Research

Primer: Understanding the 340B Drug Pricing Program

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Introduction

In 1990 Congress created the Medicaid Drug Rebate Program which regulated the prescription drug manufacturer ceiling price for drugs provided to Medicaid patients.[1] Under the statute, Medicaid became a "preferred provider", which requires manufacturers to offer Medicaid the 'best price' offered to any other health insurance provider.[2]

Though the statute was written with the intent to lower the cost of Medicaid care, it contained no exception in the 'best price' calculation for charitable giving. Before the statute was passed, many drug manufacturers regularly donated prescription drugs to health care facilities with high volumes of low-income patients in exchange for a tax deduction and the good-will of the community.[3] However, under the 1990 statute, if a drug manufacturer donated drugs to any health care facilities it would be obligated to offer the drugs at that same price for all Medicaid patients. With this mandate in place charitable giving constricted and hospitals with high volumes of low-income patients had to absorb the added cost of providing drugs.[4]

In 1992 Congress attempted to address the lack of voluntary pharmaceutical drug donations by passing the Public Health Service Act (PHS), creating the 340B program which mandates discounts to health care providers serving low-income patients under the 340B program.[5] This program was created with the purpose of "stretch[ing] scarce Federal resources" further.[6] The program functions by setting a 'ceiling price' for what drug manufacturers can charge these health care providers, known as Covered Entities (CEs), for drugs provided to "qualified patients."[7]

340B Requirements

Covered Entity

Eligibility for the program has been extended several times since the law was first passed in 1992 and now includes Disproportionate Share Hospitals (DSH), children's hospitals and cancer hospitals exempt from the Medicare prospective payment system, sole community hospitals, rural referral centers, and critical access hospitals.[8] Qualification as a CE varies based on the type of facility applying to participate. To gain eligibility, all hospitals in these categories must be owned or operated under state contract, a non-profit formally granted governmental powers by a state or local government, or a private non-profit with a state contract to provide indigent care; all must meet Medicaid payer-mix criteria based on DSH percentages. Health centers that meet all of these criteria, provide pharmacy services, and would benefit from the program are required to participate, otherwise they are at risk of receiving a negative audit, cost disallowances, or, if applicable, a decrease of grant-funding proportionate to the foregone savings.[9]

Qualified Patients

The participating CEs are given discounts on 340B covered drugs provided to “qualified patients.” “Qualified patients” must establish a relationship with a 340B eligible entity where that entity maintains records of the individual’s care, the individual receives health care services from a professional employed or contracted by the covered entity, and the individual receives the type of care for which the entity receives grant funding or federally-qualified health center status (this last requirement does not apply to DSH providers).[10] The services rendered to these patients must be outpatient care beyond simply dispensing the 340B covered drugs.[11]

Drug Distribution Methods

340B CEs may provide their services in a variety of settings such as hospitals, clinics, even off-site pharmacies. A CE may contain its own in-house pharmacy, which will own and dispense its own drugs.[12] Alternatively, CEs may use contract pharmacies where the CE purchases the drugs and the pharmacy dispenses them; the CE, however, must be the purchaser in order to be eligible for 340B drug discounts.[13]

Drug Distribution Methods

Who purchases the drugs is an important detail because of the confusion that has been caused by the variety of drug purchasing and dispensing arrangements that have developed within the 340B program. The primary methods for a CE to obtain pharmaceutical drugs are: directly from the manufacturer or distributor, through a Pharmacy Benefit Manager, a Group Purchasing Organization, or through participation in the Prime Vendor Program.[14]

Pharmacy Benefit Managers (PBMs) manage the administrative tasks CEs would otherwise have to manage themselves. PBMs are often responsible for negotiating contract prices and discounts with manufacturers and distributors, and processing and paying claims.[15]

Group Purchasing Organizations (GPOs) use collective bargaining techniques to negotiate discounted prices and other services for their members.[16]

The Prime Vendor Program (PVP) offers discounts on some drugs, including those not covered by the 340B program. PVPs can negotiate discounts even lower than what the 340B program alone could provide, and extend its influence into pharmaceuticals not covered by the program, such as vaccines and medical devices.[17] All members of the PVP must be eligible for and participate in the 340B program, though they will be permitted to take advantage of additional discounts gained through PVP negotiations, and are subject to any other contract terms of the PVPs agreement with the drug manufacturer or distributor.[18]

Price Setting Formula

The 340B program covers all out-patient prescription drugs prescribed by a covered entity (including OTC drugs if a prescription was written by a provider employed or contracted by the CE). The covered entities pay for these drugs at a steeply discounted price, and in turn, patients receiving 340B drugs pay according to a sliding fee-scale based on income.[19] Those with income above 200 percent of the Federal Poverty Level (FPL), are expected to pay full price for the drug (despite the fact that the care center from which they are buying the drug did not pay full price for it); individuals between 100 and 200 percent of FPL pay a varying amount based on their income, according to Section 330 of the PHS Act, and those below 100 percent FPL will

pay only a nominal fee for the prescription.[20]

