**Purpose:** This document recommends information to provide to the Health Resources and Services Administration (HRSA) when submitting a grantee request to establish a combined purchasing and distribution model for 340B purchased medications.

**Background:** Each covered entity with a 340B ID is considered a separate entity for purposes of the 340B Program. HRSA assigns 340B IDs for stakeholders to confirm eligibility and appropriate shipment of 340B drugs. Because of the complex nature of grantees (other than health centers) and their organizational structures and relationships, the sharing of 340B inventory across 340B IDs is not allowed unless first approved by HRSA. There are multiple instances in which a grantee may wish to purchase a medication and distribute it to its sub-grantees. This is a common model with state health departments, which may purchase expensive medications at the state level and then distribute them to all their local health clinics and contracted providers who are also sub-grantees. Because these types of covered entities (CEs) do not have associated site or parent/child relationships in the 340B Office of Pharmacy Affairs Information System (340B OPAIS), they each have distinct 340B IDs and generally may not share inventory or purchase on a single account.

HRSA recognizes that there are unique situations in which this is necessary and has developed the opportunity for entities to submit proposals for approval of a combined purchasing account. This tool was designed to assist entities with that process.

The process of combining purchasing for multiple entities into one account may be used for different 340B IDs that all share the same 340B entity type and grant number. Organizations that have multiple 340B entity types (for example, a state health department with FP, STD, and TB grantees) or grant numbers of a single entity type (for example, sites that are all STD 340B types but with different grant numbers) may submit one proposal, but should clearly articulate separate purchasing accounts and inventory handling practices for each CE type/grant number. It is recommended that entities share only drugs purchased under one entity type/grant number with an entity of the same type/grant number with an approved model. Entities should clearly explain how all entities will ensure that the drugs will be dispensed to the appropriate patients.

This tool was not designed to assist entities in determining the appropriateness of a non-routine inventory transfer, such as during a medication shortage situation or as the result of a site closure/loss of eligibility. For these types of transfers, contact HRSA directly for direction related to the specific situation.

**Instructions:** Use the tables that follow as a reference when creating a combined purchasing and distribution request to HRSA. In the letter, the entity should explain as clearly and succinctly as possible what the combined purchasing and distribution process will look like (which 340B ID will be purchasing and which 340B ID(s) will be distributed to).All combined purchasing and distribution models should be designed to comply with all 340B Program requirements, including prevention of duplicate discounts and diversion; entities should ensure that they will maintain auditable records. Include any pertinent details in addition to these items, as applicable.

**Send your written request to**  340BProgramCPDM@hrsa.gov or Office of Pharmacy Affairs, Health Resources and Services Administration, 5600 Fishers Lane, 08W05A, Rockville, MD 20857.

**Tips for request submission:**

* Ensure that the 340B OPAIS listing for each site is accurate prior to submission, including the authorizing official and primary contact, address, and grant number. Inaccurate information should be corrected using a [change request through 340B OPAIS](https://340bregistration.hrsa.gov/login) prior to proposal submission.
* Submit request on official letterhead, including all elements from Table 1 (see below).
* Include Tables 2 and 3 (see below) as an addendum to the request that lists all sites participating in the combined purchasing and distribution model. Each site and contract pharmacy listed should be active in 340B OPAIS (no future or terminated sites/pharmacies should be included in this submission).
* Include a signed attestation from the authorizing official for each participating 340B ID to indicate agreement with this proposal.

**Table 1: Areas to address in your request to establish a 340B combined purchasing and distribution model**

|  |  |  |
| --- | --- | --- |
| **Topic Area** | **Description** | **Included (check)** |
| 1. Entity Information (Table 2)
 | * List all affected 340B IDs and grant number of each.
 |  |
| 1. Applicable Sites
 | * Provide a description of the relationship of the entities included in this model (e.g., owned, contracted) and include detail of how sites will be evaluated to be included in this process.
 |  |
| 1. Policies and Procedures
 | * Include proposed policies and procedures describing the process for ensuring that all compliance elements of the 340B Program are being met and describing the checks and balances within the process between the participating entities.
	+ Each of the areas IIIa–c should be included in your policies and procedures as well as any other applicable areas to ensure 340B Program compliance.
* Explain process for maintaining policies and procedures moving forward, including staff education.
* Explain process to ensure that references to purchasing and inventory management in the policies and procedures of each involved site refer to the same combined purchasing and distribution process.
 |  |
| IIIa. Inventory Management | * Process for requisitioning from main site
* Process for requisition fulfillment
* Process for submitting purchase orders (POs) to the wholesaler/manufacturer for the main site
* Any other relevant information about inventory management (e.g., will sites still be purchasing with their own 340B IDs as well?)
* How this process will be maintained and updated, including approval from HRSA prior to any changes to the approved model
 |  |
| IIIb. Purchasing Compliance | * Clearly articulate how the main site will take responsibility for the compliance of all 340B purchases under that 340B ID, regardless of where the medication is dispensed to the patient.
	+ Checks and balances including audits
	+ Accountability structure with sites
	+ Accessibility to auditable records (patient definition and duplicate discount)
 |  |
| IIIc. Auditable Records | * Include description of record keeping for inventory transfers (11-digit NDC specific), from purchase to main site inventory, from main site inventory to satellite site inventory, from satellite site inventory to patient; records should be able to track a NDC from purchase to patient.
* Include description of how combined purchasing and distribution process will be audited for compliance.
 |  |
| 1. Contract Pharmacy

(Table 3) | * Include either a statement that you will not be using combined purchasing and distribution for your contract pharmacies or a detailed description of how the combined purchasing and distribution model will be operationalized in this setting.
* Language in policies and procedures (and each included area) should include a description of how this will be done within the contract pharmacies, if included in the proposal.
 |  |

**Table 2: List of all sites participating in combined purchasing and distribution model**

*Ensure that the information in this table matches the information in 340B OPAIS for each site and that each site is active in 340B OPAIS.*

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **340B ID** | **Entity Name** | **Grant Number** | **Physical Address** | **Shipping Address** | **Role of Entity (Purchaser or Receiver)** | **Signed Attestation from AO Included in Submission** |
|  |  |  |  |  |  |  |
|  |  |  |  |  |  |  |

**Table 3: List of all contract pharmacies participating in combined purchasing and distribution model**

*Ensure that each contract pharmacy relationship listed below is active in 340B OPAIS and supported by a current contract.*

|  |  |  |  |
| --- | --- | --- | --- |
| **Pharmacy DEA #** | **Pharmacy Name** | **Pharmacy Address** | **List information for each site for which this contract pharmacy is listed in 340B OPAIS and will be combining purchasing to a single account****(multiple lines in each cell)** |
| **340B IDs** | **Entity Names** | **Grant Number** |
|  |  |  |  |  |  |
|  |  |  |  |  |  |

*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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