What Every AMC Needs to Know about the 340B Program

by

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I. History and Purpose

A. The 340B Covered Outpatient Drug Program (the "340B Program") was created in 1992 by the Veterans Health Care Act of 1992 (the "VHCA").

B. The program received its name because the VHCA created a new Section 340B (42 U.S.C. § 256b) of the Public Health Service Act (the "PHSA").

C. The program was the upshot of unintended consequences created by the Medicaid Drug Rebate Program ("MDRP") in 1990.

1. The MDRP requires manufacturers to pay States rebates in exchange for Medicaid coverage of their drugs.

2. The rebates are calculated by subtracting the manufacturer's "best price" to any customer from their "average manufacturer price." That difference, referred to as the unit rebate amount, is then multiplied by the State's Medicaid utilization, resulting in a rebate amount.

3. Initially, pricing to safety net entities, such as family planning clinics and safety net hospitals, were included in the "best price" calculation. To avoid setting the rebate obligation excessively high, these entities no longer qualified for the special pricing they historically had enjoyed after enactment of the MDRP in 1990.

D. The VHCA thus created an exemption from "best price" for sales to specified covered entities and to the VA and certain other government agencies. It also set a mandatory ceiling price on sales to these entities. By doing so, prior practices of offering discounts to these entities have now been enshrined into law and made mandatory.

1. Congress' stated goal was to help covered entities "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." However, there is no statutory requirement that covered entities actually use their drug savings to assist the indigent.

E. Over time, the law has expanded to cover new types of covered entities. Children's hospitals were added by the Deficit Reduction Act in 2006. The

Affordable Care Act added critical access hospitals, sole community hospitals, rural referral centers, and cancer centers in 2010.

F. Like many sections of the Public Health Service Act, the 340B Program is administered by the Health Resources and Services Agency ("HRSA"). HRSA has created an Office of Pharmacy Affairs ("OPA") that is responsible for setting policy and performing audits of covered entities.

G. According to a 2011 GAO report, approximately $6 billion of drug purchasing is through the 340B Program. At that time, there were over 16,000 covered entities, of which over 1200 were hospitals.

H. Given the growing complexity of the 340B Program and the fact that many operational policies have remained uncodified, HRSA sought to memorialize its rules in a proposed "Mega-Guidance" issued on Aug. 28, 2015. That proposed guidance, however, was withdrawn in Feb., 2017 after a change in the administration.

II. Eligibility Criteria for Different Types of "Covered Entities"

A. There are 15 types of covered entities identified in the 340B statute (PHSA, § 340B(a)(4)). They largely fall into two types of entities:

1. Safety net hospitals, such as hospitals that receive disproportionate share hospital ("DSH") funding, rural referral centers ("RRCs"), sole community hospitals ("SCHs"), and critical access hospitals ("CAHs").

2. Public Health Service grantees, such as STD clinics, family planning clinics, and federally qualified health centers ("FQHCs").

B. The hospital entities all of have similar requirements, but also have individual differences.

1. <u>Ownership or operation by, or under the auspices of, a governmental entity</u>. All of the hospital entities that can qualify as 340B covered entities must either be owned or operated by a governmental entity, or they must have a contract with a governmental entity pursuant to which they agree to furnish services to uninsured, indigent patients.

2. <u>GPO prohibition</u>. For DSH hospitals, children's hospitals, and cancer centers, the covered entities cannot purchase outpatient drugs through a GPO (inpatient purchasing is, however, acceptable).

3. <u>DSH percentage</u>. For DSH hospitals, children's hospitals, and cancer centers, the disproportionate share adjustment percentage must be at least 11.75 percent. For SCHs or RRCs, the percentage must be at least 8 percent. CAHs do not have a minimum percent.

C. Hospitals and others are permitted to add "child sites" to their HRSA enrollment. A "child site" is an outpatient area of the hospital covered entity that is located at a different address from the main provider covered entity.

1. To qualify as a child site, the hospital must identify the site on a reimbursable line of the cost report, which generally means that the site must be provider-based.

