**Purpose:** The purpose of this tool is to evaluate the content in a covered entity’s 340B Program policy and procedure documents.

**Background:** HRSA has identified specific requirements to assist covered entities in developing their 340B-related policies and procedures. Policies and procedures standardize practices throughout an organization and are requested as part of the HRSA audit data request due prior to the on-site visit.

Policies and procedures should include elements of program requirements, including methods for routine self-auditing and internal corrective action. Covered entities are strongly encouraged to review and update their policies and procedures for all facets of the 340B Program on a regular basis to improve program integrity within their organization.

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| **340B Program Policy and Procedure Review** |
| 1. Parent/main site 340B ID
 |  |
| 1. Parent/main site covered entity name
 |  |
| 1. Parent/main site physical address
 |  |
| 1. Date of the **LAST** policy and procedure self-audit
 |  |
| 1. Completion date of **THIS** policy and procedure self-audit
 |  |
| 1. Name and title of the individual completing this self-audit
 |  |
| 1. Signature of reviewer
 |
| 1. Summary of results:

  |
| 1. Actions to be taken:
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| **Compliance Element: Covered entity has comprehensive, written 340B Program policies and procedures.** |
| **Assessment Question** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Do the hospital’s/grantee’s policies and procedures describe its registration/recertification process?**

Document name of the policy and procedure:Document the section or page number that includes the following elements: 1. Process for ensuring that 340B OPAIS is up to date and accurate for primary site (and registerable offsite locations, if applicable)
2. Process for ensuring 340B eligible grant designations (if applicable)
3. Process for ensuring that 340B OPAIS is up to date and accurate for contract pharmacy(ies) (if applicable)
4. Processes include frequency of regular reviews, how review is documented, and the timely update of 340B OPAIS records

Date last reviewed/updated/approved:*If response is “No,” “N/A,” or “Unsure,” explain:* |  |  |  |  |
|  |
| **Assessment Question** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Do the hospital’s/grantee’s policies and procedures describe its process for determining which sites are eligible to be registered on 340B OPAIS?**

Document name of policy and procedure:Document the section or page number that includes the following elements to address how eligibility of each service site that uses 340B drugs is determined:1. Within the four walls of parent entity (for hospitals)
2. Listed as reimbursable on entity’s most recently filed Medicare cost report (MCR) (for hospitals)
3. Approved sites/services of the grant (for grantees)

Date last reviewed/updated/approved:*If response is “No,” “N/A,” or “Unsure,” explain:* |  |  |  |  |
|  |
| **Assessment Question** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Do the hospital’s/grantee’s policies and procedures describe its procurement process?**

Document name of the policy and procedure:Document the section or page number that includes the following elements:1. Identification of all accounts used for purchasing medications at the primary site
2. Identification of all accounts used for purchasing medications at the registered off-site locations (if applicable)
3. Identification of all accounts used for purchasing medications at the contract pharmacy(ies) (if applicable)
4. Process for generating purchase orders in each environment
5. Process for purchasing 340B medications for use at non-registered offsite locations (if applicable)

Date last reviewed/updated/approved:*If response is “No,” “N/A,” or “Unsure,” explain:* |  |  |  |  |
|  |
|  |  |  |  |
| **Assessment Question** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Do the hospital’s policies and procedures describe its process for prevention of GPO Prohibition violations? (Applies to disproportionate share hospitals [DSH], children’s hospitals [PED], and free-standing cancer hospitals [CAN])**

Document name of the policy and procedure:Document the section or page number that includes the following elements:1. Definition of “covered outpatient drugs”
2. Process for handling self-negotiated contracts for individual entities and integrated delivery networks
3. Process for handling Controlled Substance Ordering System (CSOS) orders

Date last reviewed/updated/approved:*If response is “No,” “N/A,” or “Unsure,” explain:* |  |  |  |  |
|  |
| **Assessment Question** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Do the hospital’s/grantee’s policies and procedures define any exclusions to the definition of covered outpatient drugs (e.g., bundled drugs, inpatient drugs, or orphan drugs) if applicable?**

