Does 340B make sense for your pharmacy?

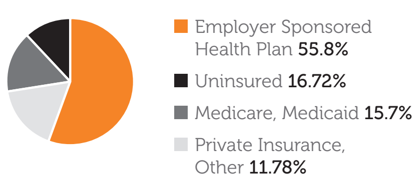
As a mechanism for providing discounted prescription medications to the people who can least afford them, Section 340B of the Public Health Service Act offers pharmacies an opportunity to positively impact their communities, open new relationship channels with providers and create additional revenue. But, as with any government program, 340B also presents significant challenges.

When 340B became law in 1992, few lawmakers anticipated the recent economic downturn or the impact it would have on Americans' ability to pay for health care. Whether those lawmakers were prescient or just lucky, 340B has become a literal lifesaver for millions of Americans.

THE PROBLEM: MILLIONS WITHOUT HEALTHCARE OR A WAY TO PAY FOR IT

The nation's economic woes have left as many as 30 percent of Americans struggling to pay for physician visits and medications, especially those with chronic conditions. Only 68 percent of Americans have employer-covered health care plans or private insurance (Figure 1). According to MSNBC[1], from 2008 through 2010, the number of uninsured grew by over 4 million people, with 3.8 million additional people living in poverty.

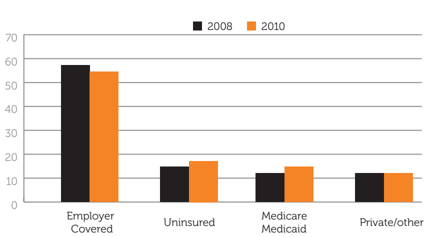
Figure 1: **2010 Census Figures % of US Population**



The totals are painful:

- 50.7 million Americans lack health insurance coverage.
- 15.7 percent of the US population or nearly 48 million Americans rely on Medicare or Medicaid.
- 43 million Americans are living in poverty.

Figure 2: **Comparison of 2008 Statistics and 2010 Census % of Americans**



Urban, suburban and rural Americans in every state are affected; however, some regions are impacted more than others, due to more severe job losses, outsourcing and off-shoring by industry, and state funding deficits.

No one expects pharmacies to single-handedly reverse the effects of the Great Recession on our ability to provide health care. However, many pharmacies are searching for ways to make a difference in their communities by helping to provide necessary medications to the people who cannot afford them.

340B: PART OF THE SOLUTION

Defined and overseen by the Office of Pharmacy Affairs (OPA) and managed by the Health Resource and Services Administration (HRSA), the 340B program enables patients of eligible hospitals, clinics and health centers ("covered entities") to receive their medications at prices discounted as much as 50 percent off retail by filling their prescriptions at a pharmacy contracted with the entity.

What is in it for the pharmacy?

The revenue generated from 340B participation comes not only from sound dispensing fees, but also from increased store traffic, enhanced customer loyalty, reaching a larger market and joint promotional opportunities with contracted entities.

While it's the patients' ultimate decision where to fill their prescriptions, it's a win-win scenario when the qualified prescription is filled at a contracted pharmacy, as the entity and pharmacy both receive the financial benefit. As of May 2010, there were 2,600 340B-contracted pharmacies[2], a number reflecting significant growth that is expected to continue.

There are intangible as well as financial incentives for pharmacies who participate in 340B. Many health centers and clinics are facing financial dilemmas directly attributable to decreased state funding. 340B participation helps entities generate additional income and reduce or eliminate budget shortfalls in these entities that would have otherwise lead to lost jobs and fewer services. Finally, there's the pride that comes with changing lives for the better.

KEY CONSIDERATIONS OF 340B PARTICIPATION BY PHARMACIES

The four key elements a pharmacy must consider when making the decision to become a 340B-contracted pharmacy are, not surprisingly, the same four considerations that determine the ongoing success of participation. These four issues are related to eligibility, customer segmentation, inventory management and compliance.

