HRSA RELEASES 340B PROGRAM AUDIT GUIDANCE

On Tuesday, June 19, 2012, the Health Resources and Services Administration ("HRSA") released new guidance related to the current ongoing 340B Program covered entity audits ("340B Audit Guidance"). Although this guidance is consistent with other related audit information communicated verbally and in writing by HRSA, it does provide additional clarity regarding the pre-audit, onsite audit and post-audit processes.

Through the 340B Audit Guidance, HRSA reiterates that they will be evaluating covered entity compliance with rules and guidelines related to 340B Program eligibility status, group purchasing organization exclusion, drug diversion prohibition and duplicate Medicaid discounts. Importantly, HRSA confirms that it will be reviewing compliance with these requirements by both covered entities and their contract pharmacies.

As part of these 340B Program covered entity audits, HRSA indicates that it will first request (and presumably review) covered entity policy and procedure documentation before confirming that they have been implemented during an onsite audit. This onsite audit process will involve, among other steps, a sample testing of 340B covered drug transactions. Once the onsite audit is complete, the HRSA auditors will conduct an exit interview with the covered entity and will share their preliminary findings, as well as any areas of concern noted. These preliminary findings will be forwarded to HRSA's Office of Pharmacy Affairs ("OPA") for review. OPA will then review the findings and discuss with the covered entity any corrective actions or disciplinary procedures that might be implemented.

One benefit of this audit process for the 340B community at large will be that HRSA is going to release final audit reports on its website. Given the limited guidance regarding a number of 340B requirements, the hope is that these audit reports will provide much needed clarity. This information might then be used to update covered entity policies, procedures and implementation mechanisms to decrease the likelihood of any potential adverse findings in the event of a future HRSA 340B Program audit.

A copy of the 340B Audit Guidance can be found here.

If you would like additional information about any of these issues, please contact Todd Nova at 414-721-0464 or tnova@hallrender.com or your regular Hall Render attorney.

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