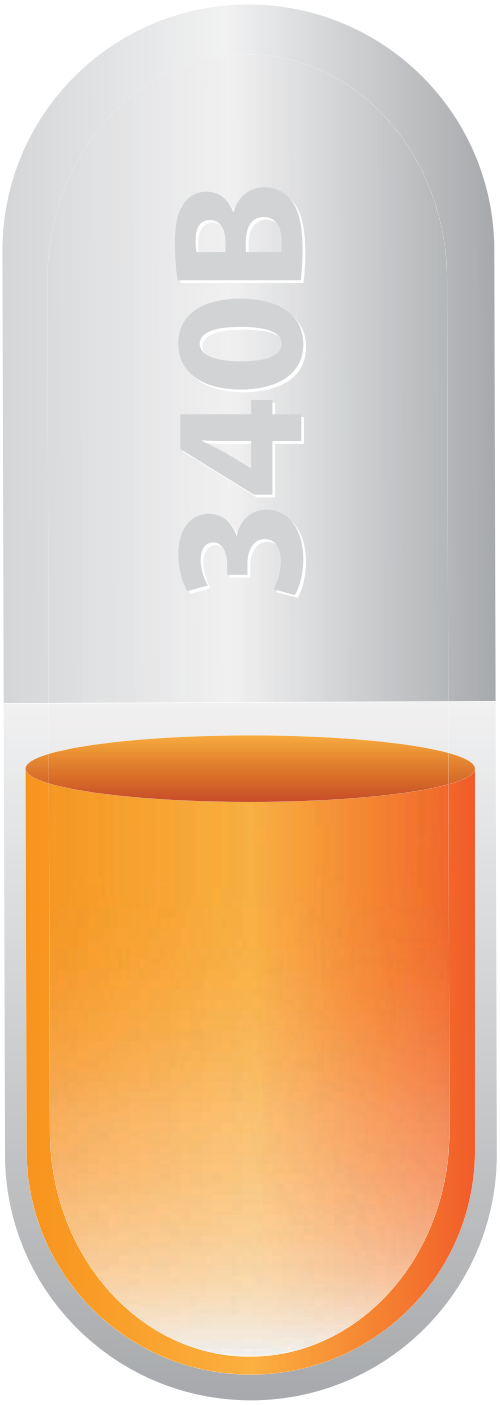


The 340B Drug Discount Program

Potentially worth millions, this program is fraught with risk

Created by Congress in 1992, Section 340B of the Public Health Service Act requires pharmaceutical manufacturers to provide outpatient prescription drug discounts to covered entities that serve high numbers of uninsured indigent patients. The exact savings is dependent on the types and amount of drugs prescribed.

By Karolyn Woo-Miles and Debra Muscio

Research commissioned by the National Association of Community Health Centers (NACHC) indicates savings can be 15 to 60 percent on the cost of drugs purchased through the 340B Program.[1]

The participating manufacturers' price discounts are based on a statutory cap referred to as the 340B ceiling price. These savings can be used to reduce pharmaceutical prices to low-income patients or to sustain or increase certain services to an expanded group of uninsured indigent patients.

The Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA) administers the program. Since 1992, covered entities have primarily used the Act[2] itself to comply with its requirements. Further guidance has come from Federal Register Final Notices published in 1994 for 340B Entity Guidelines,[3] from Patient and Entity Eligibility definitions in 1996, and from Contract Pharmacy Services[4] in 2010.

Congress and the healthcare industry have concerns and questions about the program that include:

- What constitutes an eligible 340B patient?
- Is the expansion of program consistent with Congress' original intent?
- Is oversight adequate to ensure the program is operating in a compliant and transparent manner?

[1]NACHC Study on the Benefits of the 340B Drug Pricing Program for Health Centers, May 2011
[2]HRSA Notice regarding Section 602 of the Veterans Health Care Act of 1992 Duplicate Discounts and Rebates on Drug Purchases. Federal Register Vol. 58, No. 87, May 7, 1993
[3]HRSA Final Notice regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines. Federal Register Vol.59, No. 107, June 6, 1994
[4]HRSA Final Notice regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility. Federal Register Vol.61, No. 207, October 24, 1996

Program requirements

To participate in the program, covered entities must comply with guiding principles and the following requirements.