1. **Eligibility:** Determining whether a customer qualifies for 340B pricing.

To initiate the process, an individual must visit a 340B-qualified hospital, healthcare center or clinic to receive 340B-priced prescription drugs. (HRSA specifies that 340B discounts may be applied to prescriptions associated only with outpatient services.) However, there still are very strict guidelines that govern whether patients who receive care at a

340B-covered entity qualify for discounted medications. The criteria[3] include:

- The covered entity must have established a relationship with the patient, such that the covered entity maintains records of the individual's health care; AND
- The patient 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; AND
- The patient must receive 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.)

Qualifying patients for 340B pricing can be complex, but is essential to participation in the program. The 340B process must efficiently and effectively check each patient for compliance against these criteria, and this consideration should be a pharmacy's first acid test when selecting a 340B provider. The law is clear; a pharmacy may only replenish inventory at 340B rates if the customer(s) responsible for the depleted inventory has been 340B-qualified. If a pharmacy receives replenishments of 340B-priced medications without associating them to a qualified 340B customer, the pharmacy:

- Could fail an audit;
- Be fined by HRSA;
- Pay for the unqualified distributions at retail cost; and
- Lose its right to distribute 340B medications.

2. Customer Segmentation: Who are your customers and how best can you serve them?

Three categories of customers are qualified to receive 340B pricing on the prescriptions they receive from covered entities:

- Indigents or those living locally in poverty,
- Entity employees; and
- Third-party payer patients.

Third-party payer customers can be qualified at POS or retroactively; either way, their experience is the same. Third-party customers generally do not receive a discount for 340B drugs; they are responsible for paying only their co-pay.

Like any business, pharmacies seek to reduce costs, increase revenue and improve profitability. While pharmacies may feel a moral obligation to serve customers who cannot afford to pay for their medication, the cost of doing business with a large population of indigents can have a significant impact on a pharmacy's bottom line. However, a 340B contract pharmacy can insulate its business from the need to discount drugs at a loss by creating a contract that includes a dispensing fee for every 340B transaction. Additional cost savings are realized because the entity must pay the cost of replenishing the drugs dispensed to 340B-qualified customers.

Pharmacies may already serve customers in their communities who cannot afford to pay for medications at discounted rates, which may include 340B-qualified customers. These pharmacies often employ a sliding scale or an adjusted rate of pay defined by the customer's income. However, even when servicing 340B customers through a sliding scale process, the pharmacy still sends collected funds to the entity, and the entity is still responsible for paying the pharmacy's dispensing fee and the 340B cost to replenish the drugs.

It is critical for a 340B-contracted pharmacy (or its 340B service provider) to build a best-practice process for determining whether 340B customers are indigents or entity employees at the point of sale. This is so that:

Figure 3: Money flow for a third-party customer purchasing a $100 drug

- The pharmacy can receive the sound dispensing fee associated with 340B; and
- The pharmacy's medications can be replenished at the 340B rate by the entity.

Figure 3 summarizes an example cash flow associated with third-party transactions.

1. A customer pays a $10 co-pay for a $100 retail medication.
2. The customer's healthcare provider pays the difference in cost ($90).
3. The contracted pharmacy pays the money it receives from the co-pay and from the health care provider to the entity ($100 in this example).
4. The contracted pharmacy receives a $12 dispensing fee from the entity.
   – The entity pays the distributor $50 to replenish the medication for the pharmacy.
   – The entity retains the $38 difference.

3. Inventory Management: Determining whether you need to maintain a separate inventory or whether you can maintain a virtual inventory.

Inventory recordkeeping—maintaining a record of medication on-hand and dispensed—is a critical operational function for every pharmacy, but 340B complicates this process. 340B-dispensed drugs must be tracked separately so that they are replenished properly. Most states allow pharmacies to keep a virtual inventory of 340B medications, which is definitely an advantage for the pharmacy.

