

340B UPDATE: HRSA ISSUES PROGRAM NOTICE ADDRESSING ONGOING 340B PROGRAM AUDITS

On March 5, 2012, the Health Resources and Services Administration ("HRSA") issued a new Program Notice ("Notice") that provides additional insight into the recent audits of entities participating in the 340B Program ("Covered Entities"). The Notice, which HRSA characterizes as a restatement of current policy, represents the clearest public statement to date of HRSA's 340B Program audit strategy and procedures.

First, the Notice indicates that entities currently required to obtain an audit in accordance with the requirements of OMB Circular A-133 (Single Audit Act) will, in federal fiscal year 2013, be required to review 340B Program compliance as part of that annual audit.

Second, HRSA states in the Notice that it will also conduct "random and targeted" audits that will be more detailed than the A-133 audit requirements mentioned above. These targeted audits will include a "thorough investigation of policies and procedures, [and a] review of auditable records and system compliance to prevent diversion and duplicate discounts." Interestingly, HRSA stated that the audit protocol will be made publicly available at some point in the future. Not only will this protocol assist in preparing for potential audits, but it may provide desired guidance regarding 340B Program standards generally.

The 340B Program Covered Entities at highest risk of being audited will be those "[with] higher program risk due to volume of purchases, [with] increased complexity of program administration, and [who] use contract pharmacies." Interestingly, HRSA also states that audits may be triggered by allegations of 340B Program violations made by anyone and not just whistleblowers, manufacturers or covered entities themselves.

These pending audits, though potentially burdensome to the audited Covered Entity, may not be all bad. As HRSA has noted, current 340B Program guidance is sometimes not specific enough to define situations under which individuals are considered to be Covered Entity patients as required to dispense discounted drugs under 340B Program standards. Many 340B Program Covered Entities are therefore looking to the results of these audits to provide much needed clarity surrounding 340B Program standards.

Moving forward, Covered Entities (especially 340B Program participating hospitals with high outpatient volumes or large-scale contract pharmacy implementations) may want to revisit their 340B Program compliance mechanisms, paying particular attention to eligible patient definitions and to contract pharmacy implementation mechanisms. Where questions that may be open to interpretation arise, it may make sense to take a more conservative approach pending the outcome of the HRSA 340B Program audits.

If you would like additional information about any of these issues, please contact

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