hospitals to submit their contracts for review or outline any criteria that must be included in the contracts, including the amount of care a hospital must provide to these low-income individuals." Therefore, "hospitals with contracts that provide a small amount of care to low-income individuals not eligible for Medicaid or Medicare could claim 340B discounts, which may not be what the agency intended."⁵⁰

To preserve program integrity, HRSA must clarify those eligibility criteria so that only specific types of entities, as intended by Congress, are allowed to participate in 340B. If Congress or HRSA fail to clarify these criteria,

⁴⁴Although the DSH adjustment percentage is the primary method of demonstrating that a hospital serves a disproportionate share of low-income patients, urban hospitals with more than 100 beds may use the alternate ("Pickle hospital") method. The number of hospitals that qualify as Pickle hospitals does seem likely to decline as the ACA's coverage expansion unfolds, because Pickle hospital status depends on the percentage of a hospital's inpatient care revenues that come from state or local government (excluding Medicare and Medicaid) for indigent care; presumably over time, more of these indigent patients would be covered by Medicaid or federally subsidized exchange plans.

⁴⁵Berkeley Research Group, PowerPoint presentation given at the 8th Annual Oncology Economics Summit, La Jolla, CA, Feb. 21–22, 2012, 13.

⁴⁶Social Security Act §1886(r).

⁴⁷42 U.S.C. § 256b(a)(4)(L)(i).

⁴⁸GAO 340B report, 23.

⁴⁹Health Resources and Services Administration website, FAQ page, <https://www.340bpvp.com/resource-center/faqs/hospitals/>.

⁵⁰GAO 340B report, 23.

then a real risk exists that some hospitals may qualify for 340B benefits without making any real contribution to addressing unmet medication needs.

E. The Uncertain Safety Net Status of Some 340B Hospitals

Given the purpose of the 340B program, it is important to evaluate whether current program eligibility criteria limit participation to entities that serve a safety net function. This issue has particular importance in the context of DSH hospitals, which represent an estimated 70 percent of all outpatient pharmaceuticals purchased through the 340B program.⁵¹

One option for measuring the need for 340B discounts and evaluating safety net status is to assess whether current 340B hospitals differ from non-340B hospitals across dimensions such as insurance coverage of patients, financial conditions such as operating margins, and the amount of uncompensated care provided. Avalere Health analyzed 790 short-term acute care hospitals that participated in the 340B program in 2008 and 2,643 such hospitals that did not participate in the program.⁵² Their findings suggest that some 340B-participating hospitals may not be true safety net providers, as indicated by their low uncompensated care levels and their relatively healthy financial condition.

F. 340B Eligibility and Provision of Uncompensated Care

Today, *all* outpatients of a 340B facility, both insured and uninsured, may be treated using drugs purchased via the 340B program; current HRSA guidelines allow covered entities to use 340B drugs to treat fully insured patients. Nevertheless, the expectation is that hospitals eligible for 340B serve a substantial number of uninsured indigent patients and therefore have high uncompensated care costs.

To measure the level of uncompensated care provided by hospitals, the Avalere analysis used two different

ratios for comparison purposes: uncompensated care costs to total facility costs, and uncompensated care costs to total gross patient revenues. The latter ratio was calculated to compare the findings with an Internal Revenue Service (IRS) report that reviewed the level of uncompensated care at tax-exempt organizations.⁵³

Avalere found that, on average, 340B hospitals provided more uncompensated care as a share of total costs or gross patient revenues than did non-340B hospitals; however, the level of uncompensated care varies widely among 340B hospitals, and one-third of 340B hospitals (34 percent, or 267 facilities) reported uncompensated care as a percentage of total revenues *below* the IRS-reported average (7 percent).

G. The Definition of “Patient” Under the 340B Program

The 340B law contemplates some limits on a 340B entity’s ability to use the outpatient drugs purchased at 340B-discounted prices for a given individual. For example, the law specifically prohibits covered entities from diverting 340B drugs to individuals who are not their patients.⁵⁴ Moreover, the discounts are only available for drugs that are used to treat patients in the outpatient setting, because 340B is an outpatient program. However, the law creating 340B offers no specific definition of the term “patient.” Although HRSA has attempted to define the term “patient” in guidance, the definition has been criticized for lacking clarity and for allowing entities to use the 340B program in ways not contemplated by Congress. Notably, as recently as September of 2012, HRSA has indicated that it is currently in the process of revising the definition of “patient.”

HRSA’s current subregulatory guidance on the 340B program definition of “patient,” issued in 1996,⁵⁵ outlined several principles for an individual to qualify as a “patient” of a 340B covered entity.⁵⁶ These principles include:

⁵¹Based on Avalere Health’s analysis of the 340B enrollment as of July 2011 and on Avalere’s estimation of the value of 340B discounts using outpatient drug costs reported by 340B-participating facilities in the FY 2008 Medicare cost reports.

⁵²Avalere Health used publicly available data from FY 2008 Medicare cost reports. The objective of the analysis was to assess information about patient mix, total costs, total revenues, drug costs, and uncompensated care costs. Facilities do not separately report patient days attributable to uninsured on their cost reports, instead including these patients in the “Other” days category along with the commercial patient days. Therefore, Avalere focused on the analysis of uncompensated care as a proxy for care provided to uninsured.

⁵³Final Report from the Internal Revenue Service Exempt Organizations Hospital Compliance Project that reviewed 2006 data, www.irs.gov/pub/irs-tege/frepthosproj.pdf. We note that the reporting of uncompensated care in hospitals’ Medicare cost reports does not provide all of the necessary information. For instance, charity care and bad debt are combined; and there is no separation of charity care for different types of recipients. The ACA required a revised Schedule H (Form 990), which more clearly details charity and community benefits provided by the facility, to be filed by certain hospitals. This may be an existing source of information to enable HRSA to better evaluate whether and how entities utilize 340B profit to benefit indigent and uninsured patients.

⁵⁴42 U.S.C. § 256b(a)(5)(B).

⁵⁵Notice Regarding Section 602 of the Veterans Health Care Act of 1992: Patient and Entity Eligibility, 61 Fed. Reg. 55156–55158 (October 24, 1996).

⁵⁶A separate patient definition applies to AIDS drug assistance programs.

