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340B Drug Pricing Program Proposed Guidance

OVERVIEW

On August 28th, the Health Resources and Services Administration (HRSA) issued a proposed Omnibus Guidance on the 340B Drug Pricing Program (340B Program). The 340B Program provides eligible safety net providers with discounted prices on outpatient drugs. As of January 1, 2015, there were 11,530 registered entities and 644 drug manufacturers participating in the 340B Program.

HRSA will accept comments on the proposed guidance until October 27th. The proposed guidance is available here. This document summarizes several major provisions of the guidance.

PATIENT ELIGIBLITY

The primary policy change proposed in HRSA's guidance is to clarify and narrow the definition of eligible patients to whom participating providers are able to provide 340B-discounted drugs.

Under the existing policy, any patient is eligible for the 340B Program if:

1. The covered entity has established a relationship with the individual (e.g., 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 (including referrals for consultation); and
3. In the case of Federally Qualified Health Centers (or look-alikes), the individual receives a health care service from the covered entity that is consistent with the scope of the clinic's FQHC grant funding or look-alike designation.

The proposed guidance expands the number of conditions that patients must meet to be eligible from three to six. HRSA has modified the language of the existing eligibility criteria and added three additional conditions.

1. **The individual receives services at a facility or clinic site registered in the 340B program and listed on the database**. This establishes a new location-based requirement. Patients who see a physician associated with the eligible entity in a private practice, even as follow up to care in the eligible entity, would not be eligible.

2. **The individual receives a health care service provided by a covered entity provider who is either employed by the covered entity or an independent contractor for the covered entity.** This standard includes all providers who are able to bill for services on behalf of the covered entity, but newly excludes providers who simply have admitting privileges or hospital credentials.

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3. **The individual receives a drug that is ordered or prescribed by the covered entity as a result of the services described in condition two.** This standard requires that the prescription be a direct result of a provider-patient encounter in which the provider meets the eligibility standard. Prescriptions written by outside providers will not count towards discount eligibility even if the patient has an ongoing relationship with the 340B entity where the prescription is dispensed.

4. **The individual receives services consistent with the scope of the designated federal grant, project, designation, or contract.** This requirement is largely unchanged, and does not apply to eligible hospitals.

5. **The individual's drug that is ordered or prescribed follows a service classified as outpatient.** A patient must be classified as an outpatient, and care billed as such, in order for prescriptions resulting from that care to be eligible for 340B discounts. In the case of uninsured or self-pay patients where third-party payers are not billed, Medicare standards for inpatient or outpatient designation will apply.

6. **The patient's records are accessible by the covered entity and establish that the covered entity is responsible for care.** Eligibility for the 340B discount is established on a per-patient and per-prescription basis, meaning that the eligible entity must have a record of every outpatient health service that results in a 340B prescription. This applies to renewing prescriptions, which must take place at the eligible entity.

The proposed guidance also clarifies how providers participating in the 340B program must ensure duplicate discounts are not obtained for any drug, particularly in relation to drugs provided to Medicaid beneficiaries. Manufacturers are generally required to offer discounts to state Medicaid programs for outpatient drugs. The proposed guidance allows for various arrangements between states and participating 340B providers to carve Medicaid beneficiaries in or out of 340B drug discounting as long as no duplicate discounts are provided.

OTHER PROVISIONS

- ***Hospital Eligibility***. HRSA does not propose changes to the requirements for hospital eligibility for the 340B program. In particular, HRSA does not respond to MedPAC and GAO recommendations that it provide a narrower definition of what type of contract a hospital must have in place with a local government to provide care for the uninsured or how much such care must be provided in order to be eligible.
- ***Off-Site Outpatient Facilities***. HRSA does not propose changes to its current method of determining eligibility for off-site outpatient facilities, often referred to as "child sites" because their eligibility is dependent on their affiliation with an eligible "parent" hospital or clinic. HRSA proposes to continue use of the requirement that a child site be listed on the parent site's Medicare cost report and deliver Medicare-eligible services, but is seeking comments on alternative methods.

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- ***Accountable Care Organizations (ACOs)***. HRSA clarifies that 340B eligibility of one ACO participant provider does not confer eligibility to other ACO participants; each provider submitting separate Medicare cost reports must establish eligibility and register independently.
- ***Group Purchasing Organizations (GPOs).*** The 340B statute prohibits participating hospitals from also purchasing 340B-eligible outpatient drugs through GPOs. The proposed guidance includes new exceptions to this policy, including for some off-site outpatient sites, and new clarifications regarding the enforcement of the GPO prohibition.
- ***Contract Pharmacies.*** HRSA does not propose to change its 2010 guidance allowing eligible providers to use contract pharmacies to dispense 340B drugs. The proposed guidance offers significant new clarifications about the nature of the contract required, and compliance obligations for contract pharmacies and their parent sites.
- ***Record Retention.*** The proposed guidance sets a new requirement that 340B participating entities maintain organized records of all 340B prescriptions and health records for no less than five years.