

HRSA EXTENDS 340B GPO EXCLUSION GUIDANCE COMPLIANCE DEADLINE FROM APRIL 7, 2013 TO AUGUST 7, 2013

On February 7, 2013, the United States Health Resources and Services Administration ("HRSA") released guidance entitled "Statutory Prohibition on Group Purchasing Organization Participation" ("GPO Exclusion Guidance"). This guidance addresses requirements related to drugs purchased at a discount under the 340B Program by hospitals subject to the 340B Program GPO exclusion restriction. These include disproportionate share hospitals, children's hospitals and freestanding cancer hospitals enrolled in the 340B Program and exclude entities registered as any other type of 340B covered entity.

The GPO Exclusion Guidance, which presents a variety of operational and implementation challenges, had set forth an extremely short implementation deadline of April 7, 2013. Acknowledging widespread industry concerns, HRSA has **extended the compliance deadline to August 7, 2013**. This extension was communicated via an FAQ published on HRSA's website. The full text of the **FAQ** is as follows:

HRSA published Policy Release 2013-1 (PDF - 227 KB) on February 7, 2013 to clarify its policy regarding this 340B Program statutory prohibition. HRSA initially allowed covered entities 60 days after the publication of the GPO policy release (until April 7, 2013) to make certain their drug replenishment practices comply with the GPO policy release. Based on a large number of covered entities providing comments that this deadline could not be met due to the work required to implement the needed changes, HRSA is extending the deadline to August 7, 2013 for those entities that are not able to comply with the initial April 7 deadline. No additional extensions will be granted beyond the August 7 date.

During this extension, HRSA expects that covered entities will comply with the GPO Prohibition as soon as possible prior to the August 7 deadline. HRSA reviews and follows-up on all allegations regarding non-compliance and has the ability to audit a covered entity. In such cases, covered entities should be able to demonstrate that they made their best effort to be in compliance as soon as they were able to do so and should have a legitimate reason for any delay. Any evidence of deliberate delay could result in immediate removal from the 340B Program.

If a covered entity is unable to be in compliance by August 7, the covered entity must immediately notify HRSA, and will be terminated from the program. The covered entity may reapply during the next quarterly registration period (October 1 - 15) once it determines that it is in compliance with all 340B Program requirements and can attest to such during the enrollment process. If after August 7, HRSA determines that a covered entity still participating in the program is not in compliance with the GPO prohibition, HRSA will terminate such entity from the 340B Program.

In addition, HRSA will be conducting annual recertification of hospitals after the August 7 deadline as part of the regular annual recertification process. At that time, all participating 340B hospitals must attest that they are in compliance with all 340B program requirements, including compliance with the GPO prohibition as detailed in Policy Release 2013-1 (PDF - 227 KB).

While this new FAQ guidance does not address some of the implementation challenges/concerns raised by the GPO Exclusion Guidance, it does give providers more time to ensure that their processes and systems are compliant. This HRSA FAQ guidance will also give providers additional time to communicate any implementation concerns to HRSA in the event HRSA is willing to consider altering the scope of the GPO Exclusion Guidance.

If you have any questions, would like additional information about this topic or need help preparing and submitting comments, please contact Todd Nova at 414-721-0464 or tnova@hallrender.com or your regular Hall Render attorney.