



# 340B Program Combined Purchasing and Distribution Model

IHS CA Pharmacy Directors  
Teleconference

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# Agenda

- Identify proper registration elements
- Understand compliance principles in a combined purchasing and distribution model
- Define key points for developing the combined purchasing and distribution model for your entity

# Who Needs to Submit a Combined Purchasing and Distribution Request?

## Tribal & Urban Indian Health Centers

### Eligibility

To be eligible to participate in the 340B Drug Pricing Program, these health centers must be operated by programs funded under P.L. 93-638 or 25 USCS §1651. [Indian Health Care Improvement Act - 25 U.S. Code Chapter 18](#) (PDF - 681 KB)

**Tribal Contract or Compact Health Centers** (also called a 638 contract or compact) are operated by Tribes or Tribal organizations and Urban Indian Health Centers are outpatient health care programs and facilities that specialize in caring for American Indians and Alaska natives. They are operated under the Indian Self-Determination Act.

**Urban Indian Health Centers** are designated Federally Qualified Health Centers that provide comprehensive primary care and related services to American Indians and Alaska Natives. The facilities are owned or leased by Urban Indian organizations and receive the grant and contract funding through Title V of the Indian Health Care Improvement Act.

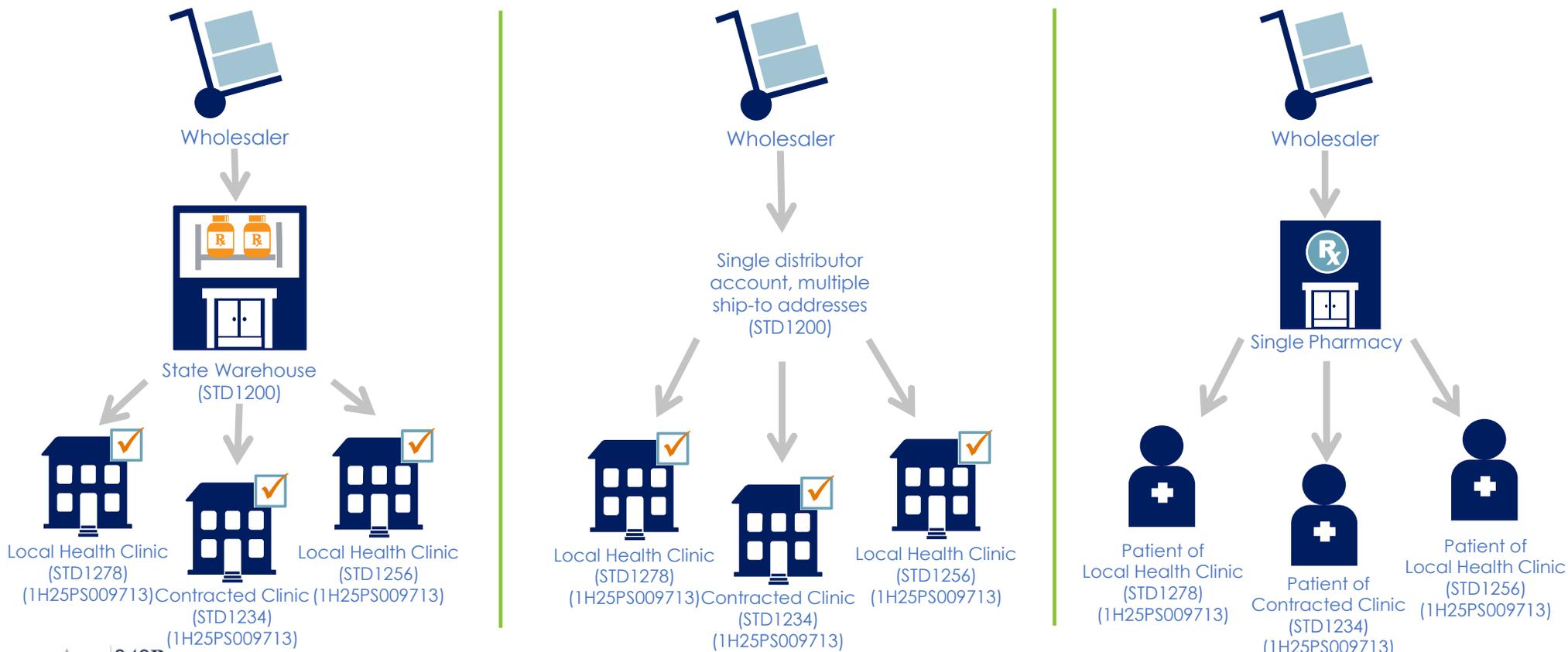
For more information on Tribal/Urban Indian Health Centers, see [Title I | Office of Direct Service and Contracting Tribes \(ihs.gov\)](#) or [Office of Urban Indian Health Programs | Indian Health Service \(IHS\)](#).

