**Purpose:** The purpose of this tool is to identify covered entity locations that receive 340B drugs and describe their associated inventory and billing set-ups.

This tool will serve as a record for the following:

* All locations that provide 340B drugs
* The inventory type, method, and system(s) used to track the purchase, dispensation, and administration of drugs at each location, including outpatient location, mixed-use pharmacy, entity-owned outpatient pharmacy, and contract pharmacy
* Document Medicaid billing and NPI numbers used to bill 340B drugs and *non*-340B drugs that must align with the location’s listing in the Medicaid Exclusion File

Additionally, this tool can be used to document non-340B drug operations as they can often affect 340B drug systems and program integrity initiatives.

**Complete the following tables:**

1. Overall 340B Universe

Each 340B ID should have its own unique entries for tables 2-4

1. 340B ID Site-Specific Drug Universe
2. Entity-Owned Pharmacy Drug Universe
3. Contract Pharmacy Drug Universe

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| Table 1: Overall 340B Universe | |
| 1. List 340B ID of the parent (hospital) or main site (grantee) |  |
| 1. List 340B IDs and names for all child sites (hospitals) or associated sites (grantees) registered on 340B OPAIS |  |
| 1. Document the name and address of any locations that receive 340B drugs and are not registered in 340B OPAIS.   *Note: Do not include retail pharmacies nor locations that are not part of the entity.* |  |
| 1. Document the name of each ENTITY-OWNED retail pharmacy.   *Note: Entity-owned retail pharmacies may not be registered as child sites or associated sites in 340B OPAIS.* |  |
| 1. Document the name of each CONTRACT PHARMACY organization (not locations) that dispenses 340B drugs to patients of the entity   *Note: A contract pharmacy organization may be a chain or independent pharmacy and have multiple service site addresses.* |  |
| 1. 340B ID Specific Drug Operations Environment completed by: (name, title, and date) |  |

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| Table 2: 340B ID Site-Specific Drug Universe | | | |
| From Table 1, list the 340B ID of the entity and any child sites or associated sites registered in 340B OPAIS in the column heading to the right and document the following: | 340B ID# 1: | 340B ID # 2: | 340B ID # 3: |
| 1. Document the location name. | Name | Name | Name |
| 1. Document the physical address, including suite number of the site | Address | Address | Address |
| 1. Do providers write prescriptions for patient self-administration that are filled with 340B drugs? | Yes or No | Yes or No | Yes or No |
| 1. Does this location administer drugs as part of outpatient encounters? | Yes or No | Yes or No | Yes or No |
| 4a. Document type(s) of drug inventory in this site. | 340B  WAC  GPO | 340B  WAC  GPO | 340B  WAC  GPO |
| 4b. Document all purchasing accounts used (wholesaler/ manufacturer). Include name and account number for each inventory type used. | 340B Account# with\_\_  WAC Account# with\_\_  GPO Account# with \_\_ | 340B Account# with\_\_  WAC Account# with\_\_  GPO Account# with \_\_ | 340B Account# with\_\_  WAC Account# with\_\_  GPO Account# with \_\_ |
| 4c. Document inventory management method used. | Physical  Virtual  Both Physical & Virtual | Physical  Virtual  Both Physical & Virtual | Physical  Virtual  Both Physical & Virtual |
| 4d. Document automated dispensing devices used. | Device Name | Device Name | Device Name |
| 4e. Document the inventory tracking system used. Specify software name, if applicable. | Vendor software  Paper tracking log  Electronic tracking log | Vendor software  Paper tracking log  Electronic tracking log | Vendor software  Paper tracking log  Electronic tracking log |
| 1. Does this site carve-in Medicaid and bill 340B drugs to Medicaid? | Yes or No | Yes or No | Yes or No |
| 5a. Document all Medicaid and/or NPI numbers used to bill 340B drugs to Medicaid.  *Note: Billing numbers used to carve-in Medicaid must be listed in the Medicaid Exclusion File.* | Billing numbers used | Billing numbers used | Billing numbers used |
| 1. Document all Medicaid and/or NPI numbers used to bill non-340B drugs to Medicaid. | Billing numbers used | Billing numbers used | Billing numbers used |
| 340B ID Specific Drug Operations Environment completed by: (name, title, and date) | |  | |

