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340B Drug Discount Program

The Program Basics

Introduction

As state and local governments struggle to manage the growing cost of prescription drug, state and local governments are looking at the federal 340B program which requires US drug manufacturers to provide Medicaid-level discounts to eligible provider entities on demand. State and local governments want to understand more about which providers access these discounts and their relationship with state and local governments.

In order to create better understanding of the role of the federal 340B program in the healthcare system, this document provides basic information about the size and scope of the current 340B program, along with key 340B participation rules and policies that can guide state and local government thinking about 340B and whether the program can be leveraged to constrain spending on prescription drugs in government-funded programs. Examples of state leveraging initiatives are highlighted as well as some newer ways to think about the program.

The state interest in 340B is driven by a lack of action on drug costs in Congress and the Administration coupled with the narrow range of state policy options for constraining spending owing to the intersection of federal law and federal caselaw, and the ever more crippling nature of the pharmaceutical industry business model on the healthcare system. Leveraging 340B may not be optimal, but it is one of the few avenues for constraining pharmacy spend.

340B Basics: The Numbers

There are about 53,000 "covered" entities in February 2022. These are health and medical facilities that participate in and are registered with the 340B program. There are 27 categories of eligible entities including, but not limited to:

- Disproportionate Share Hospitals
- Children's Hospitals
- Critical Access Hospitals
- Cancer Hospitals and the Community Oncology Practices (most community-based oncology group practices are now owned by 340B hospitals)
- Rural Hospitals
- Federally Qualified Health Centers (FQHCs)
- Tribal clinics
- Ryan White programs
- Title X Family Planning Clinics

It is important to note that hospital outpatient clinics are listed individually in the database which creates the large number of participating entities because one hospital represents multiple database listings.

There are about 198,000 retail and mail order pharmacies[1] listed as participating or having participated in the 340B program under contract to 340B entities These include large national and regional chains such as Walgreens and CVS. Importantly, one pharmacy will be under contract to more than one 340B entity. So, for a hospital with ten outpatient clinics served by one pharmacy, there would be ten contract pharmacy entries for one hospital and one pharmacy. While the federal database overstates the reality of 340B participation, hospitals and pharmacies seem to have fully maximized their participation. The role of contract pharmacy is explained below.

In 2020, the program is estimated to have accounted for $38 billion in for drugs going to 340B entities[2], There are various estimates of average 340B discounts, from 38%-50% of Wholesale Acquisition Cost (WAC, commonly considered to the be the list price).

Most if not all children's hospitals, disproportionate share hospitals and sole community hospitals participate, along with most large retail chain pharmacies and thousands of public health entities. The 340B discount percentage for any drug is generally equivalent to the net Medicaid cost after the federal Medicaid rebate.

Key Rules in the 340B Program

Importantly, 340B products can only be dispensed or administered in outpatient and retail settings without regard to the type of 340B entity dispensing or administering the drugs. Use of 340B product for inpatient hospital services is not allowed by law.

The 340B price is confidential to 340B entities, individual manufacturers, and the administering federal agency, the Health Resources and Services Administration (HRSA). Manufacturers can and do offer additional (confidential) discounts beyond the federal price control that is equivalent to the --also confidential-- Medicaid drug rebate unit amount. Additional discounting occurs in 340B as it does in the Federal Veterans Administration and the Medicaid program. Additional discounting/rebates occur for these federally price-set programs for same reason as they occur in the commercial market – competitive formulary advantage relative to any therapeutic competitor.

340B drugs can be dispensed only to people who are patients of the 340B entity (defined as having regular care with a medical record on site). And the prescriber has to be affiliated with the 340B entity. Eligibility for 340B drug dispensing is equally tied to the relationship between the prescriber and the 340B entity as well as the patient's relationship to the 340B entity.

There are different ways to identify a 340B patient prescription – at the point of service and retrospectively, which are complex and tend to require a separate vendor to review claims and identify 340B eligible dispensing.

If the patient is covered by Medicaid fee for service or the AIDS Drug Assistance Program (ADAP) the 340B dispensing entity must bill Medicaid and ADAP the acquisition cost (i.e., no profit for the 340B

[1] The database lists 233,660 current and terminated contracted pharmacies. Assuming that 15% of the listings are terminated pharmacies, there are 198,560 participating.
[2] Drug Channels, this number is presumable sales at the deeply discounted price, not market price. It has been estimated that the program moves $80 billion if the drugs were sold at list price. More information on 340B can be found here.

entity). When the patient is covered by any other insurer, the 340B entity can bill for reimbursement at market prices.

340B Basics: How It Works on The Front End

340B drugs are ordered directly from wholesalers/distributors by 340B entities, entity 'child sites' (multiple locations of the same eligible entity) and entity contract pharmacies. The drug manufacturers generally supplying 340B orders with on-invoice discount pricing (rather than back-end rebates as in the health plan market). Generally, the 340B entity is invoiced for the shipments that may have been ordered by satellite sites and contract pharmacies. Some manufacturers may use discrete vendors for 340B order fulfillment or use the regular wholesaler channel and reimburse wholesalers for the difference between what the wholesaler paid the manufacturer for the drug and the price at which the wholesaler had to sell to 340B entities.

340B entities generate revenue by billing insurers (except Medicaid and ADAP) at the market price, rather than the lower, 340B acquisition cost.

Contract pharmacies extend the reach of a 340B entity's pharmacy services to patients who might leave the 340B entity before filling their prescription and for subsequent refills. Contract pharmacies may share in the drug revenue that comes from buying low (340B prices) and selling high (at market prices) or contract pharmacies may get a flat professional fee from the 340B entity for each 340B prescription filled (which would be in addition to the professional fee billed to, and paid by, the insurer).

340B Basics: How It Works on The Back End

Presumably, the pharmacist will know that a prescription is 340B price eligible by the letterhead on the prescription and know that the entity is tied to the 340B entity with which the pharmacy has a contract for dispensing 340B product. If 340B patients have insurance, the 340B entity (or pharmacy on behalf of the entity) will bill insurance at market prices. The difference between its (low) 340B acquisition costs and market prices becomes revenue for the 340B entity.

Because there are potentially 53,000 340B entities in the US, there is likely that covered lives of state, local, and federal government health benefit programs are treated at 340B entities and prescribed drugs for which 340B stock can be dispensed and market price billed to government payors (other than billing Medicaid and ADAP, which is not allowed under federal law).

There is a standard field on a pharmacy claims form by which to identify claims where a 340B drug was dispensed. The standard was established by voluntary standard-setting organization, The National Council of Prescription Drug Programs (NCPDP). All US pharmacy claims comply with the NCPDP standard for billing and payment processing. The NCPDP Reference Guide discusses how the 340B claims identifier is underused. There are a variety of reasons for the underuse that are beyond the scope of this paper.