The 340B Drug Discount Program

An Introduction for Healthcare Professionals

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Introduction

The Federal 340B program provides deeply discounted drugs to 'safety net' hospitals. Hospitals which qualify for the program receive significant rebates on drugs provided to their outpatients, subsidized by drug manufacturers. Currently approximately 2% of all U.S. drug purchases are made through the 340B program.

Origin and Purpose

The 340B program was established by the U.S. Congress as part of the Veterans Healthcare Act of 1992. The Committee on Energy and Commerce, based on research by the Committee on Veterans' affairs, recognized a continual increase in drug prices to the Department of Veterans' Affairs. Since drugs for other Federally subsidized hospital and clinic groups shared the same list of drugs, the Committee recognized that providing a consistent drug-pricing policy across all these healthcare providers would be beneficial.

The 1992 legislation authorized several classes of covered entities" to participate in the program: Federally-Qualified Health Centers (FQHCs), family planning projects receiving grants, HIV early-intervention programs, AIDS drug purchasing assistance programs, black lung clinics, hemophilia diagnostic treatment centers, Native Hawaii Health Centers, urban Indian organizations, tuberculosis clinics, and public or non-profit Disproportionate Share Hospitals (DSHs).

Each covered entity would receive a rebate on all its drugs purchased for outpatient use from the manufacturer of each drug. This rebate system is very similar to the way Medicaid is set up. In fact, manufacturers are required to participate in the 340B program if they wish to list any of their medications on the Medicaid formulary.

The Health Resources and Services Administration (HRSA) was assigned as the regulator. HRSA was charged with developing specific definitions and guidance for covered entities.

Eligibility

The 340B program is a "replenishment" program, meaning that a hospital eligible for the program may *replenish* their inventory of drugs given to eligible patients. In order for a given dispense of a drug to a patient to be considered eligible, the patients themselves must be treated at the hospital and the prescription they are filling must be related to that treatment at the hospital.

In 1996, HRSA specified the following *Definition of a Patient* for hospitals to use as a guide in determining which dispenses to their "patients" would be eligible:

> An individual is a "patient" of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if:
>
> 1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
> 2. 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...

These guidelines mean that most dispenses provided to patients through a hospital's outpatient pharmacy are considered eligible. Exceptions include non-hospital patients using the pharmacy out of convenience, employees of the hospital who may not have been seen at the hospital, and physicians self-prescribing drugs outside their specialty.

Counter-Intuitive Aspects

In coming to understand the ins and outs of the 340B program, it's useful to highlight a few aspects that aren't necessarily obvious. Based on the political nature, certain provisions of the law and regulation may not seem to be completely consistent with the apparent intent of the program.

340B Eligibility is not proportional to Safety Net Service

The 340B program is intended to help support safety net hospitals, which are designated based on whether they meet the threshold of being critical to indigent populations. Eligibility to participate in the program, however, is not proportional to the extent to which a hospital provides indigent care; a hospital either completely qualifies for the program or fails to. A Disproportionate Share hospital (DSH) qualifies if it serves 11.75% of indigent patients or higher. It gets no additional benefit from serving a higher proportion of needy patients, nor are there limits to the savings by being just over the threshold.

A consequence of this all-in eligibility criterion is that some hospital systems may be incented to reorganize their ownership of clinics and hospitals or make other changes to their services such that more of their entities qualify for the program. Purchasing an outpatient clinic that services a large number of indigent patients and incorporating that clinic into an otherwise ineligible hospital would be one example of such a change.

The Third-Party Payer is Not Relevant to Eligibility

Because the program applies to all outpatient dispenses, whether a given patient is insured, self-paying, or indigent is not a factor in determining eligibility for 340B drug replacement. A fully insured patient may get a prescription filled through a hospital's outpatient pharmacy and get the full benefit of 340B. The patient would pay their typical copay, and the insurance provider reimburses the hospital at the usual and customary drug cost, but the cost to the hospital to replace that drug is nevertheless at the vastly discounted 340B price.

The GPO Exclusion

Most drugs are delivered to hospitals and hospital systems through drug wholesalers such as Cardinal, McKesson, and AmerisourceBergen. While each wholesaler has a "list price" for each drug, the vast majority of purchases through wholesalers are made through a Group Purchasing Organization (GPO), or similar arrangement. GPOs offer pre-negotiated prices for pharmaceuticals based on the collaboration of a group of entities. Some GPOs are simply large enough hospital networks that they can establish volume-based pricing with wholesalers directly. Smaller hospitals and clinics may become voluntary members of organizations such as Premier, Provista, or Novation, which negotiate group deals directly with manufacturers on behalf of members. GPO prices then reflect prices at the market value of each drug based on changes in availability and demand, and whether a given drug has a generic version available.

