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340B Drug Discount Program

Identifying risks and internal audit focus areas

Introduction

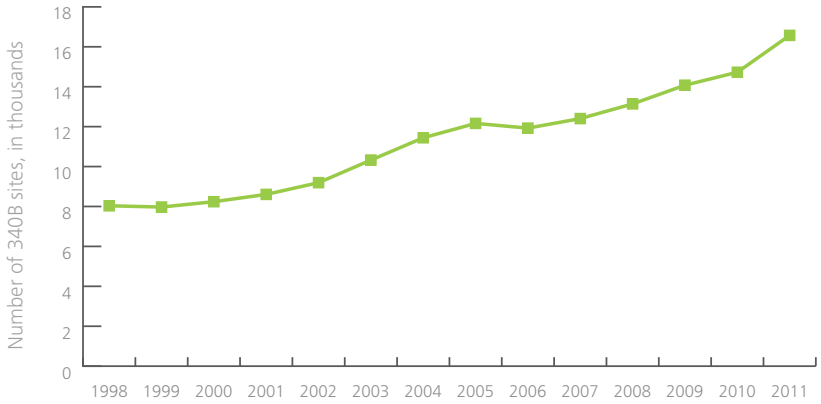
The 340B Drug Discount Program is administered by the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPA). It was formed when Congress created section 340B of the Public Health Service Act in 1992 to allow eligible health care providers — known as covered entities — to stretch Federal resources, reaching more eligible patients and providing more comprehensive services. As part of the Program, Congress requires pharmaceutical manufacturers to provide discounts on covered outpatient prescription drugs to covered entities that serve high numbers of uninsured indigent patients. Only select healthcare providers are eligible to participate in the 340B Program. The average savings on outpatient drug purchases for 340B covered entities can range from 25-50%.[1] The savings afforded by the program may be used in various ways, such as reducing the price of pharmaceuticals for patients, expanding drug formularies, or expanding services offered to patients.

[1] 340B Prime Vendor Program, 340B Program Benefits

Recent growth

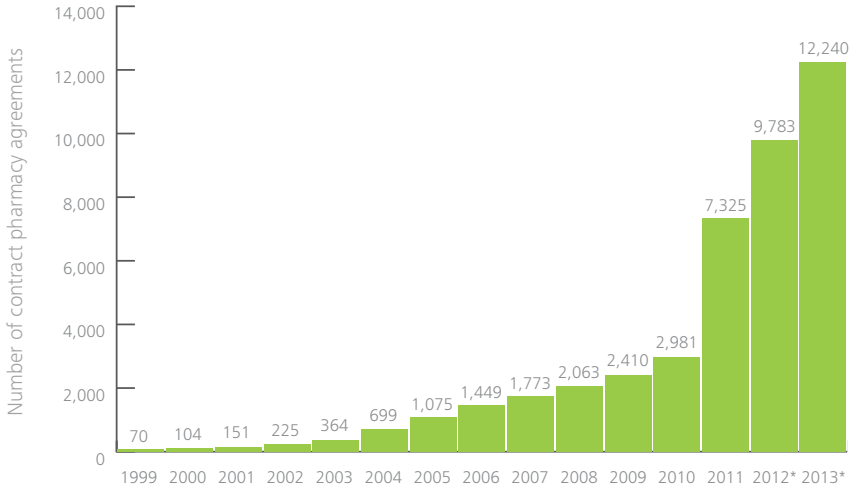
According to the Government Accountability Office (GAO), the number of 340B covered entities has doubled in just over 10 years (see figure 1). The expansion of the number of program participants has continued to accelerate with the adoption of the Affordable Care Act, which added children's hospitals, free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals as eligible covered entities. HRSA allows covered entities to dispense 340B drugs to their patients through in-house pharmacies or through an outside contracted pharmacy. Starting in April 2010, HRSA introduced sub-regulatory guidance that allows covered entities to utilize multiple contract pharmacies to expand access to 340B drugs. As a result, there has been rapid growth in the number of contract pharmacies since 2010 (see figure 2), which has led to increased scrutiny by OPA and the Health and Human Services (HHS) Office of the Inspector General (OIG).

Figure 1 — Historical growth in 340B enrollment, 1998-2011 (as of July of each year)



Source: Avalere Health analysis of HRSA 340B enrollment files

Figure 2 — Growth in 340B contract pharmacy agreements, 1999-2013 (as of July of each year)



*2012 and 2013 reflect HRSA projections

Source: Avalere Health analysis of 340B contract pharmacy arrangements files

Program requirements and enforcement

The law requires covered entities to meet certain eligibility criteria to participate in the 340B program. Covered entities must fit within one of the statute's eligibility categories, register with HRSA OPA, and abide by certain program requirements outlined below:

1. "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.

