The 340B Drug Pricing Program and Medicaid Drug Rebate Program: How They Interact

The Medicaid Drug Rebate Program and the 340B Drug Pricing Program (340B) both require drug manufacturers to provide significant discounts on their products. Under Medicaid, these discounts are provided in the form of rebates on covered outpatient drugs paid for by state Medicaid programs (§ 1927 of the Social Security Act (the Act)). Under 340B, manufacturers are required to sell drugs to participating providers, known as covered entities, at a significantly reduced price (§ 340B of the Public Health Service Act (PHSA, P.L. 78-410)). Manufacturers are only required to provide a price concession for a particular drug under one program; therefore, states may not claim a Medicaid rebate for a drug that was purchased under 340B. This is known as the prohibition on duplicate discounts. Preventing duplicate discounts is the main issue confronting state Medicaid programs with regard to 340B (NAMD 2015).

In recent years, changes to both 340B and the Medicaid drug rebate program have made it more difficult for states and providers to determine whether a 340B drug was dispensed to a Medicaid beneficiary. Specifically, the expansion of rebates to Medicaid managed care plans and the growth of contract pharmacies that are dispensing 340B drugs have made preventing duplicate discounts more complex (OIG 2014a). Federal agencies and states have taken steps to improve the interoperability of Medicaid and 340B, but issues between the two programs continue.

This issue brief begins by providing background on the history and mechanics of the Medicaid Drug Rebate Program and 340B. It then describes the issues that state Medicaid programs face in coordinating prescription drug benefits with 340B. It concludes with an overview of two other issues related to 340B: (1) whether covered entities may be using the 340B program to generate revenue, and (2) concerns about whether federal oversight is adequate to monitor the rapidly growing program.

The Medicaid Drug Rebate Program in Brief

The Medicaid Drug Rebate Program was created under the Omnibus Budget Reconciliation Act of 1990 (P.L. 101-508) and is meant to ensure that Medicaid receives a net price for a drug that is consistent with the lowest or best price for which manufacturers sold the drug. Under the program, a drug manufacturer must enter into a Medicaid national drug rebate agreement with the Secretary of the U.S. Department of Health and Human Services (HHS) in order for states to receive federal funding for use of its products (§ 1927(a)(1) of the Act).[1] In exchange for the manufacturer rebates, state Medicaid programs must generally cover all of a participating manufacturer's drugs when prescribed for a medically-accepted indication, although they may limit the use of some drugs through preferred drug lists (PDLs), prior authorization, or quantity limits.[2]

Amounts collected under the federal rebate program are shared by the federal government and states based on the state's current federal medical assistance percentage (FMAP). The rebates collected by the state are reported as an offset to drug spending on the CMS-64 quarterly expense report used to determine the federal and state share of Medicaid spending.

Medicaid drug rebates are calculated based on average manufacturer price (AMP). AMP is defined as the average price paid to the manufacturer for the drug in the US by wholesalers for drugs distributed to retail community pharmacies and by retail community pharmacies that purchase drugs directly from the manufacturer (§ 1927(k)(1) of the Act). The Centers for Medicare & Medicaid Services (CMS) calculates a unit rebate amount (URA) for each drug based on the established formula for that type of drug and provides this URA to each state.[3] The state then multiplies the URA by the number of units that it paid for that drug during the rebate period and submits a rebate invoice to the drug manufacturer.[4] The state collects the rebate dollars from the manufacturer and reports the rebate amount as an offset to the drug expenditures on the CMS-64. There are separate rebate formulas for single source and innovator multiple source drugs (i.e., brand name drugs) versus non-innovator multiple source (i.e., generic drugs).[5]

The 340B Program in Brief

The Veterans Health Care Act of 1992 authorized the 340B Discount Drug Pricing Program, which derives its name from Section 340B of the PHSA. The law is intended to help participating providers "stretch scarce federal resources" (Committee on Energy and Commerce 1992). Administered by the Health Resources Services Administration (HRSA), the program requires drug manufacturers to sell drugs to certain safety-net providers, known as covered entities, at a reduced price, known as the ceiling price. The ceiling price is the drug's AMP minus the URA—the same process used to determine a drug's rebate obligation under Medicaid. The law also established the Prime Vendor Program (PVP) to negotiate additional discounts from manufacturers (known as subceiling prices), establish distribution networks for drugs, and provide other support services (Apexus 2018).