This is in contrast with the relatively static Wholesale Acquisition Cost (WAC). Despite the "acquisition" component of the label, WAC is actually a manufacturer-specified *list price* for a drug, from which rebates, and negotiated discounts are deducted.

Like a retail list price on an expensive item, it is generally a reference price which is more than any buyer would actually pay. The important exception is 340B, where two categories of eligible covered entities may not purchase "covered outpatient drugs" using a GPO or any similar relationship. A Disproportionate Share hospital (DSH), freestanding cancer hospital and Children's Hospitals are prohibited from making *any* purchases using a negotiated discount for any of their outpatient drugs, even if a given patient is not 340B eligible. In principle, this means it's actually possible that, given few enough eligible dispenses, a hospital may pay more for its drugs overall with the discount program than without. While we're not aware of an actual case of this happening, the potential drug purchase savings are somewhat muted by dispenses to visitors to a hospital's outpatient pharmacy, and by employee use at the pharmacy. Visitors may never have been patients of a hospital, and hospital employees may see physicians at a different hospital for privacy reasons. In both cases, the patient is not eligible for 340B reimbursement and the hospital is prohibited both from using the 340B price and their typically discounted GPO price.

The hospital is not required to Directly Increase Services to Indigent Patients

Perhaps most surprisingly, there is no mandate in the law or in the regulation that requires a hospital to increase their services to the patient populations that qualify the hospital for the 340B program. The U.S. House of Representatives Report that initiated the law states the purpose this way: In giving these "covered entities" access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients in providing more comprehensive services.[1]

There is considerable political debate on the "true intentions" of the bill since the 340B program has grown so significantly since its inception. Largely depending on whether one is a manufacturer required to provide rebates to these hospitals or a hospital administrator trying to maximize its healthcare impact, people are either of the view that the scope is too broad or too narrow within current regulations.

340B prices are Confidential

The law specifies a legally-mandated "ceiling price" for each drug. The price is based on the average price a manufacturer charges for a given drug on the market, excluding Medicaid. Because their actual sale prices are proprietary, HRSA obfuscates every party from knowing this mandated price except the wholesaler, who is required to charge no more than that price for eligible drugs purchased at 340B. Because wholesalers may charge lower prices than the ceiling price, and the "true price" may be obfuscated somewhat with cash discounts, there's no list of ceiling prices available to covered entities, only the actual price their wholesaler will charge.

The result is that hospitals attempting to calculate the financial impact of participating in the 340B program will not be able to make reliable calculations.

Regulatory Guidance is Ambiguous

The law itself has no commentary on the purpose of the 340B program, nor its intended bounds beyond specifying the precise eligibility criteria of covered entities to participate in the program. This has required HRSA as the regulatory agency to determine the extent of the program based on input from hospitals, manufacturers, and the public. Several aspects of eligibility have not been addressed definitively by HRSA:

1 House Report 102-384, Part II

- Should prescription refills be eligible?
- Which departments of a hospital qualify as "outpatient"?
- Are hospital "swing beds" inpatient or outpatient?

This sort of question has been typically addressed by asking hospitals to "determine their policy" rather than making a declaration on the compliance of a particular choice.

340B is a Federal program not funded by the Federal Government

The Federal government has a responsibility to support the healthcare safety net. Programs such as Medicaid are funded directly, in part, by direct Federal funding. The Department of Veterans Affairs and the Medicare program are also receiving direct grants through the Federal budget. The 340B program, however, is funded directly by rebates from drug manufacturers. The only direct cost to U.S. taxpayers is the administrative cost of the program from HRSA's Office of Pharmacy Affairs (OPA).

Risks

By law, the penalty for a purchase made on 340B that should not have been is return of the 340B rebate to the manufacturer. While this lack of punitive penalty for the hospital in the case of error or inappropriate policy may seem advantageous to the eligible hospital, there's a significant consequence. Because neither the regulators nor the manufacturers have any effective sanction for failing to follow regulations, the first and only consequence is complete removal from the 340B program. This increases the risk of what could be hundreds of millions of dollars in drug discounts to eligible entities.