1. The covered entity must have established a relationship with the individual such that the covered entity maintains records of the individual's health care;
2. The individual must receive health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity;
3. The individual must receive services for which the entity received federal grant funding (or Federally Qualified Health Center look-alike status); and
4. An individual is not a "patient" of a covered entity if the only health care service the covered entity provides to that individual is dispensing drugs for subsequent self-administration or administration in the home setting.

In the absence of additional guidance from HRSA, some 340B entities have interpreted the law to encompass more individuals than the program was meant to include. The GAO noted in its report that HRSA's current guidance on the definition of a 340B patient is "sometimes not specific enough to define the situations under which an individual is considered a patient of a covered entity for the purposes of 340B and thus, covered entities could interpret it either too broadly or too narrowly."

HRSA informed the GAO that the definition currently includes individuals receiving health care services from providers affiliated with covered entities through "other arrangements," as long as the responsibility for care provided remains with the entity. According to the GAO,

however, "HRSA does not define 'other arrangements'." Further, HRSA also has acknowledged the need to clarify the meaning of "responsibility for care." The GAO found that "as a result of the lack of specificity in the guidance, [HRSA] has become concerned that some covered entities may be broadly interpreting the definition to include individuals such as those seen by providers who are only loosely affiliated with a covered entity and thus, for whom the entity is serving an administrative function and does not actually have the responsibility for care."⁵⁷

In 2007, HRSA published proposed guidance to clarify the definition of a patient, which would have updated the 1996 guidance. HRSA noted in its proposed guidance that "some 340B covered entities may have interpreted the definition too broadly, resulting in the potential for diversion of medications purchased under the 340B program."⁵⁸ The proposal gave examples of arrangements where individuals should *not* qualify as patients of a covered entity—for example, HRSA stated that the mere provision of administrative services by the covered entity (such as the provision of case management services from someone other than a health care provider) would not establish a "patient" relationship⁵⁹—and made clear that employees of covered entities are not "patients" unless they fulfill all the elements of the patient definition.⁶⁰ HRSA's proposal was never finalized; and although some stakeholders and members of Congress have urged the agency to issue an updated definition,⁶¹ at this time it is not clear when HRSA might do so.

H. Current Size and Recent Growth of the 340B Program

Avalere Health has estimated that there were 7,888 unique entities participating in the 340B program as of July 2011 (based on the Medicare provider number and/or unique facility name). A single unique entity can

⁵⁷GAO 340B report, 22–23.

⁵⁸72 Fed. Reg. 1543, 1544 (Jan. 12, 2007).

⁵⁹*Ibid.*, 1545 ("An individual whose sole relationship with a covered entity is through case management services or other administrative measures, not accompanied by actual medical services from a health care provider that meets criterion 2, would not be considered a patient of the covered entity eligible to receive 340B drugs."). Among other things, the proposal would have clarified that:

1. The covered entity must have established responsibility for the outpatient health care services it provides to the individual, such that the covered entity maintains ownership, control, maintenance, and possession of records of the individual's health care, including records that appropriately document health care services that result in the use of, or prescription for, 340B-discounted drugs;
2. The individual must receive outpatient health care services that result in the use of, or a prescription for, 340B drugs from a health care provider who is employed by the covered entity, or provides health care to patients of the covered entity under a valid, binding, and enforceable contract; and
3. The outpatient health care services the individual receives from the covered entity that result in the use of, or prescription for, 340B drugs must be:
 - a. Part of a health care service or range of services for which the entity received federal grant funding or FQHC look-alike status; or
 - b. Provided by a DSH or by an outpatient facility that qualifies as a provider-based facility within a DSH under 42 CFR 413.65. A patient may be referred for followup care for the same condition to an outside health care provider and still remain a patient of the covered entity if the DSH (or qualified provider-based facility) retains ongoing responsibility for the outpatient health care services that result in the use of, or prescription for, 340B drugs. To demonstrate the ongoing responsibility, HRSA proposed that, at a minimum, the covered entity will provide health care to the individual in the DSH or the qualified provider-based facility within 12 months after the time of referral.

⁶⁰*Ibid.*, 1546.

⁶¹Letter from Chairman Joseph R. Pitts and Representative Cassidy to HRSA Administrator Mary K. Wakefield, July 18, 2012.

have multiple 340B-enrolled locations, often referred to as 340B sites. According to HRSA, there were 16,572 sites enrolled in the 340B program as of July 1, 2011. Therefore, we estimate that each participating unique entity, on average, enrolled two outpatient sites to dispense drugs purchased at 340B prices. See Figure 1 for the estimated breakdown.

Dramatic Growth of the 340B Program in Recent Years

Since the 340B program was established in 1992, it has been expanded by both Congressional action and administrative actions, including subregulatory guidance. According to the GAO, the number of 340B covered entities has doubled in just over 10 years⁶² (see Figure 2). The 340B program was most recently expanded by the ACA. This

Figure 1: 340B Enrollment as of July 2011, Sorted by Number of 340B Sites

Facility Type	340B Unique Entities***	340B Sites	Estimated Outpatient Drug Costs (in millions)****
Consolidated Health Center Program*	1,386	4,826	N/A
Family Planning	2,216	3,868	N/A
DSH Hospitals	1,003	3,061	\$4,510
Other**	2,141	2,842	N/A
Critical Access Hospitals	554	941	\$219
Ryan White grantees	471	610	N/A
Sole Community Hospitals	60	200	\$94
Children's Hospitals	32	147	\$145
Rural Referral Centers	23	72	\$96
Free-Standing Cancer Hospitals	2	5	\$54
TOTAL	7,888	16,572	\$5,118

*Includes Federally Qualified Health Center look-alikes, Tribal Care organizations, Community Health Centers, School Based Programs, Health Care for the Homeless Programs, Migrant Health Programs, and Public Housing Primary Care Programs entities.

