Crowe Horwath

October 2015

# HRSA Releases Proposed 340B Mega-Guidance

By Jackie Bonny, Peter Buonincontro, and Jerry Lear, CIA, CISA


Since its inception in 1992, the 340B Drug Pricing Program has required drug manufacturers to offer outpatient drugs to eligible healthcare organizations at significantly reduced prices. On Aug. 28, 2015, the Health Resources and Services Administration (HRSA) released its much-anticipated proposed 340B Drug Pricing Program Omnibus Guidance – or "mega-guidance" – in an effort to clarify some of the concerns that have been raised over the years. However, the mega-guidance has not yet been finalized; comments are due by Oct. 27, 2015. It is unclear if this mega-guidance will replace existing, limited guidance documents or how the guidance will be treated in terms of future HRSA audits.

The guidance is comprehensive and touches all aspects of the drug pricing program. The eight parts of the guidance relate to:

- Program eligibility and registration
- Eligibility of drugs for purchase under 340B
- Patient eligibility to receive 340B drugs
- Requirements for covered entities
- Arrangements for contract pharmacies
- Manufacturer responsibilities
- Rebate options for AIDS drug assistance programs
- Program integrity

It is likely that all covered entities will be affected at some level. For some covered entities, substantial programming and process changes may be necessary to ensure compliance.

One of the most significant impacts is in the area of determining patient eligibility. The mega-guidance is proposing a new six-part test in which all parts of the test will have to be met for a patient to be eligible for inclusion in the 340B program.

Currently, only a three-part test needs to be satisfied:

1. The covered entity must have an established relationship with the individual, maintaining records of the individual's healthcare.
2. The individual must receive healthcare services from providers who either are employed by the covered entity or maintain contractual or other arrangements (e.g., referral for consultation) such that the covered entity is responsible for the care provided.
3. The healthcare services that the individual receives from the covered entity are consistent with the services for which the entity has received grant funding or federally qualified health center look-alike status. Disproportionate share hospitals are exempt from this requirement.

An individual will not be considered a patient of the covered entity if the only healthcare service the individual receives from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.

Under the proposed guidance, the following six requirements must be met for an individual to be considered a patient:

1. Services must be provided at a facility that is both registered for the 340B program and listed on the public 340B database.
2. Services must come from a provider who is either employed by a covered entity or is an independent contractor for the covered entity, which may bill for services on behalf of the provider.
3. The drug that the individual receives must be ordered or prescribed by the covered entity provider as a result of the service already described.
4. The individual's healthcare is consistent with the scope of the federal grant, project, designation, or contract.
5. The drug is ordered or prescribed based on a healthcare service classified as outpatient.
6. The covered entity has access to the individual's patient records, which show that the covered entity is responsible for care.

In addition, the following requirements will have to be met:

- Discharge prescriptions from an inpatient stay no longer will qualify; only drugs billed as part of an outpatient visit will be eligible, which may require more complex eligibility processes in the contract pharmacy setting.
- Referring providers must meet stricter requirements that will limit eligibility.
- Covered entities will have an obligation to prevent duplicates for Medicaid managed care organizations (MCOs), and contract pharmacies will have to exclude Medicaid MCOs in the same fashion that they currently carve out Medicaid fee-for-service providers from their 340B purchases.
- Bundled Medicaid drugs will not be 340B eligible.
- Contract pharmacies will be required to undergo quarterly reviews by the covered entity with which they are contracted.

These are only a few examples of the proposed changes, some of which need further clarification and are open to different interpretations. The narrower definitions may affect savings for the covered entity and its patients.

Although the mega-guidance has not yet been finalized, we recommend that healthcare organizations perform audits to manage and confirm compliance with 340B program requirements. Additionally, they should engage 340B subject-matter experts to evaluate the financial and operational effects of the proposed changes.

## Contact Information

Jackie Bonny is with CHAN Healthcare, a subsidiary of Crowe Horwath LLP, and can be reached at +1 319 272 7178 or jackie.bonny@crowehorwath.com.

Peter Buonincontro is with CHAN and can be reached at +1 630 575 4345 or peter.buonincontro@crowehorwath.com.

Jerry Lear is a senior vice president with CHAN and can be reached at +1 513 639 0147 or jerry.lear@crowehorwath.com.

www.crowehorwath.com