



**AFFORDABLE PRESCRIPTION DRUG PROJECT
340B Drug PROGRAMS Q&A SESSION
MEETING RECORD**

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Record: Deb Helber, Consultant

Welcome & Framing

Jeff Biehl welcomed everyone to the 340B Drug Program Q&A session. In continuing to engage the community in exploring strategies on how we bring more affordable prescription drugs into Franklin County, Access HealthColumbus is inviting “content” experts to come and engage in conversations with us around the questions that emerged from the Kick-Off Meetings.

Katheryne Richardson, RPh, PharmD, Director of Quality Improvement at the HRSA Pharmacy Services Support Center joined us to explore our questions around 340B Drug Programs.

Basics of 340B

What is the 340B Drug Pricing Program? The 340B Drug Pricing Program was enacted in 1992 and limits the cost of covered outpatient drugs to certain federal grantees, federally-qualified health center look-alikes and qualified disproportionate share hospitals. Significant savings on pharmaceuticals may be seen by those entities that participate in this program. Manufacturers that participate in Medicaid must also sign an agreement to participate in the 340B Drug Pricing Program.

Why 340B? 340B was developed as a way to help reduce prescription drug expenditures - subsidies - by safety net providers in order to expand health services access to low-income individuals/families and vulnerable populations. It was also intended to reduce taxpayer burden. 340B offers one of the lowest medication prices in the U.S. Although pricing is confidential, they average savings for covered medications is estimated to be between 25% - 50%. But, since pricing is confidential it is difficult to tell if manufacturers are really offering the “right” price.

What are the requirements and prohibitions?

- ***Eligible entities*** are defined in the law and include:
 - FQHC Look-alikes
 - Consolidated Health Centers
 - Migrant Health Centers
 - Health Care for the Homeless
 - Healthy Schools/Healthy Communities
 - Health Centers for Residents of Public Housing
 - Office of Tribal Programs or urban Indian
 - A family planning project receiving a grant or contract under Sec. 1001 PHSA (42 USCS§3001)
 - An entity receiving a grant under subpart II of part C of Title XXVI of the Ryan White Care Act (RWCA)
 - A State-operated AIDS Drug Assistance Program (ADAP) receiving financial assistance under the RWCA

- There is a requirement to establish a ***prime vendor***. The primary mission of the 340B Prime Vendor Program (PVP) is to improve access to affordable medications for covered entities and their patients. The program is free and voluntary to facilities that are already 340B eligible. The prime vendor contracts with all the major wholesalers – the prime vendor asks for sub-340B pricing. The current prime vendor is HealthCare Purchasing Partners International (HPPI).

HPPI's primary goals are to:

- Educate & market the advantages of the PVP to eligible covered entities, suppliers, and drug wholesalers
- Lower participant's supply costs by expanding the current PVP portfolio of sub-340B priced products
- Provide covered entities with access to efficient drug distribution solutions to meet their patient's needs
- Provide access to other value added products and services meeting covered entities' unique needs

They also offer reduced pricing on non-340B products, such as alcohol swipes. They are able to do this through the combined purchasing power of the covered entities.

- The law is unclear about the requirements for **record keeping**. There is not an agency that regularly audits 340B programs. The language refers to "customary business records" but does not define what those are.
- "**Double-dipping**" – participating entities benefiting from both the Medicaid rebate and 340B discount – is not allowed. A participating entity can do a carve-out – they can use 340B for all patients except those on Medicaid. That way they can bill Medicaid at the regular price.
- 340B entities are not allowed to **resell or transfer medications** they purchase through this program. They are not required to pass on 340B savings to the patients – they can set prices so they can subsidize other patients/services.
- The law defines an **eligible patient** as one who:
 - Has an established relationship with a covered-entity – a patient cannot be sent to a covered-entity just to fill a prescription.
 - Receives care from employed or contracted provider of a covered-entity
 - Services are provided consistent with funding received, for example, a Family Planning Clinic can only use 340B for family planning medications or an AID's clinic can only use 340B for AID's related medications.

What options are there to implement a 340B program?

- The program requirements are flexible – but **programs must adhere to law and guidelines**. New guidelines are coming out all of the time. Two new guidelines that are expected soon are:
 - To contract with multiple pharmacies will no longer require special approval (<http://www.hrsa.gov/opa/frn011207.htm>)
 - The definition of an eligible patient will be clarified as (<http://www.hrsa.gov/opa/frn011207va.htm>):
 - 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;
 - 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

- The outpatient health care services the individual receives from the covered entity that result in the use of, or prescription for, 340B drugs are:
 - 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
 - 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.