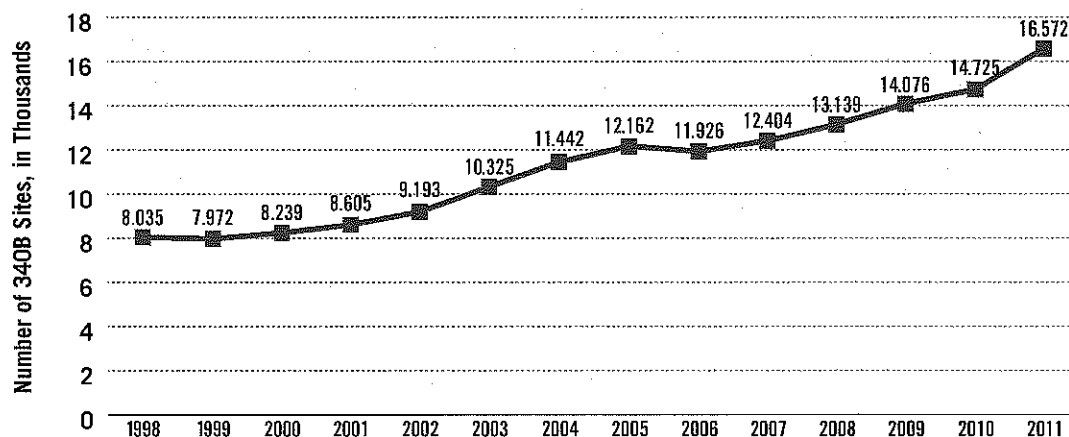
**Includes black lung clinics, HIV clinics, hemophilia centers, etc.

***Avalere Health calculated the number of unique entities based on the Medicare provider number and/or unique facility name.

****The amounts represent total outpatient drug costs (not necessarily 340B costs) and are inflated to 2011 dollars.

Source: Avalere Health analysis of HRSA 340B enrollment files and FY 2008 cost reports.

Figure 2: Historical Growth in 340B Enrollment, 1998–2011 (as of July of Each Year)



Source: Avalere Health analysis of HRSA 340B enrollment files.

⁶²GAO 340B report, 2–3.

latest expansion broadened the program to cover four new types of eligible entities, including outpatient settings of certain freestanding cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals.

In addition to this legislative expansion of the program, administrative action has also broadened the scope and reach of the program. This expansion has taken place through subregulatory guidance, so it has not required the same public notice and comment period as a regulatory procedure. One such expansion through guidance was to allow entities to use contract pharmacies; another was to allow a broad interpretation of what constitutes a “patient” of a covered entity for determining whether an entity is eligible for 340B discounts.

Rapid Growth in Contract Pharmacy Arrangements

Since 2000, there has been rapid growth in contract

pharmacy arrangements (on average 43 percent annually). Figure 3 shows the increase in contract pharmacy arrangements from 1999 to 2013 [projected]. The upward trend accelerated after April 2010 when HRSA, through subregulatory guidance (i.e., without notice-and-comment rulemaking), allowed each 340B entity to contract with multiple pharmacies. In just one year, between April 2010 and April 2011, the number of contract pharmacy arrangements grew by 161 percent. HRSA projects continued increases in 340B contract pharmacy arrangements.

Expected Expansion of 340B as a Result of ACA Provisions

As detailed above, the historically constant growth of the 340B program has accelerated in the past several years and will likely continue to trend upward. The resulting increase in the number of enrolled newly eligible entity types between September 2010 and July 2011 is illustrated in Figure 4 below.

Figure 3: Growth in 340B Contract Pharmacy Arrangements, 1999–2013 (as of July of Each Year)

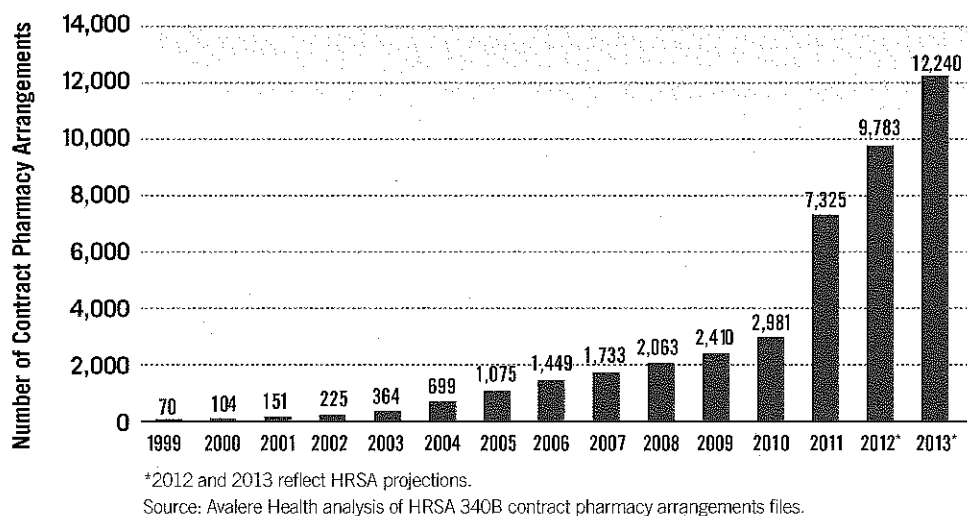


Figure 4: Enrollment of Newly Eligible Entity Types, 2010–2011

Facility Type	340B Unique Entities*					
	Q2 2010	Q3 2010	Q4 2010	Q1 2011	Q2 2011	Q3 2011**
Free-Standing Cancer Hospitals	0	1	1	2	2	2
Critical Access Hospitals	0	289	290	425	509	554
Rural Referral Centers	0	9	9	13	15	23
Sole Community Hospitals	0	30	30	46	52	60
TOTAL	0	329	330	485	569	639

*Avalere Health calculated the number of unique entities as opposed to 340B sites (based on the Medicare provider number and/or unique facility name).

**As of July.

Source: Avalere Health analysis of HRSA 340B enrollment files.

According to an analysis by the Berkeley Research Group, drug purchases under the 340B program are estimated to double, from \$6 billion in 2010 to \$12 billion by 2016. This expected growth is attributed to the ACA's expansion of eligible entities, the expansion of Medicaid (and the resulting increase in 340B-eligible hospitals), and the advent of multiple contract pharmacy networks (expected to drive half of the projected growth).⁶³

While the ACA expanded the number of entities eligible to receive 340B discounts, 30 million nonelderly people are expected to gain insurance coverage by 2022, according to the most recent Congressional Budget Office (CBO) estimates.⁶⁴ Facility enrollment and the volume of discounts provided by manufacturers to the program are likely to climb substantially between 2011 and 2020.

