

The 340B Drug Pricing Program: Opportunities for Community Pharmacists

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Goals:

After completing this program, participants will be able to:

1. Explain what the 340 Drug Pricing Program is, when and why it was created.
2. Describe a 340B-eligible entity.
3. Outline ways that medication access and pharmacy services are provided in 340B-eligible-entities.
4. Discuss opportunities for community pharmacists to partner with 340B-eligible entities.
5. Understand community resources available to help patients who cannot afford their medicines.
6. Explain the "contract pharmacy" arrangement and potential changes.

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Partnering with safety net healthcare providers not only provides an opportunity for community pharmacists to develop new business, but creates avenues for offering patient care and clinical services. Safety net providers include community health centers, migrant health centers, and other entities. Many underinsured and uninsured people in the United States access health care services through these "safety net" providers. While the creation of the Medicare Part D prescription drug benefit has provided subsidized coverage to millions of low-income people, many who are eligible for the Low Income Subsidies are not receiving them. In addition, some people whose income or assets put them just outside the assistance eligibility ceilings struggle to pay for their medications. Safety net providers often fill in these "cracks" but the level of medication access and pharmacy services vary widely.

The 340B Drug Pricing Program

Alarmed by the escalating cost of drugs in the early 1990s, a consortium of safety net providers began to strategize around the best way to provide pharmacy services for patients. Their efforts resulted in the Federal legislation in 1992 that created the Public Health Service 340B Discount Drug Pricing Program.

The 340B Drug Pricing Program refers to a federal statute that requires drug manufacturers to sell outpatient drugs to eligible health care centers, clinics, and hospitals (termed "covered entities") at a reduced price. This requirement is described in Section 340B of the Public Health Service Act, which was enacted in 1992 to provide financial relief to those facilities that provide care to the medically underserved. By saving on drug prices, the goal was to expand health services access to low income individuals and families and other vulnerable populations.

The 340B Drug Pricing program provides a discount on outpatient drugs to eligible health centers and hospitals. It's called 340B because it put the "Section 340B" of the Public Health Service Act into place. Manufacturers that participate in State Medicaid programs must also agree to participate in the 340B Drug Discount Pricing Program.

You may hear the terms "PHS Pricing," "340B Pricing," and "602 Pricing," all of which refer to the same program and the same discount. The term "340B ceiling price" is the highest price the statute allows a manufacturer to charge a participating 340B entity. Nothing in the statute prevents a manufacturer from selling covered drugs to eligible entities at prices lower than the ceiling price. You can read the statute by visiting: <http://pssc.aphanet.org/about/programstatute.htm>

The 340B Price

The 340B price is the ceiling price, meaning it is the highest price a participating entity could be charged. It is determined by the Centers for Medicare and Medicaid Services using a complex formula. The 340B price is at least as low as the price that state Medicaid agency pays. 340B prices have been reported to be 25 to 50 percent of the average wholesaler price, or AWP. They are an average savings of 19 to 22

percent of clinic purchases. The 340B savings belong to the entity that is supplying the services. There is no mandate in the law that requires the entity to pass the 340B savings to patients, although many choose to do so.

The statute also provides for a prime vendor who can negotiate additional pricing reductions, called sub-ceiling prices. Entities who participate in the prime vendor program are able to purchase medicines for even less than the 340B ceiling price. The term prime vendor means a preferred agent to negotiate prices with drug manufacturers. Thus, the term prime, or primary, and vendor or seller.

The 340B prices are updated quarterly. They are held confidential by the Health Resource and Service Administration's (HRSA) Office of Pharmacy Affairs (OPA), and they are verified. Manufacturers report price information on their products to the CMS. CMS, in turn, provides this data to the OPA so 340B prices may be calculated. The pricing formula used to calculate 340B prices is specified in the statute, and it is complex.

340B Eligible Entities

A number of the entities may participate in the 340B program. The eligibility to purchase at the 340B price belongs to the entities named in the legislation, these include: community health centers, including a number of subsets, such as migrant health centers, programs at homeless sites, schools, public housing, and the office of tribal programs or urban Indian organizations. Also eligible are HIV/AIDS clinics and their associated Ryan White drug purchasing programs, black lung clinics, hemophilia treatment programs, native Hawaiian health centers, family planning clinics, tuberculosis clinics, and certified sexually transmitted disease clinics. In addition, disproportionate share hospitals, those that take care of a greater portion of indigent people, are also qualified to participate. There are more than 12,000 340B eligible sites in 2007. Eligible entities are not automatically enrolled in the 340B program. They must submit an enrollment form by fax, mail, or online. If qualified, the entity will be added to the official database that lists participating entities at the next quarterly update. The OPA maintains a database of eligible sites that may be accessed at: www.hrsa.gov/opa. Click on covered entity. Determine if you want a list of all the entities, those added this quarter, or those to be added next quarter. The ability to verify entity participation, is especially important to manufacturers, wholesalers, and other service providers who help eligible entities.