- **638 and UI**, FP, STD and RW grantees operate as separate grantee sites that operate under the same grant number.
- These sites are not associated in OPAIS, like FQHCs or FQHC look-alike sites.
- 638s operate under P.L. 93-638 or 25 USCS §1651. [Indian Health Care Improvement Act - 25 U.S. Code Chapter 18](#).
- UIs are health centers owned or leased by Urban Indian organizations; they receive grant and contract funding through Title V of the Indian Health Care Improvement Act.

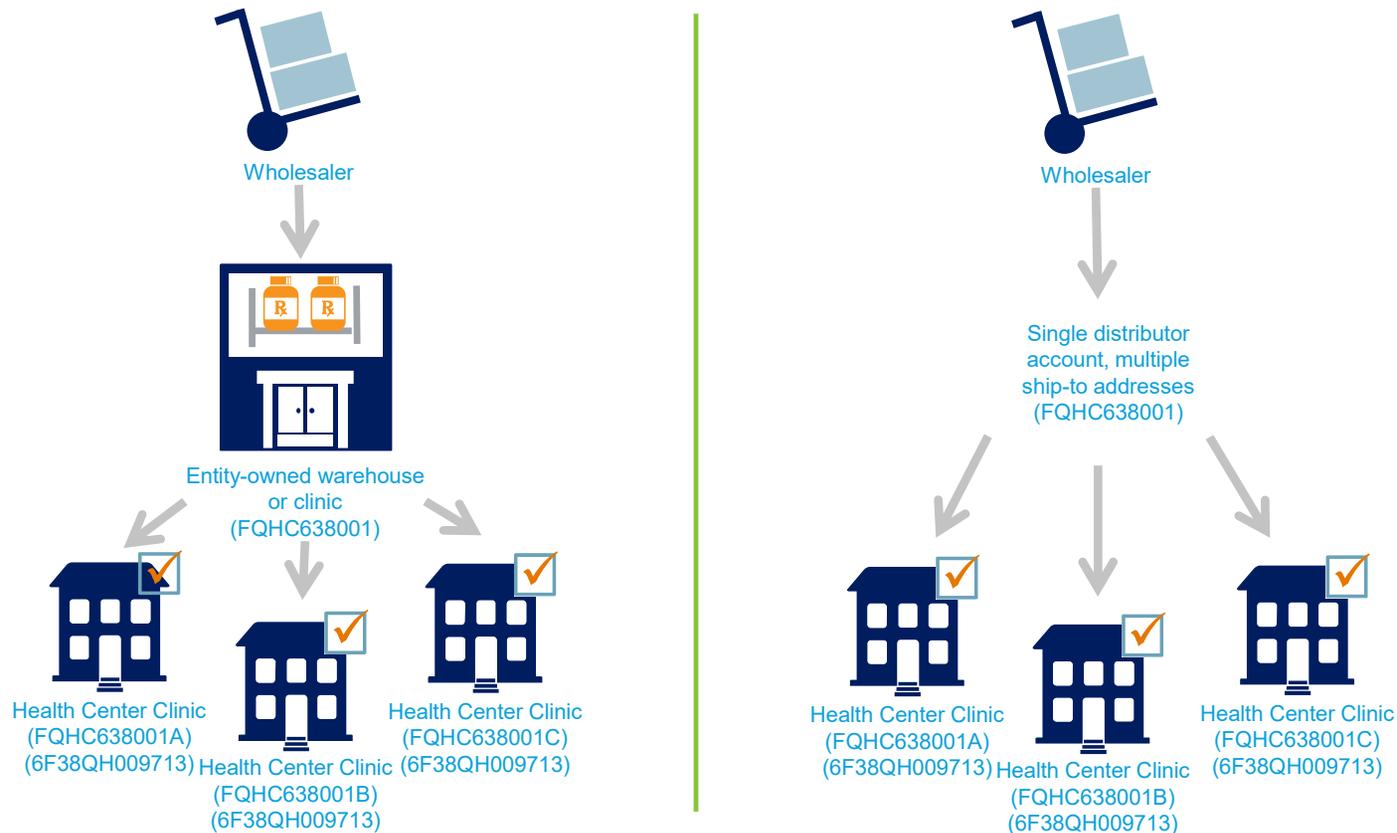