⁶³Berkeley Research Group, PowerPoint presentation given at the 8th annual Oncology Economics Summit, La Jolla, CA, Feb. 21–22, 2012, 6.

⁶⁴Congressional Budget Office estimate of uninsured, at www.cbo.gov/sites/default/files/cbofiles/attachments/43472-07-24-2012-CoverageEstimates.pdf.

II. 340B Program Distortion of Pharmacy and Hospital Markets

As the 340B program expands, the potential for unintended consequences grows, including distortions in the marketplace.

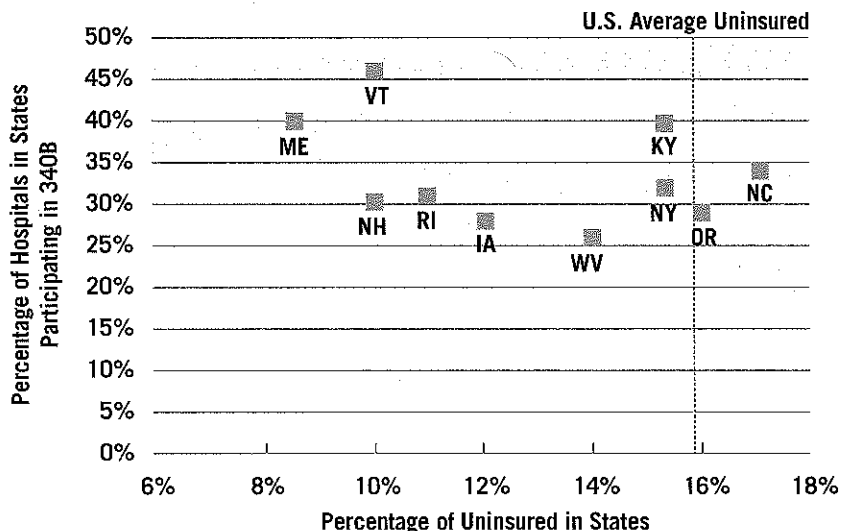
A. Potential Hospital Market Distortions

While the 340B program was intended to focus on helping certain entities within the health care safety net (known as covered entities) to access discounted prices on outpatient medicines, the program's scale has far exceeded its original intent. Today, about one-third of all hospitals in the United States are in the 340B program.⁶⁵ Moreover, 340B hospitals represent nearly half (46 percent) of outpatient drug spending at all hospital facilities in the United States.⁶⁶

Expansion of the 340B hospitals' patient population may increase those hospitals' income under the program and furthers their competitive advantage over other facilities. There is no meaningful oversight of how 340B hospitals use the revenue from the 340B program to improve access and expand services to uninsured indigent patients. The top 10 states with the highest proportion of eligible and participating 340B hospitals also tend to have lower percentages of uninsured populations than the national average uninsured rate of 16 percent (see Figure 5).

Another potential market distortion created by the 340B program may result from a recent increase in the number of hospitals with 340B pricing acquiring commu-

Figure 5: Top 10 States with the Highest Proportion of 340B Hospitals and Percentage of Uninsured Population



Source: Avalere Health analysis of HRSA 340B enrollment files and U.S. Census Bureau data.

⁶⁵Avalere Health analyzed 340B enrollment data as of January 2011 and the FY2008 Medicare cost reports.

⁶⁶Avalere Health analysis of 340B enrollment data as of January 2011.

nity oncology practices. According to a recent RAND study, trade press sources have indicated that purchases of physician practices are prevalent in the fields of oncology and cardiology.⁶⁷ This can be expected to produce rapid growth in the number of cancer patients treated per 340B hospital. These newly acquired patients will have a small effect—if any—on a hospital's ability to qualify for 340B, because the DSH adjustment percentage used in determining 340B eligibility for most hospitals is based entirely on inpatients; however, the new patients from acquired community practices may now be able to obtain oncology drugs at 340B prices, even if these patients are fully insured through commercial health plans.⁶⁸

According to the RAND study, "For oncology practices, one reason cited for the growth [in acquisitions] is the opportunity to expand the patient base for drugs purchased under the 340B discount drug purchase plan." The study notes that because the outpatient prospective payment system rates for drugs furnished to hospital outpatients are the same for all hospitals, without regard to whether the drugs were purchased through the 340B program, "hospitals have an incentive to increase margins by expanding their patient base for chemotherapy administration." Further, RAND noted, "At the same time, changes in Medicare payments for chemotherapy drugs furnished in POs [physician offices] have limited the ability of oncologists to profit on these drugs and have increased the attractiveness of affiliating with a hospital."

According to a recent article in *Oncology Business Review*, "The acquisition of community oncology practices by hospitals with 340B pricing is leading to a rapid growth in the number of cancer patients treated per 340B hospital."⁶⁹ The RAND study found that "the percentage of chemotherapy administration (CPT 96413) occurring in HOPDs [hospital outpatient departments] increased from 23 percent to 26 percent between 2007 and 2009. The payment for chemotherapy administration is 10-per-

cent higher in the HOPD." These numbers are likely to continue to grow. According to the *Oncology Business Review* article, "Within 2 years, hospitals are likely to treat as many cancer patients as community practices, reversing a trend that began in the early 1990s."⁷⁰

B. Potential Pharmacy Market Distortions

According to the 340B contract pharmacy guidelines,⁷¹ 340B entities are required to inform their patients of their freedom to choose any pharmacy to fill their prescriptions; however, there is a significant incentive to encourage use of 340B pharmacies over non-340B pharmacies, since this benefits the 340B entity directly. In-house and contract 340B pharmacies stock and dispense products purchased by 340B entities at discounted prices, so the covered entity may benefit from more patients using 340B pharmacies.⁷² If a patient fills prescriptions at a non-340B pharmacy instead of a 340B entity's in-house or contract pharmacy, the potential profit for the 340B entity is lost.⁷³

The recent growth of 340B and 340B-contracted pharmacies and pharmacy networks can have a significant impact on community pharmacists by reducing their patient base, driving utilization down and potentially forcing many community pharmacists out of business. Closings of community pharmacies are troubling, as they may create access issues, particularly for patients in rural areas. As of October 2011, 21 percent of 340B-contracted pharmacies are located in rural areas, as defined by the pharmacy zip code.⁷⁴

The majority of 340B-contracted pharmacies (at least 60 percent)⁷⁵ are large retail outlets and supermarket chains. One large chain pharmacy dominates the contracted pharmacy market, accounting for 45 percent of all 340B pharmacy arrangements.⁷⁶ The outlets with the next highest percentage of contract pharmacy arrangements each account for only about 2 percent of such arrangements.⁷⁷

⁶⁷B. Wynn, P. Hussey and T. Ruder, Policy Options for Addressing Medicare Payment Differentials Across Ambulatory Settings, RAND Technical Report (Santa Monica, CA: RAND, 2011).