The price that is set for 340B participants is the *ceiling* price above which covered entities may not be charged.[21] This price is set based on the Average Manufacturer Price (AMP), minus a discount (usually equivalent to the state Medicaid Drug Discount Program rebate). This price may increase to cover fees paid to PBMs or GPOs, but may be further reduced by PVP negotiated prices.[22]

These 340B price negotiations generally save CEs between 15 and 60 percent on the cost of drugs.[23]

Affordable Care Act Changes to the 340B Program

In 2010 the Affordable Care Act (ACA) was passed, and with it thousands of pages of reforms to the American health care system. The 340B program specifically was modified in four major ways by the legislation.

The ACA contains a provision expanding the definition of eligible entities to include outpatient settings, free-standing cancer hospitals, rural referral centers, sole community hospitals, and critical access hospitals.[24]

The law gives the Health Resource Service Administration (HRSA) the power to set and monitor ceiling prices based on a new formula: AMP minus 13 percent for generic drugs, and AMP minus 23.1 percent or the best price offered for brand-name drugs (whichever is less).[25] The law also gives HRSA the power to enforce penalties on drug manufacturers or distributors who overcharge 340B entities, and mandates affirmative action on the part of the offending party to correct the overcharge.[26]

Problems with the 340B Program

The 340B program was originally intended to correct an imbalance created by the passage of the Medicaid Drug Rebate statute.[27] It was meant to play only a small role in the health insurance market. However, as with most interferences in the free-market, the 340B rule has “expanded beyond its bounds”, in the words of outgoing Secretary of HHS Kathleen Sebelius.[28] As the program has expanded the market inefficiencies it created have been magnified.

Between 2004 and 2013, 340B purchases have grown from $0.8billion to $7.2billion per year.[29] While 340B discounts affected 3 percent of purchased drugs in 2004, the discounts impacted over a quarter of prescription drugs in 2013.[30]

By February 2014, about one-third of all hospitals participated in the 340B program, accounting for about 62 percent of all hospital outpatient drug spending.[31] However, the charity care that the 340B program was intended to replace accounted for only 1 percent of costs for a full quarter of 340B care centers.[32] Of the 2,048 hospitals participating in the 340B program, only 20 percent accounted for 80 percent of all charitable care provided.[33]

Some of these problems originate from the fact that current 340B guidance does not require cost savings to be passed on to needy “qualified patients.”[34] 340B providers may sell 340B drugs to non-qualified patients (usually those covered by an insurance plan) and pocket the difference; they justify this behavior as cross-subsidization, where the savings from the 340B program are used to provide other un- or undercompensated services to low-income patients, therefore fulfilling the program’s mission to “stretch scarce Federal resources.”[35] This is not the case in all covered entities though, as some non-hospital grantees of federal funds are

required to provide services on a sliding-fee-scale.[36]

Further problems are caused by the inaccurate use of DSH percentage as a metric for determining 340B eligibility, as it does not truly reflect a provider's share of uncompensated care.[37] DSH is calculated based on the proportion of low-income patients insured by Medicare and Medicaid treated in the facility: it reflects the number of low-income *insured* people who are cared for as *inpatients*, but not the number of *uninsured* low-income people who are given *outpatient* treatment — the type of care covered under 340B. The criterion used to determine eligibility measures factors that are entirely unrelated to the program at issue, and have in fact been shown to be uncorrelated factors.[38] This problem is compounded by Medicaid eligibility expansions of the past two decades which have increased the Medicaid population covered by hospitals, making them DSH and, ultimately, 340B eligible.

Attempts to Solve these Problems

In 2007 HRSA proposed to rein in 340B eligibility by tightening the definition of a qualified patient, more clearly delineating what types of relationships are substantial enough to justify conferring eligibility.[39] The rule saw considerable backlash and was retracted a few years later.[40]

The 340B rule was not addressed again until passage of the ACA, which largely took the rule in the wrong direction by expanding eligibility criteria for providers and doing little to clarify the ambiguity that was already inherent in the program.[41]

Now, four years later, a proposed rule that could greatly restructure the program is expected any day. The so-called 340B Mega-Reg has the potential to address any and all of the major questions around the 340B rule. We may expect an attempt to redefine what is considered a "qualified patient",[42] and by extension we may also expect to see updates to hospital eligibility criteria (specifically with regard to satellite facilities),[43] as well as new rules regulating the use of contract pharmacies,[44] generic rather than brand-name drugs,[45] and oversight procedures.[46]

[1] Omnibus Budget Reconciliation Act of 1990, Pub. L. 101-508, 104 Stat. 1388 (Nov. 5, 1990); *cf.*Payment for Covered Outpatient Drugs, 42 U.S.C. 1396, §1927.