2. Additionally, there must be Medicare charges on worksheet D relating to services at the site.

3. Secondary campuses of a main provider must enroll each separate department of the secondary campus separately with HRSA.

D. Entities can enroll (or enroll new sites) during any one of four annual enrollment periods. Such enrollments take effect at the beginning of the next calendar quarter.

E. Entities must also recertify annually compliance with applicable requirements. HRSA has also stated that it expects covered entities that fall below their DSH threshold to voluntarily withdraw from the program, even if they learn of their new DSH level in the middle of a quarter.

III. Definition of "Patient"

A. Furnishing drugs to an individual who is not a "patient" qualifies as impermissible diversion.

B. 1996 definition states as follows:

1. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care;

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; and

3. The individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

C. Open items regarding the definition of patient:

1. The record maintenance requirement is generally interpreted to mean a medical record, as opposed to a record by a covered entity regarding an employee in the covered entity's employer medical plan files. In other words, employees do not automatically qualify as "patients."

    a. Though not stated in the definition of patient, many covered entities consider it necessary that the prescription filled with 340B drugs relate to a treatment received at the covered entity.

    b. For covered entities working under that interpretation, when determining if a prescription filled at a contract pharmacy constitutes eligible utilization, they often determine whether there has been an entry in the medical record within a set number of months prior to filling the prescription, such as 6 months or a year.

2. There are questions regarding who is an eligible professional.

    a. It is unclear if it is only intended to apply to physicians, or if other professionals, such as nurses, are included. Many covered entities interpret this provision broadly to include nurses and similar clinicians.

    b. It is also unclear what more than privileges are needed for members of a volunteer medical staff. For instance, is participation on a committee needed? What about joint participation in an ACO or other gainsharing arrangement?

    c. HRSA's interpretation of the definition of patient has become more stringent over time. Accordingly, it is no longer certain that, if a hospital refers a patient for consultation without having any greater nexus to the patient, it would be acceptable to view any resulting prescriptions as covered under the 340B Program.

D. The now-withdrawn Mega-Guidance would have significantly increased the burdens associated with proving that 340B drugs were dispensed to a qualifying patient. The revised requirements would have included that:

1. The patient must be receiving care at the Parent Site or a Child Site.

2. The patient must be receiving care from an employed physician, or one who has reassigned his benefits to the covered entity.

3. The patient's prescription is the result of the service received from the eligible physician.

4. The services must be consistent with those allowed to be furnished under the PHS grant (for PHS grantees).

5. The services leading to receipt of the prescription must be outpatient services.

6. The patient records must be accessible to the covered entity.

E. Although withdrawn, pieces of these stringent requirements remain place. For instance, HRSA continues during provider audits to maintain the position that all prescriptions filled at contract pharmacies must be written in provider-based space.

F. Other pieces of the withdrawn guidance definition of patient remain controversial, but do not appear to have been implemented to date. These include the requirement that patients receiving infusions of 340B drugs must receive a medical service from a professional, and not just an infusion. Also, HRSA's prohibition against filling prescriptions written at the time of an inpatient discharge with 340B drugs does not appear to be a requirement against which HRSA is currently auditing.

IV. Definition of "Covered Outpatient Drug"

A. A drug is a covered drug under the 340B program, based in part upon how it is reimbursed under Medicaid. Drugs that are "incident to" an inpatient or outpatient hospital service, or a physician service, are not considered covered outpatient drugs for 340B purposes. PHSA, §340B(b)(1) (cross-referencing the Social Security Act, § 1927(k)). To qualify as "incident to" under the 340B program, the drug must be one "for which payment may be made [under Medicaid] as part of payment for [inpatient or outpatient hospital services or physician services] and not as direct reimbursement for the drug." *Id*. Thus, the question is whether payment is available from Medicaid only on a bundled basis, or whether separate payment is available for the drug.

B. 1994 guidance implies that whether a drug is a covered outpatient drug depends upon how it is reimbursed by a particular payer in a particular setting, implying that the same drug could be treated differently on a case by case basis by the same covered entity. 59 Fed. Reg. 25110, 25113 (May 13, 1994).

