

Best Practices for Covered Entities: Resolving Contract Pharmacy Related Non-Compliance

In a contract pharmacy arrangement, the covered entity retains responsibility to prevent diversion and duplicate discounts, maintain auditable records, and meet all other 340B Drug Pricing Program (340B Program) requirements. Any covered entity that chooses to utilize a contract pharmacy must ensure that any such contract fully addresses these requirements; and that the covered entity and the contract pharmacy adhere to the contract terms. To the extent that there has been a violation of 340B Program requirements at a contract pharmacy, the covered entity must notify impacted manufacturers and attempt in good faith to resolve issues directly with manufacturers and wholesalers. Additionally, if there is a material breach, it is HRSA's expectation that the covered entity would disclose this information to HRSA along with the covered entity's plan to address the violation. HRSA and manufacturers (pursuant to an approved audit workplan), can audit covered entities and their contract pharmacies.

HRSA is aware of a resolution practice by which a contract pharmacy and/or third party administrator (TPA) attempts to make restitution for 340B transactions that have been dispensed, but later deemed 340B ineligible. This practice involves the contract pharmacy/TPA directly providing repayment to the manufacturer(s) for transactions the contract pharmacy/TPA no longer considers 340B-eligible, and instead considers them retail pharmacy transactions. In some cases, this may occur without the prior knowledge or engagement of the covered entity. HRSA has concerns with this settlement practice and is encouraging stakeholders to review their contracts with contract pharmacies and TPAs related to this practice. A covered entity should consider the risk it assumes by agreeing to terms whereby the contract pharmacy/TPA makes repayments on its behalf in ways that may not comply with 340B policy. Based on HRSA's understanding, it may not be transparent to stakeholders. Such repayment also would not comply with 340B Program requirements that the covered entity retain responsibility for ensuring full compliance and integrity of its use of the 340B Program, including any activities performed by its contracted pharmacy and/or TPA.

The following are best practices for covered entities in order to resolve non-compliance in the contract pharmacy setting:

- In the event a covered entity determines that diversion or duplicate discounts have occurred at a contract pharmacy, it is the covered entity's responsibility to take remedial action to ensure compliance, work in good faith to resolve the issues directly with the manufacturer, and if there is a material breach, notify HRSA about such compliance problems and actions taken to remedy those problems. Covered entities are encouraged to use the following tool to report the non-compliance:
https://docs.340bpvp.com/documents/public/resourcecenter/ALL_Entities_Self_Reporting_340B_Non_Compliance.docx
- If a covered entity has found non-compliance at a contract pharmacy that results in repayment to manufacturers, the covered entity must work in good faith with the manufacturer and provide any necessary documentation as requested by the manufacturer (i.e., claims level data) to support repayment owed.

- If a covered entity wishes to reclassify a previous purchase at a contract pharmacy, covered entities should first notify manufacturers and ensure all processes are fully transparent with a clear audit trail that reflects the actual timing and facts underlying a transaction. Drug transactions may be credited and rebilled through wholesalers according to standard business practices; however, the covered entity retains responsibility for ensuring full compliance and transparency.
- Covered entities should maintain written procedures describing their processes for identifying 340B-eligible patients and meeting other 340B Program requirements at the contract pharmacy, as well as how non-compliance will be resolved.
- Covered entities should ensure they understand and agree to all the terms of a contractual agreement with a contract pharmacy/TPA. It is recommended that both parties agree to a process to resolve non-compliance in the contract.
- Signing a contractual agreement with a third party does not exempt a covered entity from 340B program requirements or from retaining responsibility for that compliance.

To learn more about HRSA's contract pharmacy requirements, please visit:

<https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf>

If you have any questions, or need further information, the 340B contracted Prime Vendor Program is available at ApexusAnswers@340bpvp.com or by phone at 888-340-2787.