⁶⁸See R. Schleif, Bruce Edelen, and Mary Lou Bowers, "340B Benefits Some, Not Others," *Oncology Business Review*, September 2011.

⁶⁹*Ibid.*

⁷⁰*Ibid.*

⁷¹75 Fed. Reg. 10272 (March 5, 2010), <http://edocket.access.gpo.gov/2010/pdf/2010-4755.pdf>.

⁷²That profit margin is potentially more lucrative depending on the patient mix and payer. As discussed previously, under current HRSA guidelines, a 340B "patient" need not be uninsured. All patients of qualified 340B entities are eligible to receive outpatient prescription medicines purchased by the entity under 340B. Entities with a higher percentage of insured patients can be expected to see high margins, since entities are keeping the difference between the discounted purchase price of a product from the 340B program and the price the product is reimbursed by a third-party payer.

⁷³A 340B facility might even encourage its employees to seek care at the facility—thus potentially qualifying as patients under the 340B rules—and to fill their prescriptions at in-house or contracted 340B pharmacies.

⁷⁴Avalere Health's analysis of the daily report of pharmacy contract arrangements accessed on the HRSA website on October 10, 2011.

⁷⁵Avalere Health's analysis of HRSA files on 340B contract pharmacy arrangements.

⁷⁶Avalere Health's analysis of the daily report of pharmacy contract arrangements accessed on the HRSA website on October 10, 2011.

⁷⁷*Ibid.*

Recent evidence also suggests that 340B entities may be expanding into long-term care (LTC) facilities. The National Community Pharmacists Association reports that at least one 340B hospital has used the 340B program for LTC facility residents.⁷⁸ Traditionally, closed-door LTC pharmacies have served this patient population. However, these closed-door LTC pharmacies are not 340B covered entities, and cannot compete. A 340B entity can purchase drugs at statutorily controlled prices that can undercut the ability of LTC closed-door pharmacies to compete for the LTC facility patient population. If this practice expands, the results will be devastating for LTC pharmacies, which serve more than 1.8 million residents.

Disruptions in established pharmacy relationships can risk harming patients or can work to undermine the objectives of the 340B program. For example, some 340B hospitals may steer their transplant patients to obtain brand-name drugs from the hospital's in-house pharmacy, which may be inconvenient for many patients if they live far away from the transplant center and would prefer to continue using their community pharmacy. One community pharmacist on the east coast has experienced losing insured patients to 340B covered entities. A very large hospital in the community began aggressively steering hospital employees that had insurance coverage to have their prescriptions filled at the 340B hospital pharmacy.

C. The Impact of 340B Incentives on Clinical Decision-Making

Concerns have been raised that clinical decision-making may also be skewed by efforts to take advantage of the profit margins available from 340B outpatient drugs that are billed to insurers at higher rates. Since the 340B discount is limited to outpatient medicines, when an entity treats a patient in an inpatient setting, that patient is not a "patient" under the 340B program. A hospital may therefore convert an inpatient to an

outpatient to avail itself of 340B prices. One presentation given at a 340B conference, for example, promoted changes to patient care pathways as a way to maximize the "spread"—the difference between the acquisition cost of a drug and the amount billed to insurers—and the potential revenue stream for the covered entity.⁷⁹ The presentation suggests changing an admission process to capture the 340B spread on drugs that otherwise would be used for inpatients. It also recommends that facilities change intravenous chemotherapy treatment protocols in order to capture the 340B spread.⁸⁰ It was also suggested that entities could discharge transplant patients for therapy to a "townhouse" purchased by the hospital in order to capture the 340B spread that would be available for drugs dispensed in an outpatient setting.⁸¹

These potential changes to clinical treatment protocols may have negative consequences for patients, as they are not driven by patients' clinical needs. Further, patients could pay a higher co-pay or cost sharing on a drug provided in an outpatient setting as compared to an inpatient setting. Likewise, changing a patient's site of care to obtain 340B prices may have adverse consequences for the patient's eligibility for other health care benefits.⁸²

D. Potential Cost-Shifting to Third-Party Payers Under 340B

Another potential market distortion as a result of 340B is the possibility that costs will be shifted to third-party payers, as 340B entities capture dollars that would otherwise flow to payers through rebates. For example, before 340B, a payer may have hypothetically received a 30 percent rebate on product A. If the cost of product A is \$100, the payer would ultimately pay \$70 after the 30 percent rebate. Post-340B, the 340B covered entity receives a discount of \$50. The manufacturer may not pay a rebate on product A when it has already provided a 340B price, since contracts may prohibit "double dipping." The payer will now pay \$100 (assuming it reimburses 340B and non-340B entities at \$100), instead of the \$70 previously paid pre-340B.⁸³

⁷⁸Nothing under the statute authorizes these types of arrangements. Arguably, these types of arrangements would qualify as unlawful diversion, since the patients do not appear to be outpatients of the 340B entity.

⁷⁹D. Evans, slide presentation at the Seventh Annual 340B Coalition Winter Conference, San Diego, Feb. 10, 2011.

⁸⁰*Ibid.*

⁸¹*Ibid.*

⁸²For example, if a patient is never admitted as an inpatient to a facility because of the entity's incentive to capture the outpatient spread, he or she would not qualify to be admitted to a skilled nursing facility under Medicare.

⁸³This is not a specific example. All product, rebate and pricing information is hypothetical and for demonstrative purposes only.

III. The Need for Oversight to Ensure 340B Is Consistent with Its Statutory Purpose

There are several areas of the 340B program that require additional oversight from HRSA and other regulatory agencies. Without improved focus on these issues, there is a potential for increased abuse of a program that should be serving needy patients at safety net hospitals.