2. "Duplicate discounts" are not permitted: manufacturers cannot be billed for Medicaid rebates on drugs purchased at a 340B discount.

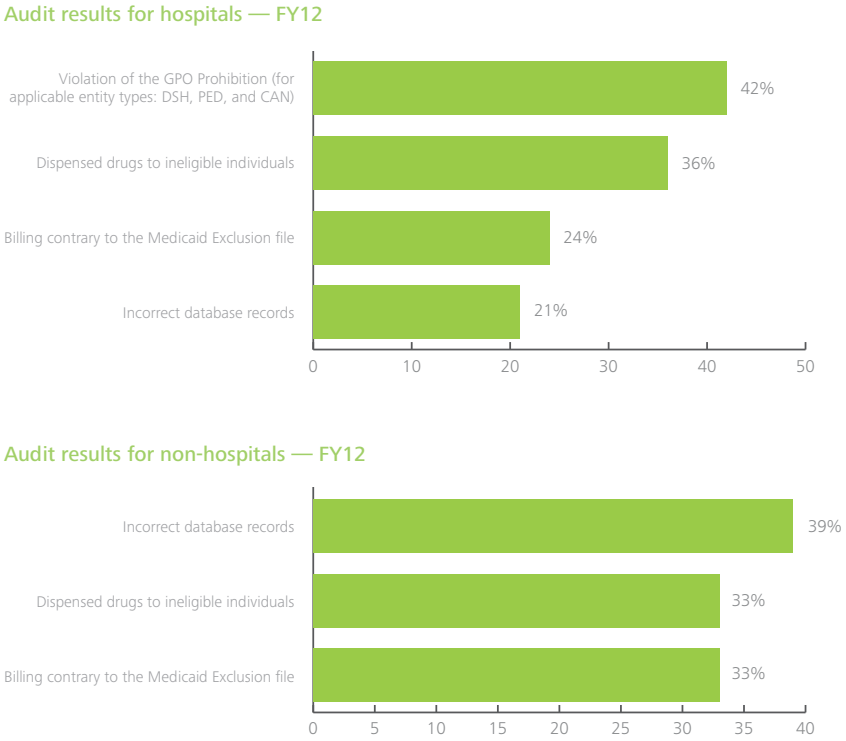
3. Group Purchasing Organization (GPO) prohibition: DSH hospitals, children's hospitals, and free-standing cancer hospitals may not obtain covered outpatient drugs through a GPO or other group purchasing arrangement.

4. Orphan Drug Exclusion: Critical access hospitals, free-standing cancer hospitals, sole community hospitals and rural referral centers are responsible for ensuring that any orphan drugs purchased through the 340B Program are not transferred, prescribed, sold, or otherwise used for the rare condition or disease for which the orphan drugs are designated under section 526 of the Federal Food, Drug, and Cosmetic Act.

5. Record maintenance and retention: HRSA and manufacturers are permitted to audit records directly pertinent to compliance with the 340B program requirements.

In 2012, HRSA OPA began conducting compliance audits of covered entities. Typical audit focus areas include policies and procedures, program eligibility, prevention of diversion, duplicate discounts and GPO purchases, contract pharmacy, and sample testing of 340B drug transactions. In May 2014, HRSA published a program update containing fiscal year 2012 audit results, which identified several recurring critical areas of non-compliance for hospitals and non-hospitals (see figure 3.)[2] As a result of not properly administering the 340B program, a covered entity may be subject to additional scrutiny, repayments to manufacturers, and temporary or permanent disenrollment from the program.

Figure 3 — HRSA FY12 audit results



Source: HRSA Audit Results: Program Update, May 9, 2014

[2] US Department of Health and Human Services, Health Resources and Services Administration, Office of Pharmacy Affairs Update, May 9, 2014

Future developments

To date, the federal government has managed the 340B program with minimal formal regulations, and rule setting through guideline documents, policy releases, and FAQs. Rulemaking could shift this year with HRSA's planned "Mega-Reg," which should provide more specific and enforceable definitions to help support 340B program integrity efforts. The new regulations are expected to be published in June 2014 for a public comment period with guidance from HRSA to follow after final adoption of these rules. However, the Mega-Reg has been already delayed once this year.[3] The new regulations and guidance are expected to address several areas, such as:

- Clarification of what constitutes a covered entity and eligible off-site facilities;
- Clarification of the definition of a patient and other patient eligibility issues such as identifying, which Medicaid Managed Care Organizations (MCOs) are in scope for participation;
- Compliance and independent audit requirements for contract pharmacy arrangements to prevent diversion and duplicate discounts, in which the 340B covered entity signs a contract with a pharmacy to provide pharmacy services; and,
- Covered entity responsibilities with regards to auditing of Program requirements.