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| Table 3: Entity-Owned Pharmacy Drug Universe | | |
| From Table 1, list the name of each entity-owned pharmacy in the column heading to the right and document the following: | Name #1 | Name #2 |
| 1. Document the physical address, including suite number if applicable. | Address | Address |
| 1. Is it a “closed door” pharmacy providing drugs *only* to 340B-eligible patients of the covered entity? | Yes or No | Yes or No |
| 1. Under which 340B ID(s) is the pharmacy purchasing 340B drugs? | 340B ID | 340B ID |
| 1. In addition to dispensing prescriptions for patient self-administration, does the pharmacy provide drugs for administration as part of medical encounters? | Yes or No | Yes or No |
| 4a. Document the type of site for which drugs are provided. | Inpatient and/or  Outpatient or N/A | Inpatient and/or  Outpatient or N/A |
| 1. Does the pharmacy provides 340B drugs to referral patients with an entity health record including an arrangement that demonstrates the entity’s responsibility for care? | Yes or No | Yes or No |
| 1. Document type(s) of drug inventory provided to patients.     *Note: A covered entity subject to the GPO Prohibition is prohibited from providing GPO drugs to outpatients.* | 340B  WAC  GPO | 340B  WAC  GPO |
| 1. Document all purchasing accounts used (wholesaler/ manufacturer). Include name and account number for each inventory type used. | 340B Account# with\_\_\_  WAC Account# with\_\_\_  GPO Account# with \_\_\_ | 340B Account# with\_\_  WAC Account# with\_\_  GPO Account# with \_\_ |
| 1. Document the inventory management method used by the pharmacy. | Physical  Virtual  Both Physical & Virtual | Physical  Virtual  Both Physical & Virtual |
| 1. Document the inventory tracking system used by the pharmacy. Specify software name, if applicable. | Vendor software  Paper tracking log  Electronic tracking log | Vendor software  Paper tracking log  Electronic tracking log |
| 1. Does the entity-owned pharmacy serve as a contract pharmacy to other covered entities? | Yes or No | Yes or No |
| 1. Does the entity-owned pharmacy carve in Medicaid and bill 340B drugs to Medicaid? | Yes or No | Yes or No |
| 13. Document the pharmacy Medicaid and/or NPI numbers used to bill 340B drugs to Medicaid.  *Note: Billing numbers used to carve in Medicaid at the pharmacy must be listed in the Medicaid Exclusion File.* | Billing numbers used | Billing numbers used |
| 1. Document the pharmacy Medicaid and/or NPI numbers used to bill non-340B drugs to Medicaid. | Billing numbers used | Billing numbers used |
| 340B ID Specific Drug Operations Environment completed by: (name, title, and date) |  | |

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| Table 4: Contract Pharmacy Drug Universe | | |
| List the name of the contract pharmacy service location in the column headings to the right and document the following: | Name #1 | Name #2 |
| 1. Document the physical address. | Address | Address |
| 1. Do the name and address of the contract pharmacy location appear on an executed contract?   *Note: Each contract pharmacy service location must be listed on an executed contract pharmacy agreement and be registered on the 340B OPAIS before providing 340B drugs.* | Yes or No | Yes or No |
| 1. Is this location listed in 340B OPAIS under the parent/primary 340B ID, such that patients of any child site or associated site receive 340B drugs? | Yes or No | Yes or No |
| 1. Does the pharmacy provides 340B drugs to referral patients with an entity health record including an arrangement that demonstrates the entity’s responsibility for care? | Yes or No | Yes or No |
| 1. Document all entity purchasing accounts used (wholesaler/ manufacturer). Include name and account number for each inventory type used. | 340B Account# with\_\_  GPO Account# with \_\_ | 340B Account# with\_\_  GPO Account# with\_\_ |
| 6a. Is each account number above set up as “bill to” the covered entity and “ship to” the contract pharmacy? | Yes or No | Yes or No |
| 1. Document the inventory management method used at the contract pharmacy for 340B drugs. | Physical  Virtual  Both Physical & Virtual | Physical  Virtual  Both Physical & Virtual |
| 1. Document the inventory tracking system used for providing 340B drugs at contract pharmacy. Specify software name, if applicable. | Vendor Software  Paper Tracking Log  Electronic Tracking Log | Vendor Software  Paper Tracking Log  Electronic Tracking Log |
| 1. If contract pharmacy is billing 340B drugs to Medicaid, has HRSA posted the carve-in contract pharmacy arrangement in 340B OPAIS?   *Note: Contract pharmacies must carve out unless HRSA has approved the mechanism to prevent duplicate discounts*. | Yes or No | Yes or No |
| 340B ID Specific Drug Operations Environment completed by: (name, title, and date) |  | |

*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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