A. The Potential for Drug Diversion

As noted by the GAO in its recent report on the 340B program, HRSA traditionally has relied almost exclusively on self-policing by program participants. Drug diversion, either to individuals who are not “patients” or for use in the hospital inpatient setting, is a major concern for manufacturers, as they have a limited view into the dispensing of 340B-priced drugs. While HRSA requires 340B entities to have systems in place to ensure that 340B drugs are dispensed appropriately, the agency does not require entities to maintain separate physical inventories; nor does it provide much guidance regarding how to fulfill program requirements, which has raised questions about how to ensure audit program requirements are met. Further, the GAO found that HRSA does not verify whether covered entities have systems in place to prevent diversion.⁸⁴

There are currently barriers to initiating audits to detect diversion of 340B drugs. Recent research has yielded materials from 340B conferences demonstrating that 340B covered entities and consultants have promoted the maximizing of spreads for 340B covered entities through a variety of mechanisms, including activities that appear to involve diversion schemes. For example, consultants and presenters at various conferences and elsewhere have endorsed strategies for securing 340B

pricing through incorrect and inappropriate interpretations of who is a 340B “patient.” In some cases, the presentations reflect specific examples that HRSA has in fact raised as diversion risks (e.g., covered entity employees who do not receive health care services from the entity, and thus do not qualify as patients).⁸⁵

Growing awareness of these issues has raised concern. For example, in its 2007 proposed clarification of the definition of “patient,” HRSA expressed significant unease about the potential for diversion due to covered entities “interpret[ing] the [patient] definition too broadly” and inappropriately classifying as “patients” individuals who only (1) are employees of the covered entity, (2) receive case management services from the covered entity, or (3) receive services from a provider that is too loosely affiliated with the covered entity.⁸⁶

Another diversion threat arises from “stockpiling” behaviors, which can create artificial shortages that incite problematic practices such as gray-market activity. As the GAO report noted:

.....
In certain cases, when the 340B price of a drug dropped, some covered entities stockpiled the drug, which resulted in shortages in the supply for other providers, including other covered entities. For example, two covered entities we interviewed reported challenges accessing drugs when their 340B prices dropped, because other entities purchased large amounts of these drugs.⁸⁷
.....

⁸⁴GAO 340B report, 22, 27.

⁸⁵E.g., a 2011 Capture Rx brochure markets its software's ability to “generate revenue” by such “benefit highlights” as “provid[ing] prescriptions to health center and hospital system employees”; a slide presentation by H. Katzman of K&S Consultants (Feb. 11, 2011) suggests that “government-funded populations,” including “prisoners,” become “patients” of the hospital “to secure the 340B prices. HRSA guidance has specifically cited covered entities for providing drugs accessed through the 340B program to employees who are not otherwise patients of the 340B entity.

⁸⁶72 Fed. Reg. 1543 (Jan. 12, 2007).

⁸⁷GAO 340B report, 20.

The GAO further reported that, in other cases when 340B prices have dropped, manufacturers have implemented managed distribution systems “to ensure that all providers had equitable access” to the product.⁸⁸

Some manufacturers and other stakeholders expressed concern to the GAO that stockpiling behaviors may actually reflect diversion attempts. In one example suggestive of planned diversion activity, the GAO noted that “one manufacturer reported that after the price of an oral contraceptive dropped to a penny as a result of HRSA’s penny pricing policy, [the manufacturer] received an order from a covered entity that exceeded the manufacturer’s current national supply by 50 percent.”⁸⁹

The GAO found that operating the 340B program in a hospital environment creates more opportunities for drug diversion than with other covered entity types. First, hospitals operate 340B pharmacies in settings where both inpatient and outpatient drugs are dispensed. Since the 340B discount applies only to outpatient medicines, the pharmacies must ensure that patients admitted in the inpatient setting do not get 340B drugs. In addition, hospitals also tend to have more complex contracting arrangements and organizational structures compared with other entity types—for example, 340B drugs can be dispensed in multiple locations, including emergency rooms, on-site clinics, and off-site clinics. According to the GAO, “broad interpretations of the [patient definition] guidance may be more likely in the hospital setting and diversion harder to detect.” Last, hospitals dispense a comparatively large volume of drugs compared with other entity types—according to the GAO, DSH hospitals alone represent about 75 percent of all 340B drug purchases.⁹⁰

B. The Need for Continued Improvement in General Program Oversight

The GAO’s 2011 study found that “HRSA’s oversight of the 340B program is inadequate because it primar-

ily relies on participants’ self-policing to ensure compliance.”⁹¹ The GAO further found that “HRSA’s guidance on key program requirements often lacks the necessary level of specificity to provide clear direction, making it difficult for participants to self-police or monitor others’ compliance and raising concerns that the guidance may be interpreted in ways that are inconsistent with its intent.” HRSA has made efforts to respond to GAO’s findings, but continued progress is critically important.

To achieve program integrity, it is essential that only facilities that meet statutory standards be enrolled as 340B covered entities. Some covered entities gain eligibility by their federal grantee status (e.g., Ryan White Care Act grantees) or by facility type (e.g., Federally Qualified Health Centers), making a determination of eligibility straightforward. As discussed earlier, however, private hospitals raise complex issues that require additional guidance.

Ensuring ongoing eligibility of DSH facilities is complicated, as a facility’s patient mix changes from year to year, necessitating regular re-evaluation. HRSA’s capacity to conduct re-evaluations may be insufficient. The agency reported to GAO in 2011 that it verifies eligibility of all entities at the time of enrollment, but that it was performing only limited followup to recertify eligibility,⁹² raising concern about the “potential for ineligible entities to remain enrolled in the program.”⁹³ Subsequently, HRSA has begun an important initiative to recertify 340B entities.

Since GAO’s report, HRSA has issued several notices announcing its plans to improve oversight of the 340B program.⁹⁴ However, given the myriad issues outlined above, a significant number of areas remain in need of continued sustained oversight, and HRSA may not have sufficient resources to address these and other issues without additional assistance.

⁸⁸*Ibid.*, 20–21.

⁸⁹*Ibid.*, 21.

⁹⁰*Ibid.*, 29.

⁹¹*Ibid.*, 21.

⁹²*Ibid.*, 24.

⁹³*Ibid.*, 25.

⁹⁴See, e.g., letter to 340B program participants from Administrator Mary Wakefield, Feb. 10, 2012, at <http://www.hrsa.gov/opa/programrequirements/policyreleases/programintegrity021012.pdf>.

