**Purpose:** This tool provides best practices for community health centers (CHCs) to verify 340B Program eligibility through routine self-audits.

**Background:** CHC entities must meet eligibility requirements of 42 USC §256b(a)(4)(A) to participate in the 340B 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**
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. Entity’s name |  |
| 1. Entity’s 340B ID |  |
| 1. Entity’s physical address (including suite number, if applicable, and associated sites) |  |
| 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.**  *Entities must meet eligibility requirements of 42 USC §256b(a)(4)(A) to participate in the 340B Drug Pricing Program.* | | | | |
| **340B Eligibility and Program Requirements** | | | | |
| **Assessment Questions** | **Yes** | **No** | **N/A** | **Unsure** |
| **Is the entity receiving grant funding from a governmental entity?**  If receiving grant funding, verify the entity’s grant type or notice of FQHC-LA designation. Obtain the Notice of Award that indicates grant designation or Notice of FQHC-LA Designation.  Grant number: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Effective date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Attach grant to self-audit. |  |  |  |  |
| *If response is “No” or “Unsure,” explain:* | | | | |

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| **340B ELIGIBILITY SITE/SERVICE VERIFICATION**  **Table 1**   * List the name of the main grantee and associated sites participating in the 340B Program in column 1.   (*Note: It is recommended to include sites/locations that purchase, dispense, administer, or otherwise generate 340B-eligible prescriptions for dispensing elsewhere.)*   * In column 2, list the 340B ID associated with each site. * Compare the information in columns 1 and 2 with the covered entity’s notice of grant award and, if applicable, HRSA Electronic Handbook (EHB) listing. * Compare the information in columns 1 and 2 with the covered entity’s HRSA Office of Pharmacy Affairs Information System (340B OPAIS) records to complete column 4.   + For sites where “NO” is selected in column 4, confirm that service is eligible and patient meets patient definition. These situations should be clearly documented in 340B policies and procedures. Register the site in OPAIS. | | | | | |
| **Table 1**  **340B Eligibility Site Verification**  **(attach actual data to substantiate eligibility of each site)** | | | | | |
| **(1)**  **Name of site** | **(2)**  **340B ID** | **(3)**  **Site listed on notice of grant award and EHB?** | | **(4)**  **Site registered on 340B OPAIS?** | |
| **YES** | **NO** | **YES** | **NO** |
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| **Table 1: Assessment Questions** | **Yes** | **No** | **N/A** | **Unsure** |
| 1. **Are all sites that participate in the 340B Program (including those that procure, dispense, administer, or prescribe 340B drugs) included on the notice of grant award as approved service sites AND listed in the HRSA Electronic Handbook?**   Answer “Yes” to the question only if all the answers are “YES” in column 3, “Site listed on notice of grant award and EHB?” in Table 1. |  |  |  |  |
| *If response is “No” or “Unsure,” explain:* | | | | |
| 1. **Are all sites that participate in the 340B Program (including those that procure, dispense, administer, or prescribe 340B drugs) registered on 340B OPAIS?**   Answer “Yes” to the question only if all the answers are “YES” in column 4, “Site registered on 340B OPAIS?” in Table 1.   * + For sites where “NO” is selected in column 4, confirm that service is eligible and patient meets patient definition. These situations should be clearly documented in 340B policies and procedures. Register the sites in OPAIS. |  |  |  |  |
| *If response is “No” or “Unsure,” explain:* | | | | |

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| **REGISTERED SITE INFORMATION: 340B OPAIS VERIFICATION**  **Table 2**   * List the name and 340B ID of the main and associated sites in columns 1 and 2 *(refer to Table 1)*. * Identify the qualifying grant number in column 3. * Identify the physical address (incl. suite number, if applicable) of the parent and associated sites in column 4. * Identify the bill-to, ship-to addresses (including entity-owned retail pharmacies) associated with the parent and associated sites in column 5. * List the name, title, and phone number of the authorizing official and primary contact of the parent and associated sites in columns 6 and 7, respectively. * Compare the information in columns 1–6 with the covered entity’s 340B OPAIS records to complete column 8. | | | | | | | | |
| **Table 2**  **Site Information: 340B OPAIS Verification** | | | | | | | | |
| |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **(1)**  **Name of site** | **(2)**  **340B ID** | **(3)**  **Grant #** | **(4)**  **Physical address** | **(5)**  **Bill-to, ship-to addresses** | **(6)**  **Authorizing official (including phone #)** | **(7)**  **Primary contact (including**  **phone #)** | **(8)**  **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 8, “All  information matches information listed on HRSA 340B OPAIS?” | | |  |  | |  | |  |
| *If response “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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