340B DRUG PRICING PROGRAM OVERVIEW

BACKGROUND

To understand the 340B drug pricing program (340B program), one must begin in 1990 when Congress created the Medicaid drug rebate program (MDRP) to lower the cost of pharmaceuticals reimbursed by state Medicaid agencies. The MDRP requires drug companies to enter into a rebate agreement with the Secretary of the Department of Health and Human Services (HHS) as a precondition for coverage of their drugs by Medicaid and Medicare Part B. Under the program, a manufacturer must pay rebates to state Medicaid programs for "covered outpatient drugs," as defined in the Medicaid rebate statute. The rebate amount for a brand name covered outpatient drug is based in part on the manufacturer's "best price" for that drug.

In 1992, Congress extended to safety-net providers the same kind of relief from high drug costs that Congress provided to the Medicaid program with the Medicaid rebate law. Congress enacted Section 340B of the Public Health Service Act, created under Section 602 of the Veterans Health Care Act of 1992. Section 340B requires pharmaceutical manufacturers to enter into an agreement, called a pharmaceutical pricing agreement (PPA), with the HHS Secretary in exchange for having their drugs covered by Medicaid and Medicare Part B. Under the PPA, the manufacturer agrees to provide front-end discounts on covered outpatient drugs purchased by specified providers, called "covered entities," that serve the nation's most vulnerable patient populations. According to congressional report language, the purpose of the 340B program is to enable covered entities "to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services."

WHO IS ELIGIBLE TO PARTICIPATE IN THE 340B PROGRAM?

The definition of "covered entities" includes six categories of hospitals: disproportionate share hospitals (DSHs), children's hospitals and cancer hospitals exempt from the Medicare prospective payment system, sole community hospitals, rural referral centers, and critical access hospitals. Hospitals in each of the categories must be (1) owned or operated by state or local government, (2) a public or private non-profit corporation which is formally granted governmental powers by state or local government, or (3) a private non-profit organization that has a contract with a state or local government to provide care to low-income individuals who do not qualify for Medicaid or Medicare. In addition, except for critical access hospitals, hospitals must meet payer-mix criteria related to the

Medicare DSH program. There are also ten categories of non-hospital covered entities that are eligible based on receiving federal funding. They include federally qualified health centers (FQHCs); FQHC "look-alikes"; state-operated AIDS drug assistance programs; the Ryan White Comprehensive AIDS Resources Emergency (CARE) Act clinics and programs; tuberculosis clinics; black lung clinics; Title X family planning clinics; sexually transmitted disease clinics; hemophilia treatment centers; Urban Indian clinics; and Native Hawaiian health centers.

WHO ADMINISTERS THE 340B PROGRAM?

The Office of Pharmacy Affairs (OPA), which is located within the Health Resources and Services Administration (HRSA) within HHS, administers the program. HRSA and OPA are located in Rockville, MD and are responsible for interpreting and implementing the 340B law. Questions about the 340B program may be submitted to HRSA's government contractor Apexus at 1-888-340-2787 or apexusanswers@apexus.com.

HOW DOES THE PROGRAM WORK?

Facilities that believe they meet the criteria of a "covered entity" can apply to participate in 340B by completing the online registration process during the first two weeks of any calendar quarter (January 1-15, April 1-15, July 1-15, October 1-15). Facilities whose registrations are approved by OPA are listed on the 340B OPA Information System (OPAIS) and eligible for discounts starting the first day of the next calendar quarter following the one during which the entity completed the registration process. Once admitted into the program, covered entities are entitled to receive discounts on all eligible covered outpatient drugs. The discounted prices are typically available through a covered entity's wholesaler unless the manufacturer requires that its drugs be purchased through some other channel, such as a specialty distributor. Covered entities may provide drugs purchased through the 340B program to all eligible patients, regardless of a patient's payer status and whether the drug is intended for self-administration or administration by a clinician.

A manufacturer may not charge more than the 340B ceiling price to covered entities regardless of whether the covered entity purchases pharmaceuticals through a wholesaler or directly from the manufacturer. The 340B ceiling price is the average manufacturer price (AMP) reduced by the unit rebate amount (URA). The URA is a minimum rebate percentage of 23.1 percent for most brand-name prescription drugs, 17.1 percent for brand-name pediatric drugs and clotting factor, and 13 percent for generic and over-the-counter drugs. Manufacturers must offer greater discounts on brand-name drugs if the manufacturer's best price for a drug is lower than AMP minus 23.1 percent for that drug and/or the price of the brand-name drug has increased more quickly than the rate of inflation. This is true for both single-source, brand-name drugs, and brand-name drugs that have generic competition. Generic drugs are not subject to a best price adjustment but, like brand-name drugs, must be offered at a greater discount if the price of the drug has increased more quickly than the rate of inflation. In addition, covered entities are free to negotiate discounts that are lower than the 340B ceiling price (i.e., sub-ceiling prices).