- As a result of discussions with covered entities, the Office of Pharmacy Affairs has established a formal process of considering the testing of ***alternative methods of participating in the drug discount program*** established by section 340B of the Public Health Service Act. Approved time-limited demonstration projects will be carefully evaluated based on the benefits provided and compliance with requirements of the 340B law. If these demonstrations are successful, the new methods of accessing discounted drugs will be incorporated into the 340B program's published guidelines.

Projects that involve one or a combination of the following features will be considered:

- The development of a network of covered entities,
- The use of multiple contracted pharmacy services sites, or
- The utilization of a contracted pharmacy to supplement in-house pharmacy services.

There are "turn-key" 340B services – if interested in this option an organization should perform a cost/benefit evaluation.

Who is the Office of Pharmacy Affairs (OPA)?

OPA has three primary functions:

- Administration of the 340B Drug Pricing Program, through which certain federally funded grantees and other safety net health care providers may purchase prescription medication at significantly reduced prices.
- Development of innovative pharmacy services models and technical assistance.
- Service as a federal resource about pharmacy.

The Pharmacy Services Support Center (PSSC) provides the following services & activities:

- **Technical Assistance (PharmTA)**
 - National consultant team
 - No cost to covered-entity
 - On-site, e-mail and telephonic support
- **Information management**
 - Organizing pharmacy expertise and resources
 - Responding to 340B inquiries
- **Policy analysis**
 - Monitoring pertinent policy developments
 - Communication and education on policy issues and Medicare
- **Networking**
 - Communication and education
 - Project development

Clinically and Cost Effective Pharmacy Services

Katheryne reminded us that just going with after the “cheapest” drug is not always the best drug to use. There are challenges with giving patients sample drugs, which are free, but may be limited in availability. Providers may have to switch samples to keep the patient supplied with medication, which could create adverse outcomes.

Clinically and cost effective pharmacy services involves operations, access, quality and outcomes. Maximizing pharmacy care for patients can include:

- Drug formulary management
- Patient-specific counseling, education and monitoring
- Medication education for providers
- Health promotion seminars
- Collaborative disease management
- Seeking reimbursement for services
- Immunizations
- Drug utilization review

Impact of Deficit Reduction Act on 340B

- The Average Manufacturer Price (AMP) changes will impact the 340B calculation.
- Exclusion from best price – if manufacturer’s prices for 340B fall too low it will impact what they offer in their “best price”

Strategies Used in Other Community Systems

- College of Pharmacy involvement – In one community the College of Pharmacy and the Health Department each pay 50% for a pharmacist who staffs a pharmacy for low-income individuals. They are able to provide a constant supply of labor with students from the college.
- PBM managed benefit – Cardinal offers this service. Walgreen provides this service in a community in Florida. There will be a fee involved but they collect and store data for contracting entity.
- Patient eligibility/enrollment triage to 340B providers
- Hybrid: 340B + PAP + Samples
- Generic formulary only
- Community networks for 340B (Alternative Method Demonstration Project) – different providers come together to provide 340B.
- Patient co-pays, sliding fees – based on income, family size, etc.

Contact Information

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Web: www.hrsa.gov/opa

PHARMACY SERVICES SUPPORT CENTER

Phone: 1-800-628-6297

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PRIME VENDOR PROGRAM

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Q&A Session

A summary of the Q&A session conversation is outlined in the following chart. Some potential strategies that emerged that the community could explore are:

- How could we design a community approach to utilize 340B, including mental health services?
- How do we build a cost-effective community formulary and how would we maintain it?