Document name of the policy and procedure:Document the section or page number that includes the following elements: 1. Definition of a covered outpatient drug (consistent with section 1927(k) of the Social Security Act)
2. Exclusion list of covered outpatient drugs and procurement process for these non-covered drugs

 Date last reviewed/updated/approved:*If response is “No,” “N/A,” or “Unsure,” explain:* |  |  |  |  |
|  |
| **Assessment Question** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Do the hospital’s/grantee’s policies and procedures describe its process for conducting oversight of its contract pharmacy(ies) operations?**

Document name of the policy and procedure:Document the section or page number that includes the following elements:1. Process used for internal audits
2. Process used for independent audit
3. Processes include methodology, frequency, and documentation of oversight
4. Process for resolving noncompliance

Date last reviewed/updated/approved:*If response is “No,” “N/A,” or “Unsure,” explain:* |  |  |  |  |
|  |
| **Assessment Question** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Do the hospital’s/grantee’s policies and procedures include inventory management procedures in place to prevent diversion of 340B drugs to ineligible patients?**

Document name of the policy and procedure:Document the section or page number that includes the following elements:1. Inventory process is outlined from the receipt of the medication to the dispensation/administration of the medication
2. Routine inventory counts
3. Reconcile inventory counts with inventory system
4. Adjusting and reconciling variances (including documentation of outcome)
5. Process for transferring inventory between sites (e.g., borrowing, loaning, etc.)

Date last reviewed/updated/approved:*If response is “No,” “N/A,” or “Unsure,” explain:* |  |  |  |  |
|  |
| **Assessment Question** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Do the hospital’s/grantee’s policies and procedures describe its process to track and account for all 340B drugs via accumulation in a virtual replenishment model?**

Document name of the policy and procedure:Document the section or page number that includes the following elements: 1. Inventory process outlined from the receipt of the medication to the dispensation/administration of the medication
2. Accumulator software settings criteria
3. Reconciliation of accumulator counts with purchases and dispensations to identify variances
4. Accumulator manual adjustment criteria (e.g., unused medication, returns to stock, outdated drug destruction)
5. Replenishment with an 11-digit to 11-digit National Drug Code (NDC) number

Date last reviewed/updated/approved:*If response is “No,” “N/A,” or “Unsure,” explain:* |  |  |
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| **Assessment Question** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Do the hospital’s/grantee’s policies and procedures describe its process for handling accumulations and replenishment at an 11-digit NDC level?**

Document name of the policy and procedure:Document the section or page number that includes the following elements: 1. Use of charge description master (CDM)-to-NDC crosswalk
2. Maintaining auditable records to demonstrate proper accumulation in a replenishment model

Date last reviewed/updated/approved:*If response is “No,” “N/A,” or “Unsure,” explain:* |  |  |  |  |
|  |
| **Assessment Question** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Do the hospital’s/grantee’s policies and procedures describe its process for the prevention of diversion at the parent entity and its off-site locations?**

Document name of the policy and procedure:Document the section or page number that includes the following elements to address the eligibility determination system(s), including how:1. A 340B drug order/prescription is generated from an eligible health care/service
2. Outpatient status is defined
3. Changes in patient status from outpatient to inpatient affect the use of 340B drugs
4. A patient health care record is defined, including which data in the health care record determine eligibility
5. Provider eligibility is determined, along with a process for handling changes in provider eligibility
6. It is determined that the responsibility for care remains with the hospital/grantee (including a referral process, if applicable)
7. Service within the scope of grant is determined (grantees only)
8. Process is used for accounting for destroyed or wasted drugs not administered to the patient

Date last reviewed/updated/approved:*If response is “No,” “N/A,” or “Unsure,” explain:* |  |  |  |
| **Assessment Question** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Do the hospital’s/grantee’s policies and procedures describe its process for monitoring its 340B split-billing software program to ensure the prevention of diversion at the parent entity and its off-site locations?**

Document name of the policy and procedure:Document the section or page number that includes the following elements: 1. Type of self-auditing activities
2. Frequency of self-auditing activities
3. Maintenance of auditable records, including description of what constitutes an auditable record in both automated and manual processes