Participation in 340B is optional for covered entities. If a covered entity chooses to participate, it must follow certain program requirements, including dispensing 340B drugs solely to its own patients. Dispensing 340B drugs to other patients is known as diversion. Manufacturers are not required to pay rebates under the Medicaid Drug Rebate Program on drugs purchased under 340B. In other words, if a covered entity dispenses a 340B drug to a Medicaid beneficiary, the state should not invoice the manufacturer for a rebate on that drug. Notably, covered entities are not required to use 340B drugs only for low-income or uninsured individuals and not all covered entities are required to pass along the savings from 340B drugs to patients (Conti and Bach 2013).

Covered entities

Covered entities are defined in statute and generally consist of federally funded clinics and hospitals that furnish care to a large number of underserved or vulnerable individuals, including Medicaid beneficiaries. Examples of covered entities include clinics that receive federal grants to provide specific services, treat specific populations, or treat specific diseases; hospitals that meet certain statutory criteria; and hospitals

that have a large Medicare disproportionate share hospital (DSH) adjustment percentage (§ 340B(a)(4) of the PHSA). The Patient Protection and Affordable Care Act (ACA, P.L. 111-148, as amended) added four types of hospitals and one type of health center to the list of eligible covered entities.[6]

To participate in the program, eligible providers must register with HRSA, certify their eligibility annually, maintain records for auditing by manufacturers or the Secretary of HHS, take steps to prevent duplicate discounts, and ensure that drugs purchased under 340B are not diverted (§ 340B(a)(5) of the PHSA).

A covered entity may have several affiliated sites, known as child sites, eligible to participate in 340B (Bach and Conti 2014, HRSA 2017b). Covered entities may also enter into arrangements with retail pharmacies to dispense 340B drugs on behalf of the covered entity, known as contract pharmacies (OIG 2014a).

Medicaid and 340B

The primary issue state Medicaid programs face with regard to 340B is preventing duplicate discounts (NAMD 2015). States and covered entities use a variety of methods to identify whether a 340B drug was used for a Medicaid beneficiary although weaknesses in these systems remain. Moreover, extending rebates to Medicaid managed care, which is the primary mechanism of delivery of health care services to Medicaid patients, and the growth in contract pharmacies has complicated this task.

The Medicaid exclusion file

HRSA maintains a list of covered entities that use 340B drugs for beneficiaries in Medicaid fee for service (FFS), known as the Medicaid exclusion file (MEF), to assist states in determining whether a 340B drug was dispensed to a Medicaid beneficiary. Upon registering with HRSA, a covered entity must notify the agency if it intends to use—or carve in—340B drugs for Medicaid beneficiaries. That decision must apply to all the Medicaid FFS beneficiaries the entity serves (HRSA 2014). HRSA lists these covered entities on the MEF and states exclude claims from providers on the MEF from their rebate invoices (OIG 2016).

States have raised concerns that the MEF can be inaccurate or outdated and that it does not allow for flexibility when a covered entity that usually carves in to 340B needs to use non-340B drugs, for example, in the event of a drug shortage (NAMD 2015, OIG 2014b). States have also expressed concern about the functionality of the MEF, particularly the difficulty in identifying which covered entities have changed decisions to carve-in or carve-out and when the covered entity made such a decision (NAMD 2015).

