Worth the Wait?

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In August 2015 the Health Resources and Services Administration (HRSA) released its much-anticipated "mega-guidance" on the 340B Drug Pricing Program, proposing new limits on the program but stopping short of a complete overhaul, prompting mixed reviews from stakeholders. ACCC has long advocated for more clarity in the program—something both covered entities and drug manufacturers can agree on—and we commend HRSA for taking this important step amid legal challenges and Congressional pressure. But just how far the guidance will go remains unclear. While HRSA's directives are not legally binding, it does inform 340B participants how the agency believes the program should operate and we can expect it will be used as a basis for future audits. Stakeholders are still working to decipher the impact the guidance will have on the day-to-day operations of the 340B program, and it remains to be seen whether Congress will codify the guidance or move any other legislation related to 340B.

While HRSA's guidance addresses many of the key issues needing clarification, including hospital and patient eligibility, contract pharmacy arrangements, and audit procedures, it most notably proposes to place tighter controls on patient eligibility. For a patient to be classified as a 340B patient of a covered entity (CE), HRSA would require the 340B prescription to satisfy six new criteria:

1. Patient received a healthcare service from a registered CE.
2. The service is provided by a CE-associated provider.
3. The drug prescription is a result of the service provided by the CE and, importantly, the service is not limited to the dispensing or infusion of a drug.
4. The service is consistent with the CE's grant or contract.
5. The prescription is the result of an outpatient service, determined by how the CE bills the payer.
6. The CE maintains access to auditable health records.

Importantly, HRSA also specifies that the revised patient definition would be applied on a prescription-by-prescription basis, meaning that each individual encounter would be evaluated for eligibility and patients would not qualify for 340B drugs for all of their needs based on being treated by the CE for one medical issue.

So what does this mean? Essentially, the guidance significantly strengthens the relationship between the covered entity and patient, requiring that the CE provide a more comprehensive service for a patient to be classified as a patient of that CE and receive discounted 340B drugs. This will likely have significant implications for referrals and follow-up care, limiting the ability of patients to move between sites of care. As an example, under the guidance, in a situation where a patient sees a physician at a non-340B site as a referral or follow-up to care, even though the patient's care originated at a CE, that patient would no longer be eligible to receive a 340B discount. However, HRSA specifies that when a patient returns to the CE for ongoing care, subsequent prescriptions would be eligible for discounts. This would also mean, for example, that if an outside physician (i.e., a non-CE-physician) sends patients to a CE for an infusion, that drug would not be eligible for the 340B discount because the guidance stipulates that the service the CE provides cannot be limited to the infusion or dispensing of a drug.

Other provisions that are important from the provider's perspective include HRSA's guidance on the eligibility of an offsite, or "child site," facility. HRSA proposes to retain the current standard that the facility or clinic be listed as a reimbursable line of the hospital's Medicare cost report, but also specifies that the services provided have associated Medicare outpatient costs and charges. Notably, HRSA is soliciting alternative methodologies to this approach. While there were no major changes to hospital eligibility, HRSA does clarify how to meet certain requirements to participate, requiring more detailed documentation, which potentially could result in increased administrative burden.

The guidance is fairly quiet on contract pharmacy arrangements, declining to impose any restrictions on the number of CE contract pharmacy locations or arrangements, and instead emphasizing a CE's compliance obligations. HRSA proposes that CEs conduct a quarterly review and annual independent audit of these arrangements.

The agency may issue final guidance sometime in the following months, so stay tuned! OI

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