HOW DO COVERED ENTITIES OBTAIN DISCOUNTS?

Upon registration, a covered entity should contact its wholesaler to set up its 340B account. The wholesaler will process the covered entity's orders under the 340B account and deliver the 340B drugs in accordance with the covered entity's wholesaler agreement. The covered entity can also request a price list for 340B drugs from its wholesaler. Covered entities should note that the price charged by wholesalers for a 340B drug might be different from the drug's 340B ceiling price (e.g., the price charged by the wholesaler might be higher than the 340B ceiling price because it includes a wholesaler fee).

Until 2019, covered entities had to rely on wholesalers and manufacturers to obtain pricing information on 340B drugs. However, on April 1, 2019, HRSA launched a secure website that lists 340B ceiling prices for covered entities interested in validating the prices they pay for 340B drugs. Access to the ceiling price website, which HRSA updates each quarter, is limited to the covered entity's authorizing official and primary contact and may not be shared with outside parties. Pricing information available through the website was initially limited to the basic unit price but was expanded on July 1, 2019 to include the following additional data elements: (1) the raw ceiling price (AMP minus URA); (2) the package size; (3) the case "pack" size; and (4) the package adjusted price (raw ceiling price multiplied by the package size and case package size). If a covered entity suspects that it is not receiving the 340B price for a given covered outpatient drug, it should immediately notify the wholesaler and/or manufacturer. In many cases, the absence of a 340B price is the result of human error and can be resolved when the mistake is identified and brought to the wholesaler or manufacturer's attention. Suspected problems that are not resolved by attempting to work in good faith with the wholesaler and/or manufacturer should be brought to OPA's attention. Covered entities can report to OPA instances in which a manufacturer charges more than the 340B ceiling price or fails to offer 340B pricing by sending an Apexus form to 340bpricing@HRSA.gov. In 2010, Congress mandated the creation of a binding administrative dispute resolution (ADR) process to settle claims by covered entities that drug companies have overcharged them for 340B drugs and claims by drug companies that audited entities have violated the prohibitions on diversion or duplicate discounts, which are explained below. The final regulation establishing the ADR process took effect in January 2021, though the process is still being implemented. Adding further uncertainty to the future of the ADR process, drug manufacturers have filed lawsuits challenging the legality of the ADR final rule.

The 340B law creates a Prime Vendor Program (PVP) to help covered entities negotiate sub-ceiling prices. Apexus has served as the Prime Vendor since 2004. A covered entity does not have to join the PVP to participate in 340B and may negotiate sub-ceiling discounts on its own. However, because the PVP can negotiate prices on behalf of many 340B purchasers, it has been able to negotiate favorable prices and develop a national distribution system that may not be possible for some covered entities to obtain individually.

TO WHOM MAY COVERED ENTITIES DISPENSE DISCOUNTED DRUGS?

The 340B law prohibits the resale or transfer of discounted outpatient drugs to anyone other than a patient of the covered entity, which is commonly referred to as "diversion." HRSA has defined a covered entity patient through an October 24, 1996 *Federal Register* notice available on OPA's website. The 1996 patient definition guidelines establish a test that individuals must meet to be eligible to receive 340B-priced drugs. Specifically, the individual (1) must have an established relationship with the covered entity such that the entity maintains records of the individual's care; (2) must receive care from a professional

employed by the covered entity or under contract or other arrangement (e.g., referral for consultation) with the covered entity such that responsibility for the care remains with the covered entity; and (3) with respect to grantees and sub-grantees, must receive health services from the covered entity that are consistent with the services for which grant funding has been provided to the entity. Under the guidelines, an individual is not considered a patient of the covered entity if the only health care service received by the individual from the entity is the dispensing of a drug for subsequent self-administration or administration in the home setting.

ARE THERE BILLING RESTRICTIONS?

Federal law protects manufacturers from giving a 340B discount and Medicaid fee-for-service (FFS) rebate on the same drug. This program rule is commonly known as the "duplicate discount prohibition." To comply with the duplicate discount prohibition, covered entities must first decide whether they will use 340B drugs for their Medicaid FFS patients (i.e., carve in). The rules for carving in for Medicaid FFS patients differ depending on whether a contract pharmacy is used. For drugs dispensed by a contract pharmacy, a covered entity may not carve in Medicaid FFS unless the entity, state Medicaid program, and contract pharmacy have established an arrangement to prevent duplicate discounts and notified OPA of the arrangement. To carve in drugs dispensed or administered at a hospital location or an entity-owned pharmacy, an entity must inform OPA of its decision to carve in and ensure that all numbers it uses to bill 340B drugs to Medicaid FFS (i.e., national provider identifier (NPI) and/or state-specific billing numbers) are listed in OPA's Medicaid Exclusion File. This allows state Medicaid agencies to exclude claims billed under those numbers from their rebate requests. Some states impose additional notification requirements, such as requiring the use of a modifier on 340B claims. In most states, entities can elect to purchase their Medicaid covered outpatient drugs outside the 340B program (i.e., carving out). Carved out drugs are generally subject to the same state Medicaid billing rules that apply to non-340B drugs.