IV. The Role of the 340B Program After Coverage Expansion

As discussed earlier, the number of uninsured is expected to *decrease* starting in 2014 with the expansion of insurance coverage under the ACA. By 2019, the CBO estimates the uninsured level will drop by about 45 percent compared with 2012 (see Figure 6). An estimated 29 million uninsured will remain in 2019, representing approximately 9 percent of the U.S. population.⁹⁵ At the same time, HRSA expects 340B provider enrollment to continue to grow above historical rates. This raises questions about whether the program can continue to meet its original goals, and about its future viability.

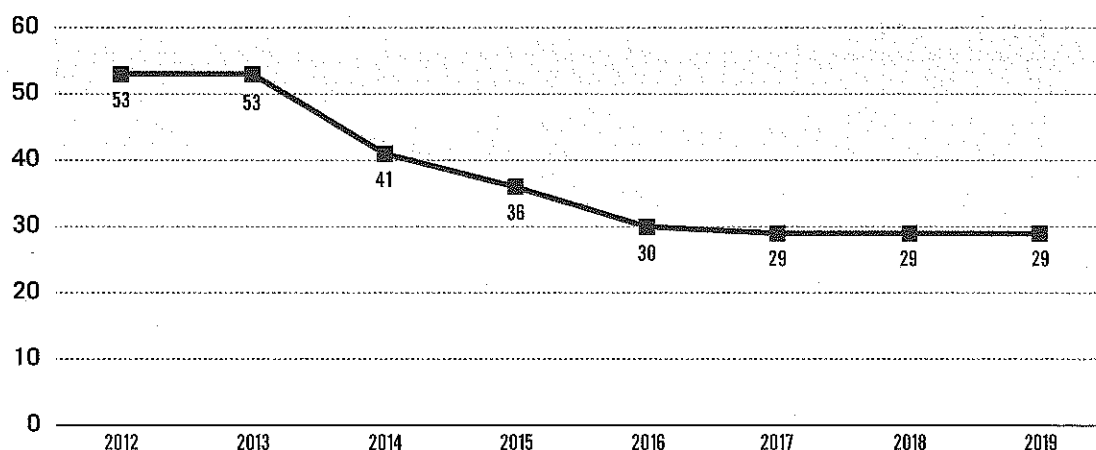
As more people gain access to Medicaid or private insurance under the ACA's coverage expansion, 340B entities will serve more insured patients and fewer uninsured patients. Since these entities will continue to have access to 340B-purchased drugs, the higher payments associated with the newly insured patients will lead to

significant gains in revenue for 340B-eligible entities, even as far fewer patients are uninsured and facilities provide less uncompensated care.

The Urban Institute has estimated that the cost of uncompensated care delivered to the uninsured will drop by 61 percent, given that more than half of these individuals will gain some kind of insurance coverage.⁹⁶ Many 340B entities will directly benefit from providing less uncompensated care.

A study conducted in Massachusetts following the state's 2006 implementation of health reform, which reduced the number of uninsured, analyzed the demand for care delivered by safety net providers after uninsured individuals gained coverage. The researchers focused on community health centers and safety net hospitals that received 20 percent or more of their net patient service revenue from three key public programs in the state.⁹⁷ They found that

Figure 6: Number of Uninsured, in Millions (Projected)



Source: CBO estimates of uninsured nonelderly population, July 2012.

⁹⁵Congressional Budget Office estimate of uninsured, at www.cbo.gov/sites/default/files/cbofiles/attachments/43472-07-24-2012-CoverageEstimates.pdf; U.S. Census Bureau population projections, at <http://www.census.gov/population/projections/>.

⁹⁶J. Holahan and B. Garrett, *The Cost of Uncompensated Care with and Without Health Reform* (Washington, DC: Urban Institute, 2010), available at www.urban.org/uploadedpdf/412045_cost_of_uncompensated.pdf.

⁹⁷L. Ku, et al., "Safety-Net Providers After Health Care Reform: Lessons From Massachusetts," *Archives of Internal Medicine* 171, no. 15 (2011):1379-1384, <http://archinte.ama-assn.org/cgi/content/short/171/15/1379>.

the demand for services from safety net hospitals grew at a higher rate than demand for services from non-safety net hospitals. The increase in demand for ambulatory care was particularly evident.⁹⁸ Again, the growth in demand is associated with a program that converted previously uninsured patients to insured patients. This suggests that 340B entities will disproportionately benefit from the increased coverage provided by the ACA, raising a significant policy question as to the structure and needs of the 340B program.

Avalere Health's analysis of short-term acute care hospitals in Massachusetts similarly showed that between 2006 and 2009, an increase in hospital enrollment in the 340B program was accompanied by a decrease in uncompensated care costs as a share of total costs for those facilities (see Figure 7 below).

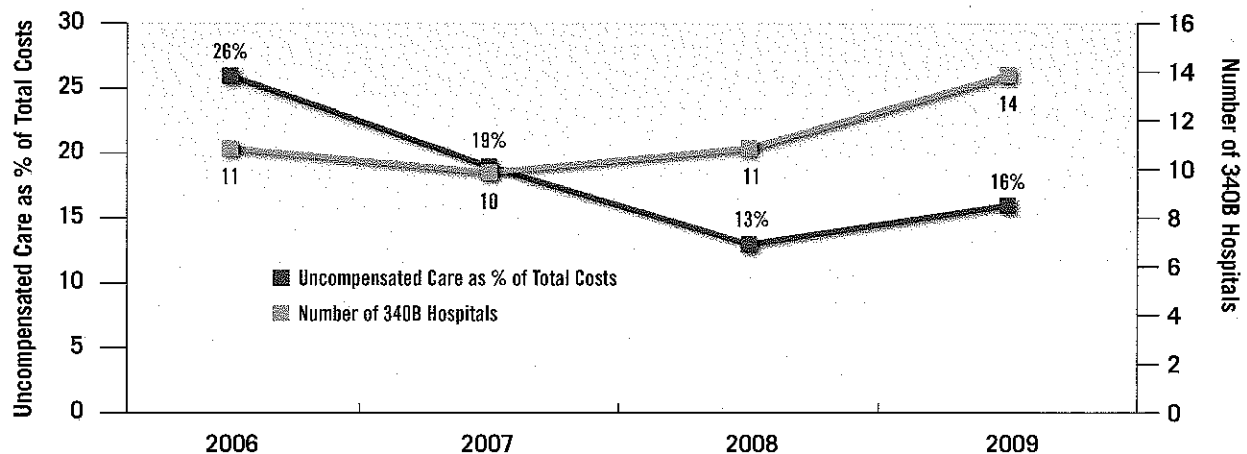
Expansion of coverage and the associated shift in patient mix, resulting in a larger share of insured patients, will increase the size of the 340B program in terms of the amount of revenue achieved via arbitrage (i.e., revenue gained by charging insurers for a drug at a rate that exceeds its 340B acquisition cost) that 340B entities will be able to retain. The newly insured population, consisting of current and new patients, will allow 340B entities to generate more revenue from the 340B

