**Purpose:** This tool provides best practices for hospitals subject to the GPO Prohibition (DSH/PED/CAN) to verify 340B Program eligibility through routine self-audits.

**Background:** DSH/PED/CAN hospitals must meet the eligibility requirements of 42 USC 256b(a)(4)(L,M) to participate in the 340B Drug Pricing Program. A key component of a compliant 340B program is routine monitoring and auditing of the entity’s eligibility status, which allows the entity to evaluate its compliance with 340B Program requirements and to identify areas for improvement.

**This self-audit tool is part of a series focusing on three compliance elements**:

**1. Eligibility**

**2. Prevention of Diversion and GPO Violation**

**3. Prevention of Duplicate Discounts**

Prior to completing the Eligibility Self-Audit Tool, covered entities are encouraged to:

* Map their 340B drug universe (this tool is available in [Word](https://www.340bpvp.com/Documents/Public/340B%20Tools/340B-universe-mapping-template.docx) and [Excel](https://www.340bpvp.com/Documents/Public/340B%20Tools/340B-universe-mapping-template.xlsx))
* Complete the [Self Audit: Policy and Procedure](https://www.340bpvp.com/Documents/Public/340B%20Tools/self-audit-policy-and-procedure.docx)

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| **340B Program Eligibility Compliance Self -Audit Tool** | |
| 1. Parent entity’s name |  |
| 1. Parent entity’s 340B ID |  |
| 1. Parent entity’s physical address (including suite number, if applicable) |  |
| 1. Date of the LAST self-audit |  |
| 1. Date of THIS self-audit |  |
| 1. Name and title of individual completing THIS self-audit |  |
| 1. Signature of individual completing THIS self-audit |  |
| 1. Summary of results:   **Note areas for improvement identified** | |
| 1. Actions to be taken: | |

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| **Compliance Element: Ensure that the entity meets all 340B Program eligibility requirements.**  *GPO Prohibition hospitals must meet eligibility requirements of 42 USC 256b(a)(4)(L,M) to participate in the 340B Drug Pricing Program.* | | | | | |
| **340B Eligibility and Program Requirements** | | | | | |
| **Assessment Questions** | **Yes** | | **No** | **N/A** | **Unsure** |
| 1. **Does the parent covered entity have a disproportionate share percentage greater than 11.75% on its most recently filed Medicare cost report?**   Disproportionate share percentage: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  DSH/CAN: Worksheet E, Part A: Line 33  PED: Worksheet S-3  Date of most recently filed Medicare cost report: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Worksheet S signature block time/date  Attach Medicare cost report to self-audit  *PED hospitals only:*  *If a children’s hospital does not file a Medicare cost report, the hospital must obtain an independent audit indicating a disproportionate share adjustment percentage that meet the requirement. More information can be found at* [*Guidelines for Children's Hospitals*](https://www.govinfo.gov/content/pkg/FR-2009-09-01/pdf/E9-21109.pdf)*.* | |  |  |  |  |
| *If response is “No” or “Unsure,” explain:* | | | | | |
| 1. **Is the parent covered entity:** 2. Owned or operated by a state or local government? 3. A public or private nonprofit corporation that is formally granted governmental powers by a unit of state or local government? 4. A private nonprofit hospital that has a contract with a state or local government to provide health care services to low-income individuals who are not entitled to benefits under Title XVIII of the Social Security Act or eligible for assistance under the state plan under this title?   Classification (SELECT a, b, or c): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Attach a copy of required documentation\* supporting the classification per the [340B Program Hospital Registration Instructions](https://www.hrsa.gov/sites/default/files/hrsa/opa/340b-hospital-registration-instructions.pdf).  HRSA requires hospitals to have the necessary documentation that demonstrates they meet statutory requirements for eligibility.  \*As of August 1, 2020, 340B OPAIS prompts authorizing officials (AOs) and primary contacts (PCs) to upload supporting documentation for the hospital classification at the time of registration of a parent hospital or if a hospital is changing classifications. | |  |  |  |  |
| *If response is “Unsure,” explain:* | | | | | |