In addition, the MEF does not apply to drugs dispensed by contract pharmacies or to drugs paid for by Medicaid managed care, both of which have expanded significantly over the past decade (Gottlieb 2017, NAMD 2015, OIG 2014a). HRSA guidance states that the MEF is limited to preventing duplicate discounts in Medicaid fee for service (HRSA 2014). HRSA guidance also states that contract pharmacies should not dispense 340B drugs to Medicaid beneficiaries unless the covered entity, contract pharmacy, and state establish “an arrangement to prevent duplicate discounts” and notify HRSA of the arrangement (HRSA 2010). Covered entities are generally allowed to make different decisions regarding use of 340B drugs for beneficiaries in Medicaid FFS and those in managed care. Accordingly, states cannot rely on the MEF to

exclude 340B drugs in Medicaid managed care (OIG 2016). Nonetheless, 17 states reported that they relied solely on the MEF to prevent duplicate discounts for drugs paid for through Medicaid managed care (OIG 2016).[7]

Some states create their own provider exclusion lists that indicate which covered entities use 340B drugs for FFS beneficiaries and managed care enrollees (OIG 2016). Other states require that covered entities make the same decision on the use of 340B drugs for both FFS and managed care populations (OIG 2016).

Covered entities may decide to use a different national provider identifier (NPI) or Medicaid billing number for 340B and non-340B claims (OIG 2016). This would allow the state to use a provider-level exclusion file to identify 340B claims while affording covered entities the flexibility to decide to use 340B drugs for some Medicaid beneficiaries and not others (OIG 2016). However, obtaining separate NPIs can be complicated for contract pharmacies and they rarely do this (OIG 2016, NAMD 2015). Furthermore, in order to use the correct NPI, a provider must know whether the individual is eligible for 340B at the time it submits the claim, information that may not be available to a contract pharmacy until later.

In addition to provider exclusion lists, a state can use claim-level methods to identify and exclude 340B drugs from its rebate invoice. Under this approach, a covered entity indicates on the claim whether the drug was purchased under 340B or not (OIG 2016). This approach is more flexible than the provider-level method because covered entities can use 340B drugs for some Medicaid beneficiaries (e.g., those in FFS) and non-340B drugs for others (e.g., managed care enrollees). Furthermore, claim-level methods allow providers that generally use 340B drugs for Medicaid to indicate individual instances when they did not do so; for example, if the provider ran out of a particular 340B drug and had to substitute a drug from general inventory, that could be indicated on the claim (OIG 2016).

Contract pharmacies and 340B administrators

Claim-level identifiers may not work in all scenarios. In order for a covered entity to use claim-level identifiers, it must know at the time it files the claim whether it used a 340B drug for a particular patient. As noted above, contract pharmacies may not have this information. A contract pharmacy will generally dispense a drug from its regular inventory and bill the claim as a non-340B drug. The covered entity will then retroactively identify which claims were eligible for 340B and purchase a corresponding number of drugs at the 340B ceiling price to replenish the contract pharmacy's inventory (OIG 2014a).

The process of determining whether a claim was eligible for a 340B drug retroactively can be complex. Generally, a covered entity will hire a 340B administrator to perform the retroactive identification of eligible claims (OIG 2014a). However, the HHS Office of the Inspector General (OIG) found that covered entities and 340B administrators use different methods to identify 340B prescriptions, with inconsistent results. Different identification methods resulted in the same prescription being categorized differently by different covered entities and administrators even when presented with the same fact patterns, raising the possibility that a 340B drug may be diverted to an ineligible patient (OIG 2014a). Properly identifying which claims are eligible for 340B drugs is a challenge for covered entities in general and is not limited to Medicaid.

Once a claim is identified as being eligible for 340B, retroactively adding 340B identifiers to the claim can increase the administrative burden on covered entities and state Medicaid agencies. Changing the status on a claim may require the pharmacy to reverse and resubmit the claim, which may occur after state deadlines for filing claims have passed (OIG 2016, NAMD 2015). Some states instruct contract pharmacies to submit spreadsheets that identify all claims subsequently determined to be for 340B-eligible prescriptions (OIG 2016). State staff must then remove these claims from the state's rebate invoice, or adjust previous quarters' rebate invoices as necessary (OIG 2016).

Administrators have also reported problems identifying whether individuals enrolled in managed care are Medicaid beneficiaries, which can complicate state efforts to prevent duplicate discounts (OIG 2014a). Administrators will typically use an insurer's bank identification number and processor control number (BIN/PCN) to determine if the plan is a Medicaid managed care plan (OIG 2014a). However, not all states have a list of all their Medicaid managed care BIN/PCNs, and some plans may use the same BIN/PCN for Medicaid and private insurance plans (OIG 2014a).