Erroneous 340B orders can happen for a number of reasons. Common causes are incorrect inclusion of all hospital employees, who are not necessarily patients of the hospital; including in a covered entity's list of prescribers physicians who are also seeing hospital patients at independent clinics; and failing to identify dispenses paid by Medicaid.

Typical Implementations

A typical hospital has separate inpatient and outpatient pharmacies. Even if they exist within the same physical space, there is often physical separation of inventories. By law, dispenses to inpatients do not qualify for 340B, so drug ordering for an inpatient pharmacy can continue without regard to 340B replenishment.

In order to utilize 340B, a covered entity must:

1. Identify which of its dispenses is 340B eligible
2. Order drugs per its usual inventory policy, making as many purchases on 340B as possible.

These are typically accomplished by first generating a list of all 340B eligible dispenses to outpatients. This is usually a database programming job done by the hospital's IT department. The program counts only the outpatient dispenses through the outpatient pharmacy to patients who are actually patients of the hospital. Then all dispenses are grouped by drug. Many dispenses are made to patients in sizes smaller than what is actually ordered from a wholesaler. For example, a patient may receive 30 pills for a 1-month supply, which are delivered from a 100-pill bottle. The hospital may not make any purchases of that drug on a 340B account until at least 100 pills have been dispensed to eligible patients. As such, the total of all

eligible dispenses are rounded down to a multiple of the wholesale orderable size.

The second step is typically to order drugs based on target inventory levels (rather than on how many drugs are currently eligible to purchase under 340B). Inventory levels are reduced based on dispenses to all patients (whether eligible or not), and replenishment orders are based on the desired amount of medicine to keep in stock. If fewer bottles are 340B eligible than are desired for inventory, the maximum number of eligible 340B--priced bottles are ordered first, with the remainder ordered at retail WAC. If more 340B-eligible bottles are available than are currently desired, then the remaining eligible bottles will be ordered at a later time, when inventory levels have been reduced

Managing the determination of which departments and dispenses are eligible and splitting a desired order into 340B and non-340B accounts is typically called "split billing"; the maximum number of bottles are ordered at the discounted 340B prices before the remainder is ordered at the higher prices. Split billing can be handled with tools ranging from a spreadsheet to software solutions that integrate with existing ordering systems such as Siemens and Epic. It's typical for a hospital to pay a 340B vendor to manage the split billing with a combination of software and services. Providers include SentryDS, Talyst, CaptureRx, SunRx, and Macro Helix.

Services from a 340B vendor also often include:

- Automatic ordering of 340B drugs
- Assistance with manufacturer or HRSA audits
- Automated reports showing eligible patients and purchases
- Technical advice on eligibility

Contract Pharmacy

By the *Definition of a Patient* guideline, a patient who is treated at a hospital, whether as an inpatient or an outpatient, and subsequently fills a prescription at a retail pharmacy may still be considered a patient of the hospital. A visit to a retail pharmacy is, in every practical case, an indication that the patient is currently an outpatient. If the prescription was written by a physician prescribing on behalf of the hospital, and the hospital continues to manage a relationship with that patient and maintain that patient's records, there is no legislative restriction on all such prescriptions to be 340B eligible for the hospital.

HRSA initially allowed experiments, known as "alternative methods demonstrations projects" to explore whether allowing hospitals to distribute 340B drugs through independent pharmacies was workable, and whether it would lead to abuses of the law. As these early relationships succeeded, HRSA subsequently allowed each covered entity to contract with no more than one outside retail pharmacy. The regulatory guidance was written in order to suggest that a hospital should physically supply a pharmacy with its own 340B eligible stock, and the single pharmacy would identify 340B eligible patients of the hospital at dispense time and fill from that stock. This was in principle no different from the way hospitals were already dispensing 340B medications from their own outpatient pharmacies. The key difference was that the newly allowed single retail pharmacy was under contract with the hospital, and no other relationship need exist between the hospital and pharmacy.