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| |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | | **340B OUTPATIENT SITE/SERVICE ELIGIBILITY VERIFICATION**  **Table 1**   * Obtain the most recently filed Medicare cost report (MCR) submitted to CMS. For individual clinics/services that operate under the same line of the MCR, reference the associated trial balance. * In column 1, list the name of all outpatient service locations participating in the 340B Program, including those within the four walls of the parent hospital and offsite from the parent hospital. *(Note: It is recommended to include sites/locations that purchase, dispense, administer, or otherwise generate 340B-eligible prescriptions for dispensing elsewhere)* * List the 340B ID associated with location in column 2. * In column 3, confirm that the outpatient service location is listed as reimbursable on the MCR with associated outpatient costs and charges as outlined in HRSA’s [1994 Outpatient Hospital Facilities Guideline](https://www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/outpatienthospitalfacilities091994.pdf).   + Compare the list to the entity’s MCR worksheet A (and trial balance, if necessary) to verify that each location is reimbursable and has associated outpatient costs.   + Compare the list to the entity’s MCR worksheet C (and trial balance, if necessary) to verify that each location is reimbursable and has associated outpatient charges. * In column 4, list the MCR cost center line number and description associated with the location. For lines attributed to more than one eligible service location, list the trial balance name and department code/account associated with the service location. * In column 5, compare the information in columns 3 and 4 with the covered entity’s 340B OPAIS records.   + For sites where “NO” is selected in column 5, confirm that the service is eligible and HRSA patient definition components are met.   + An eligible offsite location with associated outpatient costs and charges on the most recently filed MCR that utilizes 340B drugs but does not have an active 340B ID registered on 340B OPAIS should be registered during the next quarterly registration period.   + An ineligible offsite location with an active 340B registration on 340B OPAIS should be terminated.   + HRSA notes that for hospitals that are unable to register their outpatient facilities because they are not yet on the most recently filed Medicare cost report, the patients of the new site may still be 340B eligible to the extent that they are patients of the covered entity. These situations should be clearly documented in 340B policies and procedures. More information can be [found here](https://www.hrsa.gov/sites/default/files/opa/programrequirements/federalregisternotices/patientandentityeligibility102496.pdf). | | | | | | | | **Table 1**  **340B Eligibility Site Verification**  **(attach actual data to substantiate eligibility of each site)** | | | | | | | | **(1)**  **Name of service location utilizing 340B drugs** | **(2)**  **340B ID** | **(3)**  **Site listed as reimbursable clinic with associated outpatient costs/charges on most recently filed MCR?** | | **(4)**  **List MCR cost center line (e.g., 91) and/or trial balance information to support eligibility** | **(5)**  **Is the service at the same physical location as the parent hospital or registered on 340B OPAIS as a child site if offsite from the parent hospital?** | | | **YES** | **NO** | **YES** | **NO** | |  |  |  |  |  |  |  | |  |  |  |  |  |  |  | |  |  |  |  |  |  |  | |  |  |  |  |  |  |  | |  |  |  |  |  |  |  | |  |  |  |  |  |  |  | |  |  |  |  |  |  |  | |  |  |  |  |  |  |  | | | | | |
| **Table 1: Assessment Questions** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Are all outpatient service locations that participate in the 340B Program (including those that procure, dispense, administer, or prescribe 340B drugs) listed as reimbursable, with associated outpatient costs and charges, on the covered entity’s most recently filed Medicare cost report?**   Answer “Yes” to the question only if all the answers are “YES” in column 3,  “Site listed as reimbursable clinic with associated outpatient costs/charges on most recently filed MCR?”  *To register for the 340B Program and be listed on 340B OPAIS, clinics/departments/services located offsite from the parent hospital, regardless of whether those clinics/departments are in the same building (including another hospital), must be listed as a reimbursable cost center with associated outpatient costs and charges on the covered entity’s most recently filed Medicare cost report [typically identified via worksheet A and worksheet C (column 7), lines 50–118].*  For more information on hospital offsite outpatient facility registration requirements, view the [340B Program Hospital Registration Instructions](https://www.hrsa.gov/sites/default/files/hrsa/opa/340b-hospital-registration-instructions.pdf). |  |  |  |  |
| *If response is “No” or “Unsure,” specify which location and explain:* | | | | |
| 1. **Are all outpatient service locations that participate in the 340B Program (including those that procure, dispense, administer, or prescribe 340B drugs) either located at the same physical location as the parent hospital or registered on 340B OPAIS as child sites?**   Answer “Yes” to this question only if all the answers are “YES” in column 5,  “Is the service at the same physical location as the parent hospital or registered on 340B OPAIS as a child site if offsite from the parent hospital?”  For sites for which the answer is “NO” in column 5, determine how compliance with all 340B Program requirements are demonstrated.  *HRSA notes that for hospitals that are unable to register their outpatient facilities because they are not yet on the most recently filed Medicare cost report, the patients of the new site may still be 340B eligible to the extent that they are patients of the covered entity. These situations should be clearly documented in the covered entity’s policies and procedures. In addition, a covered entity is responsible for demonstrating compliance with all 340B Program requirements and ensuring that auditable records are maintained for each patient dispensed a 340B drug.* |  |  |  |  |
| *If response is “No” or “Unsure,” specify which location and explain:* | | | | |