Both HRSA and the Centers for Medicare & Medicaid Services (CMS) have clarified that the purpose of the Medicaid Exclusion File is to help covered entities, states, and manufacturers avoid duplicate discounts specific to Medicaid FFS, not Medicaid managed care. CMS regulations mandate that states require Medicaid managed care organizations (MCOs) to identify and exclude 340B claims from the utilization reports they provide to states for Medicaid rebate collection purposes, or instead require covered entities to submit 340B claims data directly to the state or the state's claims processor before the state submits invoices for Medicaid rebates to manufacturers. If a state chooses the former option, CMS said the state should specify in its contracts with MCOs which tools MCOs can use to exclude 340B claims. The agency noted several potential tools that could be used by MCOs, including requiring covered entities to submit identifiers for 340B claims and assigning a unique Bank Identification Number (BIN)/Processor Control Number (PCN)/Group number to the MCO's Medicaid line of business and requiring providers to bill 340B claims to that BIN/PCN/Group. In January 2020, CMS issued an Informational Bulletin describing state options for avoiding duplicate discounts.

Covered entities should review their Medicaid MCO contracts to ensure that their 340B billing practices comply with the contracts. Entities also should ask their state Medicaid agencies whether they have any requirements regarding billing 340B drugs to Medicaid managed care.

For many years, there was no federal requirement relating to how much state Medicaid agencies must pay for 340B drugs. However, in February 2016, CMS published a regulation requiring states to have established by April 1, 2017 reimbursement policies specific to retail 340B Medicaid FFS drugs and to pay for such drugs based on their actual acquisition cost (AAC). In the agency's discussion of the rule, CMS noted that states have flexibility in setting AAC-based rates for retail 340B Medicaid FFS drugs, which may allow rates that are higher than cost. In a subsequent communication to state Medicaid programs, CMS said that reimbursement for retail 340B Medicaid FFS drugs cannot exceed the 340B ceiling price. Prior to the regulation, many states already required covered entities to bill retail 340B Medicaid FFS drugs at AAC and paid them that amount plus the state-allowed dispensing fee. CMS also said that states may pay higher dispensing fees for retail 340B Medicaid FFS drugs to accommodate 340B pharmacies' increased dispensing costs. There is no federal billing requirement for non-retail (i.e., physician-administered) 340B Medicaid FFS drugs, and state AAC billing requirements for these drugs are less common. There also is no federal billing requirement for physician-administered or retail 340B drugs provided to Medicaid MCO beneficiaries. Providers should contact their state if they have any questions regarding the state's Medicaid billing and reimbursement rules for 340B drugs.

Medicare historically reimbursed all hospitals under the outpatient prospective payment system (OPPS) for separately payable drugs at average sales price (ASP) plus 6 percent. On November 1, 2017, CMS published a final OPPS rule for calendar year 2018 changing reimbursement from ASP plus 6 percent to ASP minus 22.5 percent for most separately payable Part B drugs purchased by hospitals through the 340B or PVP programs. The reimbursement cut does not apply to rural sole community hospitals, critical access hospitals, children's hospitals, and cancer hospitals participating in the 340B program and, at the time, did not apply to certain recently opened, off-campus clinics, often referred to as "site-neutral" clinics. CMS continued the cuts for calendar years 2019, 2020, and 2021 and expanded the scope of these cuts to include 340B drugs administered in site-neutral clinics. Rural sole community hospitals, critical access hospitals, children's hospitals, and cancer hospitals were still exempted from the payment cut.

CAN A COVERED ENTITY USE A CONTRACT PHARMACY TO DISPENSE DISCOUNTED DRUGS TO ELIGIBLE PATIENTS OF THE COVERED ENTITY?