# Combined Purchasing and Distribution

- Combined purchasing and distribution occur when one covered entity purchases medications under one account to send to multiple locations that have the same grant number (multiple 340B IDs)
  - Lack of transparency in ordering process
- Common in state health departments
  - Limited space/resources/operating hours
  - Desire to oversee medication ordering
  - Ability to pay for and give “free” drug to site
- Without HRSA approval, this practice of transferring inventory between sites has a 340B compliance risk

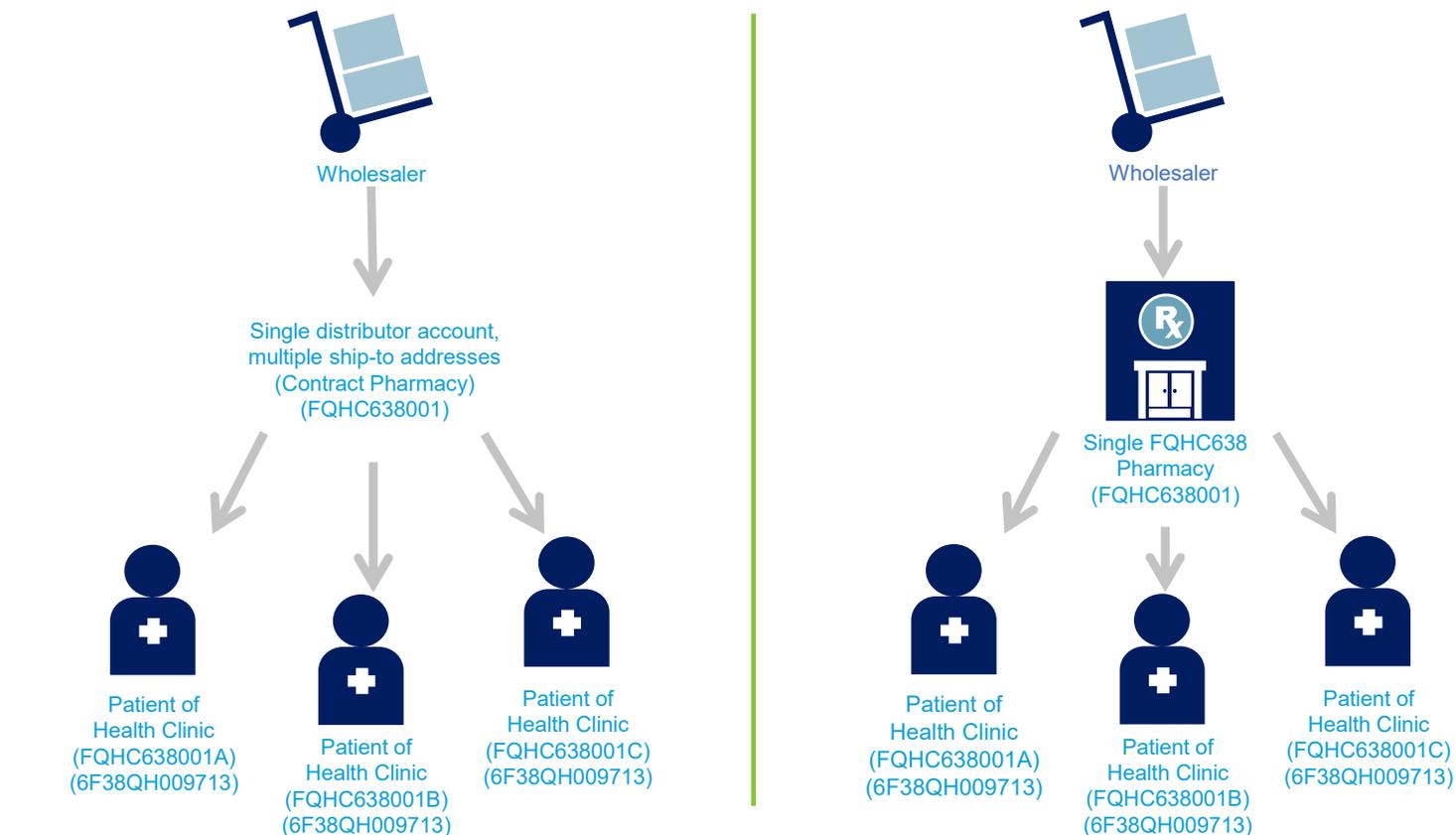
# Grantee Combined Purchasing and Distribution (Examples)