A contract pharmacy relationship may work as illustrated:

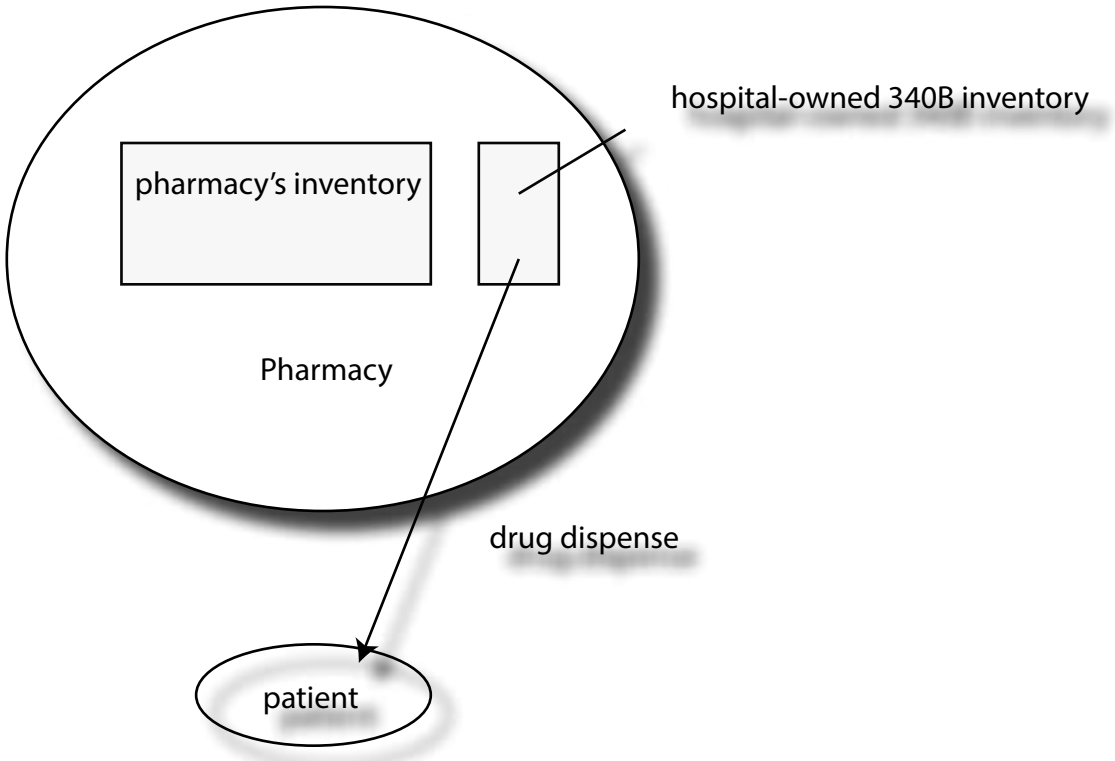

Figure 1: Contract Pharmacy with Physical Inventory

A patient, having been seen a at an eligible 340B hospital, visits a pharmacy convenient to her. Her prescription is identified as being written by a prescriber affiliated with the hospital, and she is identified as a patient of the hospital. In this typical example, she has insurance. She pays the copay, her insurance pays the remainder of the medication cost, and the pharmacy fills the prescription from the hospital's stock.

The hospital receives the entire copay amount plus the entire amount paid by insurer or other third-party

payer. It replaces the physical stock at the pharmacy. Because the pharmacy was never out any of its own inventory, it does not need to be reimbursed for the drug and instead may only ask a nominal dispense fee.

In 2010, after a public commentary period, HRSA determined that the allowance of a single contract pharmacy neither attracted abuse of the program, nor was it appropriate to arbitrarily restrict the number of pharmacies. This was disproportionately helpful to smaller hospitals and those with a single nearby pharmacy, and disadvantageous to larger hospitals and those in areas with much pharmacy competition.

At this point, HRSA established new guidance allowing a covered entity to contract with any number of pharmacies. This led to a growth in the number of contract pharmacy relationships from a few hundred to over 16,000 in early 2015.

For a number of reasons, including limited shelf space at a typical pharmacy and the difficulty in identifying patients of the hospital at the moment they appear at a pharmacy, the physical inventory suggested by HRSA and illustrated above has fallen out of favor. With several pharmacies per covered entity, almost all hospitals are choosing to use a software service provider and a virtual inventory.