HRSA has developed guidelines to allow covered entities to contract with one or more outside pharmacies to act as a dispensing agent. Under these guidelines, the covered entity is required to purchase the drugs, and the contract pharmacy provides some or all the pharmacy services. Covered entities with contract pharmacies use a "ship to-bill to" procedure in which the covered entities purchase the drugs, and manufacturers and wholesalers bill the covered entities but ship the drugs directly to the contract pharmacies. Among other things, the contract pharmacy must provide the covered entity with quarterly financial statements, a detailed status report of collections, and a summary of receiving and dispensing records. It must maintain those records as long as is required under applicable law. The covered entity and contract pharmacy must establish and maintain a tracking system to prevent diversion of drugs to individuals who are not patients of the covered entity. Covered entities are responsible for monitoring and ensuring contract pharmacy compliance with 340B program requirements such as patient definition and the duplicate discount prohibition. Many covered entities use software vendors and processors to help manage their contract pharmacy arrangements.

In 2020 and 2021, several pharmaceutical manufacturers implemented policies refusing to offer or restricting 340B pricing for drugs dispensed at contract pharmacies. Multiple drug companies have filed lawsuits challenging HHS' position that the agency has the authority to require drug companies to sell covered entities drugs at or below the 340B ceiling price when the drugs are dispensed at contract pharmacies. Litigation is still pending before multiple courts.

HOW MUCH DO 340B PROGRAM PARTICIPANTS SAVE?

Pharmaceutical prices available through the 340B program are significantly lower than both retail and wholesale prices. In 2015, the Government Accountability Office reported that program participants can save an estimated 20-50% off drug costs.

HOW IS COMPLIANCE WITH 340B REQUIREMENTS MONITORED AND ENFORCED?

The 340B statute explicitly authorizes HRSA to audit covered entities and manufacturers to make sure they are compliant with 340B statutory requirements. HRSA began auditing covered entities in 2012 and currently conducts approximately 200 audits of covered entities per year. Information about completed audits is posted on the HRSA 340B program integrity website: http://www.hrsa.gov/opa/programintegrity/index.html. Manufacturers are also authorized to audit covered entities but must do so under HRSA guidelines that require demonstration of reasonable cause and HRSA's prior approval of an audit work plan. Manufacturers can only audit covered entities for compliance with patient definition and the duplicate discount prohibition. Several manufacturer audits of covered entities have taken place, although far fewer than the number of audits performed by HRSA.

Covered entity compliance is also enforced through the annual recertification process. All 340B entities are required to recertify each year. The authorizing officials at 340B covered entities must attest to 340B compliance during recertification, including compliance at contract pharmacies. In addition, as part of recertification, covered entities agree to self-report to HRSA when they uncover a breach of 340B program requirements. HRSA recommends that each covered entity establish and document criteria that signify when a material breach of compliance requiring HRSA notification has occurred.

Like covered entities, manufacturers are subject to audits by HRSA to ensure compliance with 340B requirements. Covered entities have no authority to audit manufacturers, and there is no annual recertification process for manufacturers. Both covered entities and manufacturers are subject to penalties if they violate 340B program requirements. For covered entities, the penalty for failing to comply with the program's diversion and duplicate discount provisions is repayment of the discounts back to the manufacturer. Where a diversion violation is knowing and intentional, covered entities may be required to pay interest on the discounts that they refund. If the diversion violation is systematic and egregious as well as knowing and intentional, a covered entity may be disqualified from 340B participation for a reasonable time, to be determined by HRSA.

For manufacturers, the consequence for charging in excess of the ceiling price is to refund those overcharges. HHS is also authorized by statute to impose civil monetary penalties (CMPs) on companies that knowingly and intentionally overcharge covered entities for 340B drugs. The only other penalty for manufacturer non-compliance is termination of the manufacturer's PPA which, in turn, would mean that the manufacturer's covered outpatient drugs are excluded from Medicaid and Medicare Part B coverage.

HOW DO YOU RECEIVE THE LATEST INFORMATION ON THE PROGRAM?

OPA disseminates information to program participants through its website at http://www.hrsa.gov/opa/index.html and the PVP website located at http://www.340Bpvp.com. The OPA website includes the names of participating covered entities and manufacturers, Federal Register notices and current program guidelines, and other 340B program-related information. Other helpful information is available at 340B Health's website located at http://www.340bhealth.org. In addition, 340B Health publishes a 340B blog called 340B Informed that can be found online at http://www.340Binformed.org. 340B Health also produces the 340B Insight Podcast that provides 340B supporters with timely news updates and discussion around the 340B program and can be found at https://www.340bpodcast.org/ .

For questions, please visit www.340bhealth.org or contact Amanda Sellers Smith, Assistant Counsel at amanda.smith@340bhealth.org or 202-552-5851.

340B Health is a membership organization of more than 1,400 public and private nonprofit hospitals and health systems participating in the federal 340B drug pricing program. To support our members, 340B Health monitors, educates, and serves as an advocate on federal legislative and regulatory issues related to drug pricing and other matters affecting safety-net providers.

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