The statute defines the following entities:

- (A) Federally-qualified health center (as defined in section 1905(l)(2)(B) of the SSA)

This category includes:

- *FQHC Look-alikes*
- *Consolidated Health Centers (Sec. 330(e) PHSA)*
- *Migrant Health Centers (Sec. 330 (g) PHSA)*
- *Health Care for the Homeless (Sec. 330(h) PHSA)*
- *Healthy Schools/Healthy Communities*

- *Health Centers for Residents of Public Housing (Sec. 330(i) PHSA)*
 - *Office of Tribal Programs or urban Indian organizations (P.L. 93-638 and 25 USCS §1651)*
- (B)** A family planning project receiving a grant or contract under Sec. 1001 PHSA (42 USCS§3001)
- (C)** An entity receiving a grant under subpart II of part C of Title XXVI of the Ryan White Care Act (RWCA) (relating to categorical grants for outpatient early intervention services for HIV disease) - Early HIV Intervention Services Categorical Grants (Title III of the RWCA)
- (D)** A State-operated AIDS Drug Assistance Program (ADAP) receiving financial assistance under the RWCA
- (E)** A black lung clinic receiving funds under Section 427(a) of the Black Lung Benefits Act (30 USCS§901)
- (F)** A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the SSA
- (G)** A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988 (42 USCS§11701)
- (H)** An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act (25 USCS§1601)
- (I)** Any entity receiving assistance under title XXVI of the PHSA (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary
- (J)** An entity receiving funds under section 318 (42 USCS §247c) (relating to treatment of sexually transmitted diseases) or section 317(j)(2) (42 USCS§247b(j)(2)) (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary
- (K)** A disproportionate share hospital (as defined in section 1886(d)(1)(B)) of the SSA -
- (i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this title;*
 - (ii) for the most recent cost reporting period that ended before the calendar quarter involved had a disproportionate share adjustment percentage*

(as determined under section 1886(d)(5)(F) of the Social Security Act) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act; and

(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

Who Can 340B Entities Call a Patient?

Because 340B eligibility belongs to the entities but the ultimate recipients of the drugs are patients, a guideline was issued to clarify under what conditions patients of the entity were eligible for 340B prices. This guideline is referred to as the "definition of a patient."

Specifically, an individual is a "patient" of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if:

- The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
- The individual receives 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; and
- The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.
- An individual will not be considered a "patient" of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.
- An individual registered in a State operated AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHS Act will be considered a "patient" of the covered entity for purposes of this definition if so registered as eligible by the State program.

For more information, please refer to the October 1996 Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992. [ftp://ftp.hrsa.gov/bphc/pdf/opa/FR10241996.pdf](http://ftp.hrsa.gov/bphc/pdf/opa/FR10241996.pdf).

The OPA has proposed a new Patient Definition Guidance in 2007. The new guidance will clarify limitations on covered entity "patient" and provide a clear and enforceable definition. This is essential to preventing non-eligible persons from receiving 340B drugs and to ensure program integrity. The guidance provides specific examples of unacceptable practices and will replace all previous guidances. You can access the

new guidance at: <http://www.hrsa.gov/opa/frn011207va.htm>
Under these proposed guidelines, the criteria determining whether an individual is a "patient" of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) are:

1. The covered entity has 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 drugs;
2. The individual receives outpatient health care services that result in the use of, or a prescription for, 340B drugs as part of the diagnosis and treatment 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. If the individual received health care services from a health care provider employed by or under contract with the covered entity, then the individual may be referred for follow-up care for the same condition by that health care provider, to an outside health care provider and still remain a patient of the covered entity for purposes of this guidance, so long as ongoing responsibility for the outpatient health care service that results in the use of (or prescription for) 340B drugs, remains with the covered entity; 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 are:
 - a. Part of a health care service or range of services for which grant funding or Federally-Qualified Health Center look-alike status has been provided to the covered entity; or
 - b. Provided by a Disproportionate Share Hospital (DSH) or by a location that qualified as a provider-based facility within a DSH under 42 CFR 413.65. If the individual received care from such DSH or qualifying provider-based facility, then the individual may be referred for follow-up care for the same condition by such a health care provider to an outside health care provider and still remain a patient of the covered entity for purposes of this rule, so long as the covered entity (either the DSH or a qualified provider-based facility) retains ongoing responsibility for the outpatient health care service that results in the use of (or prescription for) 340B drugs. To demonstrate the necessary retention of ongoing responsibility for the health care it is expected that, at a minimum, the covered entity will provide health care to the individual in the DSH or the qualified provider-based facility of the DSH within 12 months after the time of referral.