The resulting flows work as illustrated in figure 2:

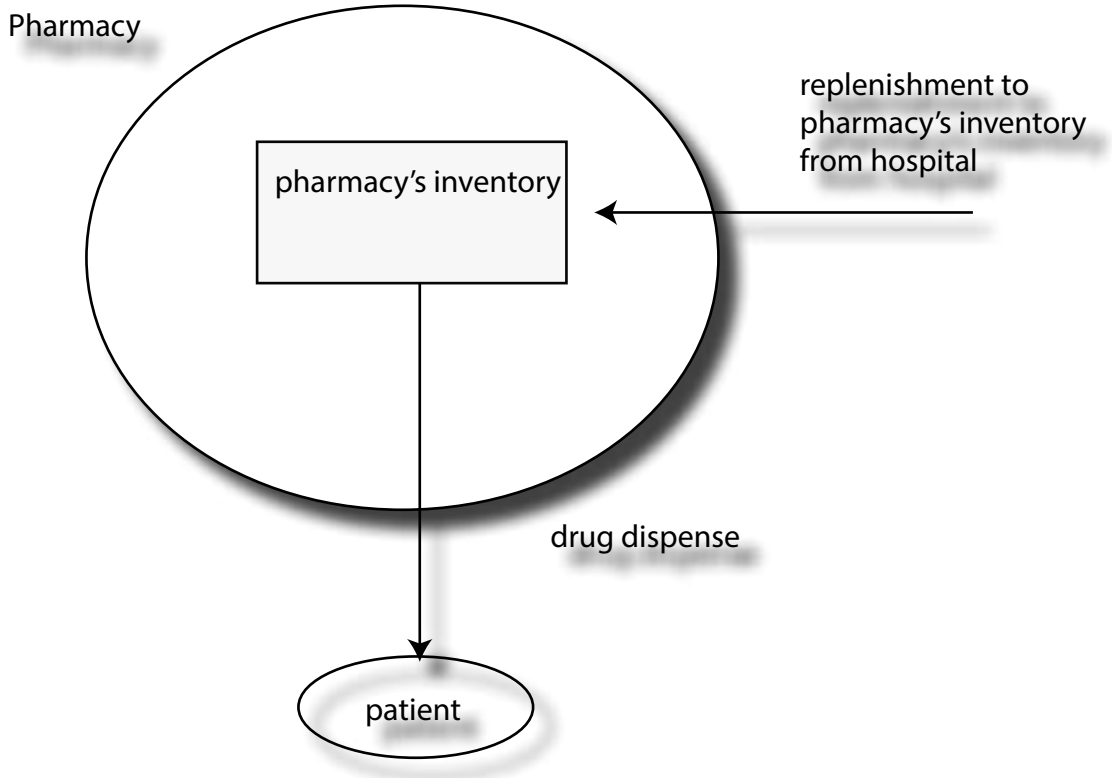

Figure 2: Contract pharmacy with virtual inventory

The patient receives the same drug, makes the same copay, and is equally unaware that the 340B program was involved for her transaction. This time, the pharmacy used its own inventory. This is typically not a problem for the pharmacy because it is already in the business of anticipating need for drugs, and the patient was not incented to come to this particular pharmacy when she hadn't planned on it already.

Differences between the physical and virtual inventory models have some implications:

1. The pharmacy needs no additional inventory area for storing the hospital's drugs

2. There is less work for the pharmacy, as it's not necessary to identify patients as they present at the pharmacy.

3. The pharmacy has lost some control over their inventory, as the hospital will ship drugs unexpectedly.

The History and Future of 340B

Since its inception, the 340B program has attracted controversy commensurate with its growth. Proponents and detractors both make salient points, although much of the perception among the public is based on rhetoric or misperceptions. There are several aspects to the program as it currently stands that make it difficult for parties to agree:

The Program Has Grown Beyond Expectations

The original House of Representatives Committee report had a larger percentage of indigents population required in order to qualify as a disproportionate share hospital. At the time of drafting of the report, the Committee calculated that 190 hospitals would qualify. The final legislation included many more hospitals based on a lower qualification threshold, and many more hospitals qualify based on serving higher percentages of uninsured patients. Although it might be supposed that The Patient Protection and Affordable Care Act, in providing broader health insurance coverage, might reduce the number of qualifying hospitals, this has not been the case. There are still a large number of uninsured patients at hospitals, and the Affordable Care Act itself authorized additional categories of 340B entities.Today almost one in three hospitals are eligible for the 340B program.

The Regulators Have Received No New Legislative Guidance

HRSA's only known guidance is the law itself, and the Committee report that spurred the law. In principle, there is a fixed number of eligible outpatient dispenses. The law allows all eligible dispenses to be captured. In practice, the definitions used to describe patients can make a huge difference on the number of dispenses actually captured. The change in guidance allowing contract pharmacies, for instance, has dramatically expanded the reach of covered entities.