Q&A Session

Theme	Question	Response/Discussion
Pricing	What pricing is Access HealthColumbus now getting through its program with Kroger's? Is it 340B?	- A patient's medical home has to be a covered entity to receive 340B pricing.
	When the AMP takes off, will there be a decrease in the positive revenue stream in 340B?	- Yes, but it's not knows how much the margins will decrease.
	What is the difference between AWP and AMP?	- Average Wholesale Price (AWP), which is what was used to calculate discounts, was intended to be an average across all wholesalers. It turned out to be just one wholesaler so it wasn't a true reflection of AWP. Average Manufacturer's Price (AMP) is supposed to be a truer number, but AMP lacks transparency. Also AMP's are leaving off the package size so the amount of pills in a bottle that is being priced is unknown.
	If you are a covered entity and you have privately insured patients, what price is billed to the insurer?	- When negotiating with a PBM or when contracting with a 3 rd party payer, they usually spell out what they will pay. So, they should pay the negotiated price, which would provide the covered entity a profit on the medication. But, some PBM's and 3 rd party payers are beginning to put language in around 340B, i.e. if you are purchasing the medications through 340B they will reimburse you at that price. - This would hold true for Medicaid HMO's but not for Medicaid FFS.
Patient Eligibility	If a patient's primary care site is a covered entity but their prescription is written by a specialist can it be purchased through 340B? If yes, how is it enforced?	- If the patient is referred to a specialist by a provider within a covered entity, then yes, they can utilize 340B pricing to fill the prescription. - It is not enforced. No audits are conducted at this time. The deterrent in the law is that the covered entity must uphold the guidelines are risk being ineligible for the program. It is expected that in the future it will be enforced.
	Any chance that qualification for 340B will rest with the patient, not the entity?	- No. Patients don't lobby – it's the groups that lobby for the program that want to keep eligibility within their control. - The clarification of the definition of patient will be more specific then it is now.
Community Network	Could you have a centralized community pharmacy?	- Yes. It does require a lot of upfront work. It could be done using a central pharmacy that has contracts with all participating 340B entities or have all participating 340B entities become partners. Ownership and control issue in the second option may make this more complicated, as will sharing a formulary.
	What is the process for submitting an AMDP?	- There is a formal process outlined on the OPA website. It is very specific. - It takes about 6 months to get approval.
	Is there a community that has a best practice community network?	- Columbus, Georgia (find a link under the AMPD) - Spokane, Washington
	Are there any financially sustainable network models?	- Spokane is. - Have seen one fail

		<ul style="list-style-type: none"> - Payer mix will determine if the network will be financially sustainable. PSSC can run a model, based on the payer mix of the different participating entities, to predict if the network can be financially sustainable.
	Do we know the savings we get as a community network? How many patients are not getting 340B pricing that are eligible?	<ul style="list-style-type: none"> - There is an assessment form that can be used to determine what this might be. It helps identify the percent that are not being captured and what the total possibility might be. - In Columbus, we have some covered entities who are not working with 340B. - There is also an issue of affordability – supply (access) can be increased by having all covered entities participating. Demand (who has difficulty in accessing medication) is impacted by each individual's definition of what is affordable. - 340B is a piece of the puzzle. Most models are hybrids. Payer mix impacts sustainability, as does inventory control.
	What are the advantages of a network approach?	<ul style="list-style-type: none"> - The advantage is that you spread risk over a larger group. - If it is a jointly owned entity the profits go back to each individual entity. There would have to be language in the contract that specifies those profits come back into the program to help support the community – if that is the intent.
	How could we design an approach as a community?	<ul style="list-style-type: none"> - Need to have: <ul style="list-style-type: none"> o Agreement o Trust o Shared formulary
Mental Health	Is there a community with a best practice model for mental health services and 340B pricing?	<ul style="list-style-type: none"> - It has been done through a DSH. To do this through a FQHC, mental health services must be within their scope of services.
Inventory	Can 340B inventory be kept “virtually”?	<ul style="list-style-type: none"> - Yes, it no longer as to be kept separate, physically.
Data	Is there data on what's best for patients with regards to access, compliance, and quality?	<ul style="list-style-type: none"> - Yes. The Senate has asked the same question. The data is being looked at right now. - There was also a study a couple of years ago – an outcome based report. What it showed was there is not one best model because the needs of patients are so different. - Clinical Pharmacy data in underserved populations: The purpose of these projects was to examine the effects of expanded access to clinical pharmacists and comprehensive pharmacy services on the health outcomes of medically underserved populations. This report is an evaluation of expanded access and improved outcomes due to the Clinical Pharmacy Demonstration Projects. <ul style="list-style-type: none"> o Volume I (data) -ftp://ftp.hrsa.gov/bphc/pdf/opa/CPDPvolume1finalreport.pdf - Volume II (case studies) - ftp://ftp.hrsa.gov/bphc/pdf/opa/CPDPvolume2finalreport.pdf
	Is there a demographic analysis?	<ul style="list-style-type: none"> - Yes. - Prescription and associated cost data in special populations: visit the AHRQ website: http://www.meps.ahrq.gov/mepsweb/

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