Problematic examples cited in the notice include:

Example 1: Certain Case Management Constructs

HRSA has become aware that some covered entities may be using case management arrangements that inappropriately expand their "patient" populations, diverting 340B drugs to individuals who are not eligible patients of the 340B covered entity. In some cases, the covered entities claim to provide the requisite "health care services" through a third party that operates through a case management construct or call center. Although the covered entity may retain records of the encounters, supervise personnel, oversee billing, payment, and other administrative tasks in the program, the covered entity is not providing the actual outpatient health care services that can be linked to the prescriptions written for the individuals in question.

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.

Example 2: Loose Affiliation Networks

Some DSHs have been contracting with health care providers to create a loose affiliation model for outpatient health care services. The individuals, receiving services from affiliated health care providers, have been filling prescriptions written by these health care providers with 340B drugs. The "contracts" are often simple, one-page documents that do not create contractually enforceable duties or obligations for either the health care provider or covered entity. These affiliation models claim to meet the patient definition by specifying that the individual's health care records would be available at the covered entity, that "responsibility for the patient" would also reside with the covered entity, and that in some instances, individuals would be seen by a case manager at the covered entity at specified intervals.

Under this model, the services being provided directly by the covered entity are often more appropriately characterized as administrative services rather than health care services. Ultimately, the treatment plan followed is determined by the affiliated health care provider and not the covered entity. The ongoing responsibility for the individual's health care resides with the affiliated health care provider and not the covered entity. The individuals enrolled in these programs are treated by health care providers too loosely affiliated with the covered entity for the ongoing responsibility to rest with the covered entity for the patient's health care resulting in the use of, or prescription for, 340B drugs.

This model improperly seeks to expand the definition of a patient beyond that envisioned by Congress in prohibiting the resale of 340B drugs outside the eligible covered entity limits. In particular, HRSA is concerned that the affiliation model extends the ability of covered entities to purchase 340B drugs for individuals who are not receiving healthcare from a health care provider employed by or having a valid, binding, and enforceable contract with the covered entity. In the DSH context, since such affiliated healthcare providers may have privileges without actually being required to provide health

care services at the DSH, HRSA believes that it is reasonable to require that either the prescribing, or the referring, health care provider be employed by or have a valid, binding, and enforceable contract with the covered entity to provide outpatient medical care to patients of the DSH.

Example 3: Provider-Based Designations

HRSA is concerned that a number of DSHs may be attempting to expand their eligible facilities to include locations that are not integrated parts of the qualifying DSH. As noted above, HRSA has chosen to rely on a location's status as a provider-based facility as provided under 42 CFR 413.65 to demonstrate that the secondary facility is functioning as part of the DSH. While HRSA is aware of the 35 mile distance exemption that exists for certain 340B-DSHs under 42 CFR 413.65(e)(3)(i), these DSH provider-based facilities remain subject to the other requirements as set forth in 42 CFR 413.65. This requirement also applies to nursing home facilities, rehabilitation hospitals, hospice, and home health agencies. Please note that even if these facilities qualify as part of the DSH, only patients receiving outpatient health care services in these facilities would be eligible to receive 340B drugs. In addition, if HRSA suspects that these entities are being improperly designated as provider-based facilities, HRSA will decline to add the facilities to the HRSA 340B database of covered entities until it has received portions of the Medicare Cost Report demonstrating provider-based status and/or the attestation of provider-based status the covered entity provides to its fiscal intermediary pursuant to 42 CFR 413.65. Likewise, if HRSA discovers that certain covered entities may have improperly listed facilities on the 340B database with the implication that they are provider-based, HRSA will request the covered entity to provide the relevant portions of the Medicare Cost Report and/or attestation within 45 days to verify the facility's provider-based status and to verify that such health care services are being provided on an outpatient basis. If HRSA does not receive appropriate documentation to verify provider-based status within this time period, it will remove the facility from the 340B covered entity database. The covered entity shall be required to notify HRSA immediately if its provider-based status has been rejected or questioned by CMS or its fiscal intermediary. In cases where provider-based status has been rejected, the facility will be removed from the 340B covered entity database immediately.