Definition of an Eligible Patient

The law prohibits diverting 340B drugs to individuals who are not covered entity patients; moreover, the drug discounts are only available to patients treated in outpatient settings. HRSA has attempted to define the specific term 'patient' in their guidance documents, but the definition still lacks clarity.

In 2012, HRSA indicated it was revising the definition of 'patient,' but the revision has not been published. HRSA's 1996 definition outlines several principles for an individual to be qualified as a patient of a 340B covered entity.

These principles include:

- The covered entity must have established a relationship with the individual such that the covered entity maintains records of the individual's healthcare.
- The individual must receive healthcare services from a healthcare professional who is employed by the covered entity or who provides healthcare under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity.
- The individual must receive services for which the entity received federal grant funding (or Federally Qualified Health Center look-alike status).
- An individual is not a patient if the only healthcare 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 covered entities may be broadly interpreting the patient definition to include individuals receiving healthcare services from providers at their private practices, or from providers who are loosely affiliated with the covered entity but who do not actually have the responsibility for care. These broad interpretations could potentially result in the diversion of medications to ineligible patients.

Diversion

The Act prohibits "diversion" by forbidding covered entities from reselling or otherwise transferring drugs purchased under the program to anyone other than their own patients. It also prohibits use of those drugs in an inpatient setting. Drug diversion is a major concern of drug manufacturers.

The Act prohibits "diversion" by forbidding covered entities from reselling or otherwise transferring drugs.

Duplicate discounts

Duplicate discounts are not permitted. This protects drug manufacturers from having to give a 340B discount to covered entities and in addition pay a Medicaid rebate on that same drug purchased at the discounted price.

At enrollment time, covered entities electing to purchase 340B drugs through the program are required to inform HRSA that they will purchase and dispense program drugs to the Medicaid population.

Covered entities should work with the Medicaid state agency to choose whether they will dispense 340B drugs to Medicaid patients and bill to Medicaid at the drug acquisition cost, or dispense from their non-340B inventory and seek a higher Medicaid reimbursement.

Expansion of the 340B Program

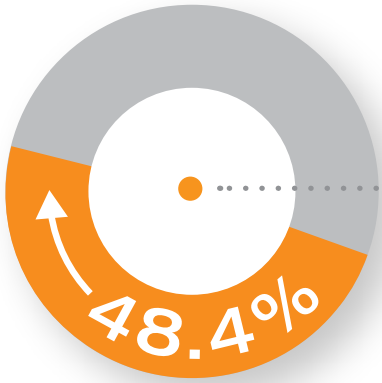
According to the Government Accountability Office, in a little over ten years the number of 340B covered entities has doubled. The expansion has accelerated with the adoption of the Affordable Care Act. The Act added children's hospitals, freestanding cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals as covered entities.

HRSA allows covered entities to dispense program drugs to their outpatients through in-house pharmacies or through an outside pharmacy with which they contract. To expand access to 340B drugs, in April 2010 HRSA began allowing covered entities to utilize multiple contract pharmacies. Since 2010, growth in the number of contract pharmacies has averaged 43% annually, leading to increased scrutiny by the OPA, Office of Inspector General (OIG) and certain Congressional leaders.

340B Entities by Number of Contract Pharmacies, July 2014

340B Contract Pharmacies in Network	340B Entities	Share of 340B Entities	Total # of 340B Contract Pharmacy Relationships	Share of 340B Contract Pharmacy Relationships	Avg. Pharmacy Network Size
0	19,967	80.6%	0	0	0
1	1,931	7.8%	1,931	5.5%	1
2-5	1,574	6.4%	4,659	13.2%	3
6-10	560	2.3%	4,334	12.3%	8
11-25	446	1.8%	7,329	20.7%	16
More than 25	290†	1.2%	17,090	48.4%	59
Total	24,768*	100%	35,343	100%	

*Apexus analysis of HRSA's master database of covered entities, April 2014
†290 = 140 disproportionate share hospitals + 120 children's hospitals + 30 other
SOURCE: Pembroke Consulting, Inc. analysis of HRSA's Office of Pharmacy Affairs Daily Contract Pharmacy Database (7/1/14), published on Drug Channels (www.DrugChannels.net) July 16, 2014.