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[3] 340B Prime Vendor Program, 340B news announcement and updates

Considerations when conducting an internal audit

Echoing comments from the OPA to covered entities that they must exercise "vigilant oversight" of their 340B program, it is critical that an organization's internal audit function address controls over implementation of the 340B program. The following are some example activities to consider when conducting an internal audit:

- Review publications by the Apexus 340B Prime Vendor Program on 340B Program and Best Practices.[4]
- Ensure your organization is either owned or operated by a unit of state or local government, or a non-profit corporation, which is granted governmental powers by a unit of State or local government, or a private non-profit hospital, which has a contact with a state or local government to provide health care services to low income individuals.

It is critical that an organization's internal audit function address controls over implementation of the 340B program.

- Verify the HRSA database is accurate with respect to accountable administration and child site registration.
- Understand the your organization's 340B program governance model in terms of who is the responsible executive and is there a standing oversight committee that meets regularly and includes internal audit representative.
- Perform business process walkthroughs, inquiries and document reviews to assess whether procedures and internal controls exist to comply with 340B program requirements.
- Where contract pharmacies are used by your organization, ensure they are being monitored for compliance and consistency in the provision of benefits at both your in-house and contract pharmacies.
- Review pharmacy generated list of areas using 340B drugs and compare with the reimbursable clinics listed on the most recently filed Medicare Cost Report.
- Assess the definitions of a qualified 340B patient that have been established specific to your covered entity:
  - What type of relationship must be established with the patient in order to be considered a qualified patient?
  - Who maintains a copy of the patient's medical record and are documentation of encounters resulting in prescriptions easily accessible?
  - How are referrals for consultation handled in terms of establishing patient eligibility?
  - How refills are authorized and processed, are refills authorized and maintain from the same prescription number?
- Assess the definitions of an eligible provider specific to your covered entity:
  - What type of relationship must be established with the health care professional in order to be considered a qualified provider?
  - How is the eligibility of physicians and other clinicians who can write prescriptions tracked (e.g. nurse practitioners, residents, psychologist, and medical residents?)
  - How are National Provider Identification (NPI) numbers maintained, tracked and interfaced with key pharmacy and billing and systems?

[4] 340B Prime Vendor Program, 340B Policy to Practice Guide

- Assess the controls to prevent drug diversion:
  - Medications purchased through the 340B program are not supplied to any non-340B eligible patients.
  - Medications purchased through the 340B program are dispensed pursuant to a prescription written by an eligible provider.
  - Medications purchased through the 340B program are being dispensed from eligible locations.
- Assess the controls to prevent duplicate discounts:
  - Medicaid Exclusion File information recorded on the OPA database is accurate and complete for all entity sites, based upon state policy, and reflects current practice by the entity.
  - Obtain the State Medicaid policy for billing 340B outpatient drugs. Determine if covered entities are mandated to carve in or carve out 340B drugs when billing the State Medicaid agency.
  - Determine if State Medicaid requires UD modifier for billing purposes.
  - Is the covered entity billing State Medicaid claims with the correct National Drug Code (NDC) number?
  - How is the covered entity treating 340B claims for Medicaid Managed Care Organization (MMCO) patients?
- For disproportionate share (DSH) entities, assess the controls to comply with GPO Prohibition:
  - Review the policy addressing procurement criteria for 340B use in mixed use and outpatient pharmacies.
  - Assess how transactions flow from the pharmacy to the split billing software which is used to identify and capture drugs used in the inpatient versus outpatient setting, and to track those drugs eligible for reordering under the 340B contract price.

It may be prudent for covered entities to consider investing a portion of the savings garnered from the 340B program to enhancing their compliance efforts. Such as developing a robust auditing and monitoring compliance program including using internal audit to provide support for the auditing portion of the auditing and monitoring compliance requirement. HRSA is expected to continue its focus on covered entities that fit the profile as "higher risk" program types. Internal audit can serve as a valuable catalyst to identify and draw attention to those compliance areas that prove challenging to the covered entity given the complexities and "gray areas" within the 340B program. Since drug companies are also reviewing covered entities, such audits can also help appease the providers of the 340B discounts and perhaps reduce their audit efforts.

Example Continuous Monitoring Opportunities:

- Purchasing volume analyses — Monthly review of purchasing volume to monitor purchases are made from the correct account and review significant changes in purchase volume.
- Eligible drugs used in mixed use areas — Monthly review 340B drug purchases which are typically only utilized for inpatients.
- Purchases at 340B ineligible sites — Monthly review of purchases from ineligible locations should be purchased from the Wholesale Acquisition Cost account.
- Physician database accuracy — Monthly comparison of the prescriber database records, electronic medical record and contract pharmacy data feed to capture only 340B eligible providers

References

U.S. General Accounting Office (GAO). *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836. Washington, DC: General Accounting Office, 2011. http://www.gao.gov

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