Other approaches

Due to the complexity in identifying 340B claims in contract pharmacies, some covered entities do not dispense 340B drugs to Medicaid beneficiaries through their contract pharmacies (OIG 2014a). In 2016, Delaware submitted a state plan amendment (SPA) that took this approach further and proposed to prohibit all covered entities from using 340B drugs for Medicaid beneficiaries (DMMA 2016). Several 340B covered entities and their parent organizations opposed this action (NACHC, THA, PPFA, et al. 2016). The SPA was eventually amended and approved to require covered entities to notify the state if they use 340B drugs for Medicaid beneficiaries, similar to the MEF but at a state level (CMS 2016a).

Other Issues Related to 340B

Policymakers have raised a number of other issues about 340B outside of its interaction with Medicaid, which generally relate to covered entities' ability to generate revenue from the program and the proper level of oversight. Some of these issues affect Medicaid to a lesser degree than other payers.

Revenue-enhancing activities

Covered entities can generate revenue by purchasing drugs at the discounted 340B price while charging insurers and patients a non-discounted rate (Conti and Bach 2014). The difference between the discounted purchase price and higher payment rates is referred to as the spread (McCaughan 2017).[8] Some covered entities (e.g., federally qualified health centers) are required to reinvest 340B revenue in services (NACHC 2015). Other covered entities (e.g., hospitals) are not limited in how they use their 340B revenue (Bach and Conti 2014).

The ability of 340B covered entities to generate revenue from the program without passing along the discount to low-income or uninsured individuals has led some observers to conclude that 340B has moved away from its original mission of serving at-risk populations and has become a funding stream for some providers (Bach and Conti 2014). Alternatively, some covered entities take the position that the original

intent of the law was for covered entities to use 340B to generate revenue to support general operations, which ultimately benefits patients (Pollack 2013).

Covered entities can enhance the revenue they generate from 340B through a variety of tactics, such as focusing on outpatient settings or expanding into more affluent communities. For example, one study showed that patients who live in an area with a 340B hospital are more likely to receive cancer treatment in the hospital's outpatient setting—where they would be able to receive 340B drugs—rather than a doctor's office (Jung, Xu, and Kalindindi 2018). Another study found that 340B hospitals have begun to purchase affiliated sites located in more affluent communities. Patients that visit these affiliated sites are more likely to have insurance with higher payment rates, allowing hospitals to generate greater revenue through spread pricing (Conti and Bach 2014).

In response to these revenue-enhancing tactics, in 2017, CMS reduced Medicare drug payments to 340B hospitals by nearly 30 percent (CMS 2017). CMS cited reports from the Government Accountability Office, the OIG, and the Medicare Payment Advisory Commission that showed spending on certain drugs was higher and grew faster at 340B hospitals than non-340B hospitals (CMS 2017). However, Medicaid is affected less by spread pricing because payment for outpatient prescription drugs is based on the cost at which the provider purchased the drug. The Medicaid Covered Outpatient Drugs final rule with comment requires state Medicaid programs to reimburse retail community pharmacies at their actual acquisition cost (AAC) of the covered outpatient drug. For covered entities that carve in to 340B, the AAC would generally be the 340B ceiling price. There is some potential for spread pricing in Medicaid if a covered entity purchases drugs at subceiling prices, but the magnitude of the spread would be less than it would be for payers that do not reimburse based on acquisition cost (CMS 2016b).[9]

Concerns about oversight

A second concern about 340B has been whether the program has become too large for HRSA to effectively oversee (Committee on Energy and Commerce 2017). The number of covered entities participating in 340B grew from 3,200 in 2011 to 12,148 by October 2016 (GAO 2011, Committee on Energy and Commerce 2017). The number of contract pharmacies have expanded rapidly as well, reaching 19,868 unique locations as of July 2017 compared to fewer than 3,000 locations in 2010 (Fein 2017a). In 2016, 340B purchases by hospitals increased to more than 50 percent of their total drug expenditures during a period when uncompensated care was generally on the decline (Fein 2017b).