290 healthcare providers (1.2% of covered entities) account for half of all 340B contract pharmacy relationships

HRSA audits and results

In 2012, OPA began auditing 340B covered entities, focusing primarily on drug diversion and duplicate discounts. Covered entities found to have violated these rules may be required to repay the discount to the drug manufacturer. Other potential penalties include paying interest on the discounted amount and being disqualified from participation in the 340B Program.

Initially the audits focused on diversion and duplication, and on randomly selected programs based on purchase volume, complexity of program administration or use of contract pharmacies. A few targeted audits were performed that centered on policies and procedures, auditable records, and system compliance to prevent diversion and duplicate discounts.

Typical audit process

1 ***Pre-audit*** – Selected covered entities receive an engagement letter explaining what to expect from the onsite audit and how to appropriately prepare. An introductory teleconference is conducted with the entity to request Medicaid ID, NPI and NCPDP numbers, key staff and their contact information, and documents including:

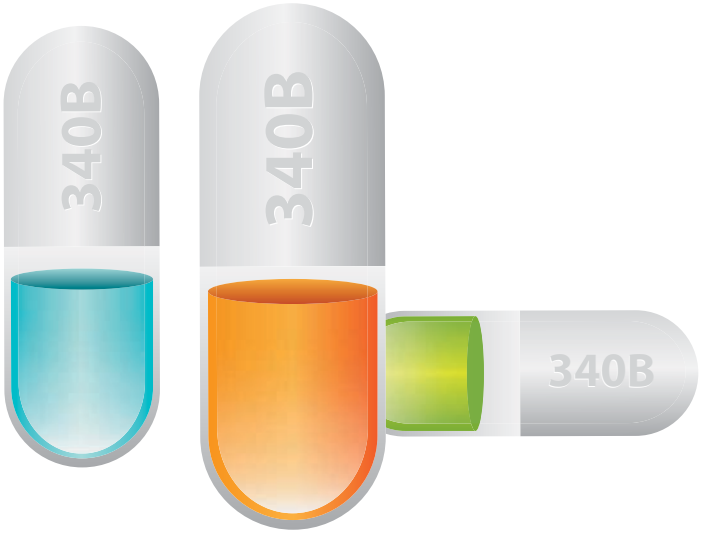
- Policies, procedures and reports
- Medicare Cost Report (searchable)
- List of dispensed prescriptions between selected dates with requested data elements
- Purchase history with dollar values by 340B, GPO and other purchases
- Latest inventory report with purchase price
- List of contract pharmacies and contracts for dispensing, and internal controls

An entrance conference is scheduled with key staff to discuss expectations for the onsite audit.

2 ***Onsite audit*** – Field auditor's review of 340B Program data and internal controls. Audit procedures include, at a minimum:

- Review of relevant policies and procedures and how they are operationalized
- Verification of eligibility, including GPO and outpatient clinic eligibility
- Verification of internal controls to prevent diversion and duplicate discounts, including how the covered entity defines whether a patient is considered inpatient or outpatient
- Verification of HRSA Medicaid Exclusion File designations and accuracy of the covered entity's 340B database records
- Review of 340B Program compliance at the covered entity, outpatient or associated facilities and contract pharmacies
- Testing of 340B drug transaction records on a sample basis
- Exit interview, sharing areas of concern and preliminary findings

3 ***Post-audit*** – OPA reviews the preliminary findings from the field auditors, drafts a Final Report and issues the report to the covered entity, with a request for a corrective action plan (CAP), if applicable.



In May 2014, HRSA published a program update containing fiscal year 2012 audit results to date, that identified critical areas of noncompliance for hospitals and nonhospitals.[5]

OIG report on contract pharmacies

On February 5, 2014, the OIG released its report on contract pharmacy arrangements operated under the 340B Program.