This process uses a 340B service provider's technology to maintain and track a separate, "virtual" inventory of 340B drugs while the pharmacy need only manage a single physical inventory of all their drugs. The virtual inventory method enables the pharmacy to replenish inventories of 340B-dispensed drugs at 340B rates by using the 11 NDC code.

For the pharmacy, the key advantages of a virtual inventory are:

- Lower start-up costs associated with servicing these new patients, as the medications are typically already on-hand (or start-up costs may be deferred to covered entities);
- Lower ongoing maintenance costs associated with maintaining a separate physical inventory, including floor and shelf space, manpower and paperwork; and
- The pharmacy doesn't have to make any changes to its processes or procedures.

A few states require separate physical inventories for retail and 340B medications, which requires the pharmacy to order duplicate medications to serve their 340B clientele. Pharmacies should contact the state Board of Pharmacy to determine whether their states require a separate inventory for 340B drugs; if a pharmacy has locations in more than one state, this determination must be made in each state in which the pharmacy operates.

The pharmacy's 340B service provider should create best-practices procedures for implementing and maintaining the appropriate inventory method and replenishment process for each location.

4. **Compliance:** In advance, at POS, ongoing and easily auditable

As with any government-run program, 340B brings with it a set of detailed compliance requirements that pharmacies must meet. In addition, that compliance must be easily demonstrated and auditable so the pharmacy doesn't spend so much on compliance resources that the program becomes burdensome.

Key to compliance for a 340B-contracted pharmacy is the ability to audit the connection between the customer's qualification information and the medication dispensed. To ensure efficiency and peace of mind at audit time, pharmacies should make sure their 340B service providers have best practices procedures in place for comprehensive and precise inventory tracking that easily connects customers' qualifications with the dispensed and replenished quantities of 340B medications.

HOW TO BECOME A CONTRACT PHARMACY

To qualify for 340B participation, a pharmacy must register with the OPA as well as contract with at least one covered entity. There are many types of entities that may be qualified by OPA for 340B by OPA, including:

- Disproportionate share hospitals (DSH)
- Children's hospitals
- Critical access hospitals
- Rural referral centers
- Free standing cancer hospitals
- Sole community hospitals
- Ryan White Clinics
- Title X Family Planning clinics
- State-operated AIDS clinics
- Black lung clinics
- Comprehensive hemophilia treatment centers
- Sexually transmitted disease clinics
- Native Hawaiian health centers
- Urban Indian organizations

The easiest method to contract with an entity is to build a relationship with an existing 340B-qualified site. Pharmacy decision-makers can contact one or more local qualified entities on the HRSA website at http://opanet.hrsa.gov/opa/default.aspx .

Once a partnership opportunity is agreed upon, the pharmacy and entity must create a contract containing the agreed-upon dispensing fee, which is typically greater than the dispensing fee associated with drugs at retail pricing. Additional conditions may be included in the contract upon the agreement of both parties. Sample contracts are available at http://www.hrsa.gov/opa/legalresources.htm. The site also contains links to frequently asked questions about 340B, recorded webinars and help desk call center numbers.

ABOUT PDMI

Pharmacy Data Management, Inc. (PDMI), founded in Poland, Ohio, in 1984, provides custom technology and other solutions for managing health through prescription drug programs for national and regional health plans, hospice organizations, drug manufacturer assistance programs and other health care-related industries.

[1] *Galewitz, Phil and Villegas, Andrew (2010, September 16) Number of uninsured Americans hits record high, msnbc.com, Retrieved from http://www.msnbc.msn.com/id/39215770/ns/health-health_care/*

[2] *Slafsky, Ted (2010, May 10) Challenges and Opportunities Under the 340B Program, Safety Net Hospitals for Pharmaceutical Access*

[3] *Retrieved from HRSA website at: http://www.hrsa.gov/opa/patientdefinition.htm*

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