C. FAQ, however, states as follows:

> If the covered entity interprets the definition of covered outpatient drug referenced in the 340B Statute (Social Security Act 1927 (k)) and decides that drugs do not meet this definition, a GPO may be used for drugs that are not covered outpatient drugs. The decision the covered entity makes should be defensible, consistently applied in all areas of the entity, documented in policy/procedures, and auditable." (Apexus FAQ 1355, last modified 2/25/2015, accessed 9/4/2015

D. Thus, a defensible, consistently applied methodology should be acceptable, even if a determination is not made for each drug in each setting for each payer, individually.

E. The withdrawn Mega-Guidance, however, would have followed the 1994 policy.

V. GPO Prohibition

A. Only applies to DSH hospitals, cancer centers, and children's hospitals.

B. Drugs used for inpatients can be purchased through a GPO, but outpatient use cannot be.

C. Most hospitals have virtual inventory. Pursuant HRSA Release 2013-1 (Feb. 7, 2013), the initial purchase must be at WAC, and then can be replenished with GPO or 340B drug as applicable.

D. The same release identifies that contract pharmacies are not subject to the GPO prohibition, but hospitals cannot purchase via contract pharmacies from a GPO for outpatient use.

1. "Ship to" pharmacies that are part of the main covered entity are subject to the GPO prohibition.

E. An exception applies to sites that:

1. Are located at a different physical address from the parent;

2. Are not registered as a Child Site;

3. Purchase drugs through a separate pharmacy wholesaler account; and

4. Have records demonstrating that any covered outpatient drugs purchased through the GPO at these sites are not utilized or otherwise transferred to the parent hospital or any outpatient facilities registered on the OPA 340B database.

VI. Prohibition on Duplicate Rebates on Medicaid Utilization

A. Statute prohibits use of 340B drugs for Medicaid patients, where the State is separately seeking rebates for that utilization under the Medicaid Drug Rebate Program. PHSA, § 340B(a)(5)(A). Pursuant to the Affordable Care Act, Medicaid managed care utilization is now included in the Medicaid utilization subject to the Medicaid Drug Rebate Program.

B. HRSA has established an "Exclusion File" such that covered entities can alert the State that they are 340B covered drugs for Medicaid beneficiaries. The States can then exclude such utilization from their rebate invoices to manufacturers.

C. In 2016, CMS published a rule requiring States to devise systems so that they pay Medicaid providers at their actual acquisition cost ("AAC"). 81 Fed. Reg. 5170, 5355 (Feb. 1, 2016). To ensure that 340B covered entities are reimbursed

correctly, many States require the use of modifiers for covered entities that use 340B drugs for Medicaid beneficiaries. States then pay a lower price to these entities to reflect their lower costs of purchasing.

VII. Contract Pharmacy Arrangements

A. HRSA has allowed the use of contract pharmacies since 1996. These arrangements permit covered entities to contract with an outside pharmacy (such as CVS or Walgreens) to allow covered entities to have these pharmacies dispense 340B drugs to individuals qualifying as the covered entity's patients.

B. Generally, these arrangements require the use of a software product, often referred to as the "340B administrator" that compares pharmacy utilization with lists of covered entity eligible providers and medical record dates, so as to determine if any of the pharmacy's patients also qualify as patients of the covered entity. If so, the covered entity pays the pharmacy a dispensing fee, orders replenishment drug for the pharmacy at 340B pricing, and receives payment of the reimbursement amount received by the pharmacy.

C. HRSA formalized the requirements for contract pharmacies in 2010, and allowed covered entities to expand their arrangements to cover multiple pharmacies. The arrangements must include some version of the standard contract terms included in HRSA's guidance.

VIII. Sanctions

A. No FCA liability for misuse of 340B drugs.

B. Generally, if there has been diversion to non-patients, repayment to manufacturers for the improperly dispensed drugs is all that is needed.

C. If there has been knowing and intentional non-compliance, then interest payments may also be due.

D. If the misuse of 340B drug is systematic and egregious, as well as knowing and intentional, the covered entity can be removed from the 340B Program for some period of time, as determined by HRSA.