Example 4: Employees

HRSA receives many questions about whether employees of a covered entity are "patients" for purposes of the 340B Program. These questions come from covered entities that provide health care coverage to employees under their own self-insured health plan, and those whose employees have third party health coverage as an employment benefit. Employees of a covered entity, regardless of their health care coverage, are not considered patients of the covered entity for the purpose of the 340B Program unless they receive health care from a provider employed by or under contract with the covered entity. The fact that the person is an employee of the covered entity, or that they receive health care benefits from their covered entity-employer is not relevant. The relevant

circumstance is that the employee is a patient of the covered entity. If an employee is a patient of another provider in the community, and is referred to and receives health care from the covered entity, they can receive 340B drugs only if the other provisions of the patient definition are met. Where a covered entity operates a self-insured health plan, the covered entity retains the requisite responsibility for the individual as a patient only if the individual receives outpatient health care services under the terms of this notice. Responsibility for the patient does not extend to cover the individual if the covered entity's sole responsibility for the individual is as the administrator of its self-insured plan. Meeting administrative requirements for maintaining employee health records so as to ensure that the employees are compliant with both State and Federal health care provider regulations alone, is not sufficient for the purpose of establishing patient eligibility for the 340B Program. Rather, the covered entity must provide health care to these individuals that results in the use of, or prescription for, 340B drugs. Furthermore, employees who merely receive required health physicals as a condition of their employment by a covered entity with no other health care provided are not patients of the covered entity.

Example 5: Indian Tribes and Tribal Organizations

In the case of Indian tribes or tribal organizations, any attempt to serve non-Indian Health Service beneficiaries must receive prior formal approval by the Indian Health Service.

Example 6: Grantee Subgrantees and Subcontractors

In certain circumstances, organizations may be functioning as subgrantees to grantees who are eligible to purchase 340B drugs (section 340B(a)(4) of the PHS Act). In these situations, subgrantees are reminded that they must meet the standards set forth in 45 CFR Part 74 and 45 CFR Part 92, as applicable. As subgrantees of a covered entity's grant, these organizations are eligible to access 340B drugs for only those patients to whom they are providing health care services under the scope of their subgrant. In these instances, individuals may only receive 340B drugs for the pharmaceuticals utilized under the scope of the project for which grant funds were received by the subgrantee.

Subgrantees must register with HRSA in order to participate in the 340B Program and must be listed in the HRSA 340B database of covered entities to purchase 340B drugs. Subgrantees must maintain information systems that permit them to segregate the 340B eligible patient population from the rest of their patients, and to order 340B drugs only for 340B eligible patients.

If an entity is a subcontractor of a covered entity, rather than a subgrantee, all 340B drugs must be purchased by the covered entity. The covered entity, in turn, must maintain records documenting its purchase of 340B drugs for its subcontractors. Both the covered entity and the subcontractor would be responsible for ensuring the 340B drugs were ordered only for the portion of the subcontract which is within the scope of a covered entity's grant.

Additional requirements and prohibitions were associated with the 340B program. Requirements include keeping

accurate records to document that no prohibited activities have occurred. Manufacturers and the federal government may also audit entities and if any compliance problems are found, the entity may have to pay back discounts to the manufacturer. In addition, the prohibitions associated with the 340B program include: an entity cannot resell or transfer a 340B drug to a person who is not a patient of the entity. This is called diversion, and it is specifically prohibited. The entity cannot participate in both group purchasing organization pricing and 340B pricing for their outpatient drugs unless they buy through the prime vendor program.

Finally, entities cannot double dip. Medicaid programs typically receive rebates on drugs purchased for patients. The rebates are dollar amounts paid by the manufacturers to Medicaid after the sale of the drug. The 340B legislation specifically prohibits double-discounts, that is, charging the manufacturer both the rebate and 340B discount on the same drug. To ensure there is no overlap of 340B drug discounts and Medicaid rebates, the Office of Pharmacy Affairs requests the Medicaid billing status and number of the entity and maintains this information on their website. Medicaid agencies receive an exclusion list each quarter from the Office to ensure that they are not requesting a rebate of drugs purchased for 340B patients.