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| **REGISTERED SITE INFORMATION: 340B OPAIS VERIFICATION**  **Table 2**   * List the name and 340B ID of the parent hospital and offsite outpatient locations in columns 1 and 2, respectively *(refer to Table 1)*. * Identify the physical address (including suite number, if applicable) of the parent and offsite outpatient locations in column 3. * Identify the bill-to, ship-to addresses (including entity-owned pharmacies) associated with the parent and offsite outpatient locations in column 4. * List the name, title, and phone number of the authorizing official and primary contact of the parent and offsite outpatient locations in columns 5 and 6, respectively. * Compare the information in columns 1–6 with the covered entity’s 340B OPAIS records to complete column 7. | | | | | | | | | | | | |
| |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | | **Table 2**  **Site Information: 340B OPAIS Verification** | | | | | | | | | **(1)**  **Name of Site** | **(2)**  **340B ID** | **(3)**  **Physical address** | **(4)**  **Bill-to, ship-to addresses** | **(5)**  **Authorizing official (including phone #)** | **(6)**  **Primary contact (including**  **phone #)** | **(7)**  **All information matches information listed on 340B OPAIS?** | | | **YES** | **NO** | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | |  |  |  |  |  |  |  |  | | | | | | | | | | | | | |
| **Table 2: Assessment Question** | | | **Yes** | | | **No** | | **N/A** | | | **Unsure** | |
| 1. **Is the information maintained on the covered entity’s 340B OPAIS record accurate?**   Answer “Yes” to the question only if all the answers are “YES” in column 7, “All information matches information listed on 340B OPAIS?” | |  | | |  | | | | |  | | |
| *If response is “No” or “Unsure,” explain:* | | | | | | | | | | | | |
| **SITE PURCHASING ACCOUNTS VERIFICATION**  **Table 3**   * List the name and 340B ID (if applicable) of the parent and offsite outpatient service locations that dispenses/administers drugs in columns 1 and 2, respectively. * In column 3, list each 340B account number used to purchase drugs that are dispensed/administered at the location (including wholesaler, controlled substances ordering system [CSOS], direct, and self-negotiated contract accounts). * In column 4, list each GPO account number used to purchase drugs that are dispensed/administered at the location (including wholesaler, CSOS, direct, and self-negotiated contract accounts). * In column 5, list each non-GPO/WAC account number used to purchase drugs that are dispensed/administered at the location (including wholesaler, CSOS, direct, and self-negotiated contract accounts). | | | | | | | | | | | | |
| |  |  |  |  |  | | --- | --- | --- | --- | --- | | **Table 3**  **Site Purchasing Accounts Verification** | | | | | | **(1)**  **Name of location** | **(2)**  **340B ID** | **(3)**  **Dispenses or administers**  **drugs purchased under**  **340B account number(s)** | **(4)**  **Dispenses or administers drugs purchased under**  **GPO account number(s)** | **(5)**  **Dispenses or administers drugs purchased under Non-GPO/WAC account number(s)** | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | |  |  |  |  |  | | | | | | | | | | | | | |
| **Table 3: Assessment Questions** | **Yes** | | | **No** | | | **N/A** | | | | | **Unsure** |
| 1. **Does the parent hospital location have a non-GPO/WAC purchasing account established?**   Answer “Yes” to the question only if there is a non-GPO/WAC account listed in column 5 for the parent hospital location. |  | | |  | | | | |  | | | |
| *If response is “No” or “Unsure,” explain:* | | | | | | | | | | | | |
| 1. **Does each offsite outpatient service location dispense or administer only covered outpatient drugs purchased on a 340B or non-GPO/WAC account?**   Answer “Yes” to the question only if 340B and/or non-GPO/WAC accounts are used to purchase covered outpatient drugs (i.e., GPO accounts are NOT used to purchase covered outpatient drugs). |  | | |  | | | | |  | | | |
| *If response is “No” 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 all stakeholders to include legal counsel as part of their program integrity efforts.*

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