Purpose: The purpose of this tool is to provide a checklist to the covered entity of review points that are necessary for the implementation of a compliant 340B pharmacy operation.

Instructions:
1. Perform at least quarterly.
2. Request hard copy prescriptions from the contract pharmacy for each audit.
3. Target at least 25 charges per quarter and review the data elements below for each charge.

Data Element | Check | Notes
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1. **Patient Definition**
The patient meets the patient definition if accumulated in the 340B account.
   - The entity has a relationship with the patient and the entity maintains records of the patient’s health care.
   - The patient receives health care services from a health care professional:
     - □ Employed by the entity OR
     - □ Under contractual or other arrangements (e.g., referral for consultation) with the entity
   - If health care provided under referral for consultation, HRSA-recommended documentation is accessible:
     - □ Request for referral
     - □ Summary of the referral visit
   - The entity maintains responsibility for the patient’s health care services.

2. **Charge Capture**
   - The patient had an encounter within the previous ____ months of medication dispense date at an eligible clinic registered on the HRSA 340B Database.
   - The information entered into the pharmacy system matches the data on the prescription hard copy.

3. **Accumulation**
   - The 11-digit NDCs accumulated match the 11-digit NDCs dispensed.
   - The correct quantity of medication was accumulated (e.g., were 60 tablets accumulated as 2 packages of 30 tablets?).

4. **Billing**
   - In contract pharmacy arrangement, the claim should **not** be billed to Medicaid.

5. **Order Placement**
   - The order placement reduced the accumulators by the appropriate quantity.
   - Accumulators were manually adjusted for manual orders.

6. **Order Reconciliation upon Receipt**
   - The quantities received were the same as the quantities ordered. If not, the accumulators were adjusted accordingly.
   - The 11-digit NDCs received match the 11-digit NDCs ordered.

Verification performed by: ___________________________ Date: ___________________________