Date last reviewed/updated/approved:*If response is “No,” “N/A,” or “Unsure,” explain:* |  |  |  |  |
| **Assessment Question** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Do the hospital’s/grantee’s policies and procedures describe its process for the prevention of diversion at its contract pharmacy(ies)?**

Document name of the policy and procedure:Document the section or page number that includes the following elements to address the eligibility determination system(s), including how:1. A 340B drug prescription is generated from an eligible health care/service
2. Outpatient status is defined
3. Changes in patient status from outpatient to inpatient affect the use of 340B drugs
4. A patient health care record is defined, including which data in the health care record determine eligibility
5. Provider eligibility is determined, along with a process for handling changes in provider eligibility
6. It is determined that the responsibility for care remains with the hospital/grantee (including a referral process, if applicable)
7. Service within the scope of grant is determined (grantees only)

Date last reviewed/updated:*If response is “No,” “N/A,” or “Unsure,” explain:* |  |  |  |
| **Assessment Question** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Do the hospital’s/grantee’s policies and procedures describe its process for monitoring the 340B split-billing software program of its contract pharmacy(ies) to ensure the prevention of diversion?**

Document name of the policy and procedure:Document the section or page number that includes the following elements:1. Process for performing self-audits
2. Frequency of self-auditing activities
3. Maintenance of auditable records

Date last reviewed/updated:*If response is “No,” “N/A,” or “Unsure,” explain:* |  |  |  |  |
| **Assessment Question** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Do the hospital’s/grantee’s policies and procedures describe its process used to prevent duplicate discounts at entity and off-site outpatient facilities?**

Document name of the policy and procedure:Document the section or page number that includes the following elements:1. State Medicaid agency requirements for the prevention of duplicate discounts for both Medicaid fee-for-service (FFS) and Medicaid managed care organization (MCO), including multiple state Medicaid agencies, if applicable
2. List of all Medicaid provider number(s) /NPI number(s) used to *carve in* 340B drugs in the Medicaid Exclusion File at each registered site that bills Medicaid. The data included in the Medicaid Exclusion File are provided by covered entities for drugs billed under Medicaid FFS and does not apply to Medicaid MCOs.
3. Process used to prevent duplicate discounts for each Medicaid provider number/NPI number listed in the Medicaid Exclusion File
4. Process used to ensure that 340B drugs are *not* billed to Medicaid for each Medicaid provider number/NPI number *not* listed in the Medicaid Exclusion File
5. Process for billing physician-administered drugs to Medicaid
6. Process for billing outpatient prescription drugs to Medicaid
7. Process to ensure the accuracy of information contained in the Medicaid Exclusion File

Date last reviewed/updated/approved:*If response is “No,” “N/A,” or “Unsure,” explain:* |  |  |  |  |
| **Assessment Question** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Do the hospital’s/grantee’s policies and procedures describe its process used to prevent duplicate discounts at its contract pharmacy(ies)?**

Document name of the policy and procedure:Document the section or page number that includes the following elements:1. Process used to carve out Medicaid FFS *or* carve in Medicaid FFS, including the listing of a carve-in contract pharmacy arrangement on 340B OPAIS
2. Process used to prevent duplicate discounts for Medicaid MCO claims based on state policy

Date last reviewed/updated/approved:If response is “No*,” “N/A,” or “Unsure,” explain*: |  |  |  |  |
|  |
| **Assessment Question** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Do the hospital’s/grantee’s policies and procedures describe how the hospital/clinic defines a material breach and the process for when and how it would self-disclose?**

Document name of the policy and procedure:Document the section or page number that includes the following elements: 1. Definition of noncompliance material breach
2. Established threshold for what would constitute a material breach of compliance that would require self-disclosure is established
3. Assignment of responsibility for material breach assessment
4. Articulates when, how, and by whom
5. Process for self-disclosure
6. How is self-disclosure to HRSA and/or manufacturers accomplished?
7. How are corrective action plans submitted, approved, and completed?
8. Maintenance of records of materiality assessments and violations

Date last reviewed/updated/approved:*If response is “No,” “N/A,” or “Unsure,” explain:* |  |  |  |  |

*This tool is written to align with Health Resources and Services Administration (HRSA) policy, and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages each stakeholder to include legal counsel as part of its program integrity efforts.*

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