program, as the entities may be able to bill and get paid at a profit for drugs dispensed to those patients.

At the same time that the 340B program is expected to grow in terms of eligible entities, the ACA has also increased minimum Medicaid basic rebate levels from 15.1 percent to 23.1 percent for most brand-name drugs, from 11 percent to 13 percent for generic drugs, and from 15.1 percent to 17.1 percent for clotting factor and pediatric drugs. The increased Medicaid rebate percentages have already yielded larger 340B discounts, since the required minimum amount of the 340B discount is linked to the level of Medicaid rebates.

In short, with the overall drop in the number of uninsured, health care providers will see improved financial performance. Since most 340B entities will serve fewer uninsured patients compared with the numbers that such entities might have served prior to health reform, they may not require financial relief in the form of discounted drug prices offered by the 340B program. Yet many of these entities may still be 340B eligible (and in fact more hospitals may be 340B eligible) because, as noted earlier, the DSH adjustment percentage used as a 340B hospital eligibility criterion does not take into account the percentage of uninsured patients, and actually increases as Medicaid coverage expands.

Figure 7: Massachusetts Example of Increased 340B Enrollment and Decreased Level of Uncompensated Care Among Acute Care Hospitals, 2006–2009



Source: Avalere Health analysis of FY 2006–FY 2009 Medicare cost reports.

⁹⁸*Ibid.*

V. Conclusion

Since its creation in 1992, the 340B program's intent was to provide an avenue for certain entities that serve high numbers of uninsured indigent patients to access low-cost outpatient medicines. Over the years, Congress has expanded the types of entities eligible to participate in 340B, and enrollment has increased considerably.

Throughout this paper, we focused on the original intent of the 340B program while conducting a data-driven evaluation of the extent to which the 340B program has evolved in a way that aligns with that intent. As implementation of the ACA progresses and fewer Americans are uninsured, monitoring the 340B program will be important to ensure that it is true to its original objectives.

The 340B program should be examined to ensure that it meets its intended objectives and that patients

who need the program the most benefit. To meet its intended purpose and reduce occurrences of the unintended consequences discussed in this paper, the 340B program requires significant oversight to ensure overall program integrity and appropriate targeting of eligibility. In addition to the issues raised in this paper regarding indirect effects of the program—market distortions, cost shifting to the privately insured, etc.—there is also a potential for direct violations of 340B program policy involving drug diversion that need to be addressed.

Without concerted efforts to achieve program integrity, the potential for continued program misuse is high. Lack of appropriate oversight and the absence of rules consistent with Congressional intent, along with the looming explosive growth of the 340B program, highlight the need for program reform. HRSA has recently taken significant steps to improve oversight, which must continue and expand.

Appendix

340B Hospital Eligibility Criteria⁹⁹

Hospital Designation	340B Requirements
DSH Hospital (included in Medicare prospective payment system [PPS] under §1886(d)(1)(B) of the Social Security Act [SSA])	<ol style="list-style-type: none"> 1. Status: The hospital must be: (1) owned or operated by state or local government; (2) public or nonprofit, and formally granted governmental powers by state or local government; or (3) private nonprofit, with a contract with state or local government to provide care to low-income people who are not Medicare or Medicaid beneficiaries. 2. DSH adjustment percentage greater than 11.75% (or Pickle hospital). 3. Hospital does not obtain outpatient drugs through a group purchasing organization (GPO) or other group purchasing arrangement. 4. Outpatient clinics that are integral parts of the hospital and registered with HRSA may participate in 340B.
Free-Standing Cancer Hospital (excluded from PPS under §1886(d)(1)(B)(v) of the SSA)	<ol style="list-style-type: none"> 1. Status: Same as above. 2. DSH adjustment percentage greater than 11.75%. 3. Hospital does not obtain outpatient drugs through a GPO or other group purchasing arrangement. 4. Outpatient clinics that are integral parts of the hospital and registered with HRSA may participate in 340B.
Children's Hospital (excluded from PPS under §1886(d)(1)(B)(iii) of the SSA)	<ol style="list-style-type: none"> 1. Status: Same as above. 2. DSH adjustment percentage greater than 11.75% (or Pickle hospital). 3. Hospital does not obtain outpatient drugs through a GPO or other group purchasing arrangement. 4. Outpatient clinics that are integral parts of the hospital and registered with HRSA may participate in 340B.
Critical Access Hospital (defined in §1820(c)(2) of the SSA)	<ol style="list-style-type: none"> 1. Status: Same as above. 2. No DSH adjustment percentage requirement. 3. Outpatient clinics that are integral parts of the hospital and registered with HRSA may participate in 340B.
Rural Referral Center (defined in §1886(d)(5)(C)(i) of the SSA)	<ol style="list-style-type: none"> 1. Status: Same as above. 2. DSH adjustment percentage equal to or greater than 8%. 3. Outpatient clinics that are integral parts of the hospital and registered with HRSA may participate in 340B.
Sole Community Hospital (defined in §1886(d)(5)(C)(iii) of the SSA)	<ol style="list-style-type: none"> 1. Status: Same as above. 2. DSH adjustment percentage equal to or greater than 8%. 3. Outpatient clinics that are integral parts of the hospital and registered with HRSA may participate in 340B.

⁹⁹42 U.S.C. § 256b(a)(4)(L)–(O). Criteria noted in Table 1 regarding participation in 340B by a hospital outpatient clinic are based on HRSA guidance rather than on the statute.

