
Proposed 340B Drug Pricing Program Omnibus Guidance - Defines "Eligible Patient"

October 2015

Public Comments Due by October 27, 2015

On August 28, 2015, the Health Resources and Services Administration (“HRSA”) published the proposed 340B Drug Pricing Program Omnibus Guidance (“Omnibus Guidance”) which is intended to clarify for covered entities, such as Federally Qualified Health Centers (“FQHC”), the standards for participation in the 340B Drug Pricing Program (“340B Program”). While the Omnibus Guidance covers many aspects of the 340B Program, the guidance regarding eligibility of individuals to receive 340B drugs (an “Eligible Patient”) is arguably one of the most significant changes. It is likely that this change will not greatly impact FQHCs. Nevertheless, it is important to understand how the definition of Eligible Patient has changed to ensure compliance with this aspect of the 340B Program.

The definition of an Eligible Patient is perhaps one of the most important, yet confusing aspects of the 340B Program. At present, there is a three-part test for determining Eligible Patient status. Briefly, to be considered an Eligible Patient (i) the individual must have an established relationship with the covered entity and the covered entity must maintain records of that individual’s health care, (ii) the individual must receive health care from a health care professional who is either employed by the covered entity or provides health care under contract with the covered entity such that the responsibility for the care remains with the covered entity, and (iii) the individual must receive a health care service or range of services from the covered entity that is consistent with the service or range of services for which the covered entity receives Federal funding.

The Omnibus Guidance proposes a new six-part test whereby the individual will be considered an Eligible Patient on a prescription-by-prescription basis if all of the following requirements are met:

1. The individual receives a health care service at a facility or clinic site that is registered for the 340B Program and listed in the public 340B database;
2. The individual receives a health care service provided by a covered entity provider who is either employed by the covered entity or is an independent contractor of the covered entity, such that the covered entity may bill for services on behalf of the provider;

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3. The individual receives a drug that is ordered or prescribed by the covered entity provider as a result of the services described in 2, above;
4. The individual's health care is consistent with the scope of the Federal grant, project, designation or contract;
5. The individual's drug is ordered or prescribed pursuant to a health care service that is classified as outpatient; and
6. The individual's patient records are accessible to the covered entity and demonstrate that the covered entity is responsible for care.

The six-part test would not only narrow the definition of Eligible Patient, but HRSA is proposing that covered entities apply the six-part test for each 340B prescription written. If you are concerned about the impact of the new six-part test for an Eligible Patient, or any other aspect of the Omnibus Guidance, HRSA is accepting comments until October 27, 2015.

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