HRSA's administrative capacity to oversee 340B has not grown commensurate with growth in 340B. The HRSA Office of Pharmacy Affairs (OPA), which oversees 340B, has 22 full time equivalent employees and conducts 200 covered entity audits annually (HRSA 2017a). HRSA began auditing covered entities in fiscal year 2012, when it conducted 51 audits. Since 2012, HRSA has audited no more than 200 covered entities annually (Committee on Energy and Commerce 2017). The growth in 340B participation along with the limited number of audits have led some to question whether HRSA is providing adequate oversight of the program (Committee on Energy and Commerce 2017). The size and scope of the program may also complicate state efforts to prevent duplicate discounts and ensure proper rebates are collected. HRSA proposed comprehensive guidance to address some of these complexities, but this guidance was never finalized and was withdrawn in January 2017.

Endnotes

[1] In addition to a Medicaid drug rebate agreement, drug manufacturers must also enter into an agreement that meets the requirements of Section 340B of the Public Health Service Act and a master agreement with the Secretary of Veterans Affairs as a condition for Medicaid coverage. A drug not covered under a rebate agreement may be eligible for federal funding in limited circumstances if the state has determined that the drug is essential to the health of its beneficiaries.

[2] A medically accepted indication means any use for a covered outpatient drug that is approved under the Federal Food, Drug, and Cosmetic Act (P.L. 75-717) or the use of which is supported by one or more citations included or approved for inclusion in one of the following three compendia: American Hospital Formulary Service Drug Information, United States Pharmacopeia-Drug Information, or the DRUGDEX Information System.

[3] The rebate amount for brand drugs has two components: a basic rebate amount and an additional inflationary component. The basic rebate amount is calculated as the greater of 23.1 percent of AMP or AMP minus best price. For blood clotting factor drugs and drugs approved by the FDA exclusively for pediatric indications, the minimum rebate percentage is 17.1 percent of AMP instead of 23.1 percent of AMP. An additional rebate based on an inflationary component is added if the increase in a drug's AMP exceeds the increase in the Consumer Price Index for All Urban Consumers (CPI-U) over time.

The basic rebate amount for generic drugs is calculated as 13 percent of AMP. There is no best price provision. The Bipartisan Budget Act of 2015 (P.L. 114-74) added the inflationary rebate to generic drugs, which went into effect in the quarter starting January 1, 2017.

[4] While CMS calculates the URA to assist states in developing the rebate invoice, the manufacturer remains responsible for the correct calculation of the URA.

[5] Generally, an innovator—or brand—drug is a drug produced or distributed under a new drug application approved by the Food and Drug Administration (FDA). Single source drugs are innovator drugs manufactured by only one company and innovator multiple source drugs are innovator drugs that now have at least one generic equivalent available. Non-innovator multiple source—or generic—drugs are multiple source drugs that are not innovator drugs. Generally, these are drugs that have been approved under an abbreviated new drug application by the FDA.

[6] Eligible covered entities include the following: federally qualified health centers, federally qualified health center look-alikes, native Hawaiian health centers, tribal/urban Indian health centers, Ryan White HIV/AIDS Program grantees, children's hospitals, critical access hospitals, disproportionate share hospitals, freestanding cancer hospitals, rural referral centers, sole community hospitals, black lung clinics, comprehensive hemophilia diagnostic treatment centers, Title X family planning clinics, sexually transmitted disease clinics, and tuberculosis clinics.

[7] Subsequent to HRSA's 2014 guidance, OIG followed-up with the surveyed states and found that 15 of the 17 states continued to rely solely on the MEF to prevent duplicate discounts in managed care (OIG 2016).

[8] In some instances, there may be practical reasons that covered entities do not pass along 340B discounts to their patients. Contract pharmacies in particular may have difficulty determining at the point of sale whether an individual is eligible for a 340B drug.

[9] CMS explained in the final rule that it would not require state AAC methodology to reflect subceiling prices for 340B covered entities because this information may be difficult to obtain (CMS 2016b).

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