Medication Access and Pharmacy Service Options

Once an entity has signed up to participate in the 340B program they need to decide what drug delivery system they are going to implement. There are three traditional methods. These include when medication is administered and/ or dispensed to patients by providers such as nurses and physicians; the entity may create an in-house pharmacy, or it may contract with an outside pharmacy for services.

The 340B program permits entities that are eligible to participate in 340B to contract with external pharmacies to provide pharmacy services to the covered entity's patients. Current guidelines allow each entity site to contract only with a single pharmacy for services. Since 2001, HRSA has allowed the development of Alternative Methods Demonstration Projects (AMDPs), some of which have permitted covered entities to contract with more than one pharmacy or to use an outside pharmacy to supplement in-house pharmacy services. To date, there has been no evidence of drug diversion or duplicate manufacturers' discounts on 340B drugs in the AMDP program. The success of these projects has served as the basis for a proposed change in the program that would allow entities to contract with multiple pharmacies and to utilize contract services to supplement an in-house pharmacy.

The covered entity would bear the responsibility for full compliance with the 340B program requirements, such as preventing diversion and duplicate discounts and maintaining appropriate records. Additionally, the contract pharmacy and covered entity will abide by all Federal, State, and local laws and requirements. Finally, each covered entity using contract pharmacy services would be required to complete, along with the contract pharmacy, a self-certification that all parties are in compliance with all 340B program standards. Such

requirements would apply whether a covered entity chooses to contract with a single pharmacy or with multiple pharmacies.

The proposed guidance also contains a suggested model agreement format and suggested contract provisions in the document's Appendix. You can access this information at: <http://www.hrsa.gov/opa/frn011207.htm>

340B entities have many considerations when determining how to offer pharmacy services. These include:

- Potential to serve the underserved
- Best service availability
- Proven competency
- Ability to attract patients
- Use of limited facilities
- Start up and operating costs
- Personnel & staffing issues
- Management issues
- Provision of clinical services
- Inventory management

Fortunately, they are able to access expert consultants through PSSC's Pharmacy Technical Assistance Program, many of whom are community pharmacists. Entities are able to use PharmTA services to design programs to contract for pharmacy services with community pharmacies. Contracts range from providing medication dispensing services, to managing manufacturer prescription assistance programs (PAPs), and providing comprehensive medication therapy management and clinical services.

Partnering with 340B eligible entities to provide services presents an excellent opportunity for community pharmacists to help the underserved community.

Besides PAPs (see pparx.org for a comprehensive website of manufacturer programs and patient eligibility checking and enrollment), other methods used by safety net providers and their pharmacy partners include: generic dispensing, medication formularies, samples, state assistance programs, among others.

340B Resources

340B program resources all focus on the program's mission of integrity, access, and value.

The primary integrity resource is the OPA, which is a component of the Health Resources and Services Administration Healthcare Systems Bureau. OPA has three primary functions:

- ❖ They administer the 340B program.
- ❖ They develop innovative pharmacy services models.
- ❖ They provide technical assistance.
- ❖ They serve as a federal resource about pharmacy practice, and
- ❖ They promote comprehensive pharmacy services as being an integral part of primary health care.

Comprehensive pharmacy services include patient access to affordable pharmaceuticals, application of "best practices" and efficient pharmacy management and the application of

systems that improve patient outcomes through safe and effective medication use.

The Pharmacy Services Support Center

The primary access resource is the Pharmacy Services Support Center, or PSSC. PSSC was established in September 2002 through a contract between HRSA and the American Pharmacists Association (APhA.) The mission of PSSC is to provide information, education, and policy analysis to help eligible entities optimize the value of the 340B program and provide clinically and cost effective pharmacy services that improve medication use and advance patient care. PSSC operates a call center, a web-site, and outreach program to assist all 340B stakeholders. In addition, it offers pharmacist-expertise to 340B entities through its Pharmacy Technical Assistance Program.

Concise, easy to follow information can be found on the HRSA Pharmacy Services Support Center (PSSC) website (<http://pssc.aphanet.org>) or visit the HRSA Office of Pharmacy Affairs Web site at www.hrsa.gov/opa for more information. You can also contact the PSSC at pssc@aphanet.org to get answers to your specific questions regarding the 340B Drug Pricing Program.

Contact PSSC to learn more about becoming a contract pharmacy partner and keep your eyes open for sessions at national and state meetings highlighting pharmacy services in the underserved population