> Covered entities must exercise *vigilant oversight* over their contract pharmacy arrangements to *ensure compliance.*

The limited-scope report focused primarily on the statutory prohibitions of diversion and duplicate discounts. It raised issues that HRSA is expected to address with the release of the proposed mega-rule sometime in 2014.

The issues centered on:

- Inconsistent application of the definition of an eligible patient
- Inconsistent application of criteria used to determine 340B eligible prescriptions
- The time limits applied to when a prescription can be 340B-eligible relative to the physician visit
- The criteria used to determine eligibility

The report additionally noted that many contract pharmacy arrangements excluded the uninsured population from accessing 340B discounted drugs.

Contract pharmacy administrators are typically making the patient eligibility determinations after the drug is dispensed at the point of sale. As a result, the contract pharmacies may be unknowingly charging uninsured patients the full prescription cost. Some covered entities offering 340B discounts to uninsured patients have addressed this issue by providing patients with a 340B discount card. When presented, the card notifies the contracted pharmacy to charge the prescription at a discounted rate.

Role for internal audit

The OPA has issued a statement stressing that covered entities must exercise "vigilant oversight" over their contract pharmacy arrangements to ensure compliance with the 340B Program requirements.

Commander Krista Pedley spoke at the 340B Winter Coalition Conference, repeating the call for vigilant oversight. She said, "HRSA expects covered entities to conduct annual audits of contract pharmacies that are performed by an independent auditor. If HRSA finds a covered entity not providing oversight of its contract pharmacy arrangements, this is a violation of program requirements and HRSA will no longer permit the participation of that contract pharmacy arrangement."

HRSA also indicated that at a minimum, to prevent diversion and duplicate discounts, covered entities must regularly perform effective self-audits (monitoring) of their contract pharmacy arrangements. To accomplish this, covered entities should develop policies and procedures for performing self-audits (compliance monitoring) and explore the availability of independent audits by internal auditors or external audit firms.

[5]HRSA Audit Results: Program Update, May 9, 2014, www.hrsa.gov/opa/updates/140509auditresults127kb.pdf

HRSA has stated that if covered entities do not exercise appropriate oversight over a contract pharmacy, the HRSA will discontinue the contract pharmacy arrangement within the 340B Program.

The OIG report, coupled with HRSA's public statement, means it is important for covered entities to ensure they are proactively monitoring contract pharmacy arrangements for compliance.

What's coming?

The government has managed the 340B Program with few formal regulations, electing to set 340B rules through mechanisms such as guidelines, policy releases and Frequently Asked Questions.

HRSA's planned mega-regulation (a.k.a. mega-reg) could change that. This could provide specific and enforceable definitions to help prevent diversion and duplicate discounts, and to support 340B Program integrity. The new regulations were to be published for public comment in June 2014 with HRSA guidance to follow after final adoption of the rules. However, the mega-reg has been delayed.

The new regulations and guidance are expected to address many of the issues discussed in this article, including:

- Clarification of what constitutes a covered entity
- Clearer definitions for eligible off-site facilities
- Clarification of the definition of a patient, and other patient eligibility issues
- Compliance requirements for contract pharmacy arrangements
- Covered entity responsibilities for auditing of program requirements

In addition to the mega-reg, HRSA is expected to move ahead with three other significant program regulations:

> Covered entities should develop policies and procedures for performing *self-audits.*

- Create a mandatory administrative dispute resolution process
- Impose fines on drug makers for knowing and intentional overcharges
- Impose fines on covered entities for violating the 340B statute knowingly and intentionally, and remove them from the 340B Program for their engagement in systematic and egregious misconduct

Conclusion

Covered entities would be wise to invest some savings garnered from the 340B Program to enhance internal audit and compliance efforts, including a robust monitoring compliance program with separate independent internal or external audits. HRSA is expected to continue to focus on covered entities fitting the profile of "higher risk" programs. Internal auditors can serve as valuable catalysts to identify and focus attention on the challenging compliance areas within the 340B Program. NP

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