

PUBLICATION

Drastic Changes in "Patient" Definition as HHS Releases the Long-Awaited Proposed 340B Omnibus Guidance [Ober|Kaler]

September 03, 2015

After years of fits and starts, the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services (HHS) has finally released its proposed omnibus guidance [PDF] for the 340B Drug Discount Program. The lengthy proposed "mega guidance" released on Thursday, August 27 is designed to "clarify" many of the issues that various 340B Program stakeholders have been struggling with over the past several years.

While much of the guidance should not come as a surprise to those who have been operating in the 340B world, HHS has managed to throw a few curve balls — particularly with the change in "patient" definition, which will likely require many 340B covered entities to re-evaluate certain programs designed to optimize access to 340B pricing.

HRSA is proposing to formalize its guidance on many topics of interest to 340B stakeholders, including the following:

- HRSA's (sometimes complicated and onerous) registration and certification requirements;
- Who, precisely, qualifies as an "eligible" covered entity;
- When and how the prohibition on obtaining outpatient drugs through a group purchasing organization (GPO) or other group purchasing arrangement applies to hospital covered entities;
- Audits, both HHS audits as well as manufacturer audits;
- Contract pharmacy arrangements;
- The Medicaid exclusion file;
- Record retention requirements; and
- Consequences for covered entities that find themselves out of compliance with 340B Program requirements.

The most significant change for hospital covered entities comes in the form of a new, considerably more narrow, six-prong definition of "patient." This new definition could have a drastic impact on covered entities relying on the previous test, which permitted individuals receiving health care services from health care professionals under "contractual and other arrangements" with a covered entity to receive 340B drugs, so long as the responsibility for the care remained with the covered entity. Now, the test will require a much stronger nexus between the covered entity and the healthcare professional providing care.

Specifically, under the proposed patient definition, an individual will not be considered a patient of the covered entity unless the following criteria are met:

1. The individual receives a health care service *at a **covered entity site** which is registered for the 340B program and is listed on the public 340B database;*
2. The individual receives a health care service from a health care provider employed by the covered entity or who is an independent contractor of the covered entity *such that the covered entity may bill for services on behalf of that provider;*

3. An individual *receives a drug that is ordered or prescribed by the covered entity provider as a result of the service* described in (2). An individual will not be considered a patient of the covered entity if the only health care received by the individual from the covered entity is the infusion of a drug or the dispensing of a drug;
4. The individual receives a health care service that is consistent with the covered entity's scope of grant, project, or contract. [Note: this does not apply to hospital covered entities];
5. The individual is *classified as an outpatient* when the drug is ordered or prescribed. The patient's classification status is determined by how the services for the patient are billed to the insurer (e.g., Medicare, Medicaid, private insurance). An individual who is self-pay, uninsured, or whose cost of care is covered by the covered entity will be considered a patient if the covered entity has clearly defined policies and procedures that it follows to classify such individuals consistently; and
6. The individual has a relationship with the covered entity such that the covered entity has a provider-to-patient relationship, that the responsibility for care is with the covered entity, and that each element of this patient definition in this section is met for each 340B drug.

80 Fed. Reg. 52319 (August 28, 2015). (Emphasis added).

Ober|Kaler's Comments

While HRSA has taken positions during audits of covered entities that are consistent with some aspects of this new definition, including the site-of-service requirement, the criteria noted in the second prong (requiring that the covered entity be able to bill on behalf of the health care professional) and fifth prong (that the patient must be classified as an outpatient) are new and very limiting. This may create some concern for hospitals that have designed new programs over the past several years intended to maximize savings realized through 340B purchases, including, among others, infusion centers and employee wellness programs. Further, requiring that the patient be "classified as an outpatient" would effectively preclude inpatients from filling discharge prescriptions with 340B drugs.

While the preamble to the proposed guidance attempts to address stakeholder questions, there will undoubtedly be a great deal of uncertainty as to the specific application of this new definition to many current practices as well as existing and proposed arrangements for hospital covered entities. Covered entities that believe the new requirements are unclear or will be unnecessarily burdensome should consider filing comments to the proposed guidance. **Deadline for the submission of comments is October 27, 2015.**