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# Proper Registration

- Purpose of 340B IDs
- 340B IDs are considered unique separate entities
  - Diverse and complex relationships between non-health center grantees (e.g., Title X, STD, RW, FQHC638)
- Grant numbers provided at registration
  - OPA may request funding agreement for 638s in lieu of grant number
- HRSA recognizes that non-health center grantees operating under the same grant number may want to share inventory

# Compliance Principles

- Auditable records—recording the chain of custody from purchase to patient
- Policies and procedures—describing the processes in place to ensure compliance
- All 340B IDs involved
  - Purchasing
  - Receiving
- Ensure that drugs will not cross entity types or grant numbers
- All involved authorizing officials (AOs) must attest
- Contact HRSA if any approved components of the model change
- Comply with all federal, state, and local laws

# Key Points

- Keep 340B OPAIS records up to date
- Keep auditable records
- Update policies and procedures
- Informs auditors that model is approved

You just realized that you need to submit a proposal to HRSA...now what?



# Determine How to Structure Your Proposal

## **PVP tool can act as a guide**

- Contains core elements for submission
- [340bpvp.com/resource-center/340b-tools](https://340bpvp.com/resource-center/340b-tools), contact Apexus Answers with questions

## **How many covered entity types do you have?**

- All one covered entity type, all one grant number  
Submit one proposal, additional considerations if not all sites are owned
- Multiple covered entity types or grant numbers  
Submit one proposal that contains purchasing and inventory model for each entity type/grant number (e.g., do not combine FP, TB, and STD purchasing on one account)

# PVP Tools and Resources

## Grantee Combined Purchasing and Distribution Request For HRSA



**Purpose:** This document recommends information to provide a grantee request to establish a combined purchasing and distribution model.

**Background:** Each covered entity with a 340B ID is considered a stakeholder to confirm eligibility and appropriate relationships (e.g., owned, contracted) and their organizational structures and relationships first approved by HRSA. There are multiple instances in which grantees. This is a common model with state health departments distribute them to all their local health clinics and contracted pharmacies (CEs) do not have associated site or parent/child relationship they each have distinct 340B IDs and generally may not share.

HRSA recognizes that there are unique situations in which there are proposals for approval of a combined purchasing account. The

The process of combining purchasing for multiple entities into one entity type and grant number. Organizations that have multiple entities (e.g., TB grantees) or grant numbers of a single entity type (for example, submit one proposal, but should clearly articulate separate purchase orders for each grant number. It is recommended that entities share only drugs purchase orders with an approved model. Entities should clearly articulate appropriate patients.

## Grantee Combined Purchasing and Distribution Request For HRSA



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

Topic Area	Description	Included (check)
I. Entity Information (Table 2)	<ul style="list-style-type: none"> <li>List all affected 340B IDs and grant number of each.</li> </ul>	
II. Applicable Sites	<ul style="list-style-type: none"> <li>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.</li> </ul>	
III. Policies and Procedures	<ul style="list-style-type: none"> <li>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.                             <ul style="list-style-type: none"> <li>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.</li> </ul> </li> <li>Explain process for maintaining policies and procedures moving forward, including staff education.</li> <li>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.</li> </ul>	
IIIa. Inventory Management	<ul style="list-style-type: none"> <li>Process for requisitioning from main site</li> <li>Process for requisition fulfillment</li> <li>Process for submitting purchase orders (POs) to the wholesaler/manufacturer for the main site</li> <li>Any other relevant information about inventory management (e.g., will sites still be purchasing with their own 340B IDs as well?)</li> <li>How this process will be maintained and updated, including approval from HRSA prior to any changes to the approved model</li> </ul>	
IIIb. Purchasing Compliance	<ul style="list-style-type: none"> <li>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.                             <ul style="list-style-type: none"> <li>Checks and balances including audits</li> <li>Accountability structure with sites</li> <li>Accessibility to auditable records (patient definition and duplicate discount)</li> </ul> </li> </ul>	



# First Steps

## 1. Develop list of all covered entities participating in the model

Ensure that all sites are registered and up to date in OPAIS (grant number, address, AO)

## 2. Ensure that P&Ps are up to date

Include information about inventory management, auditable records

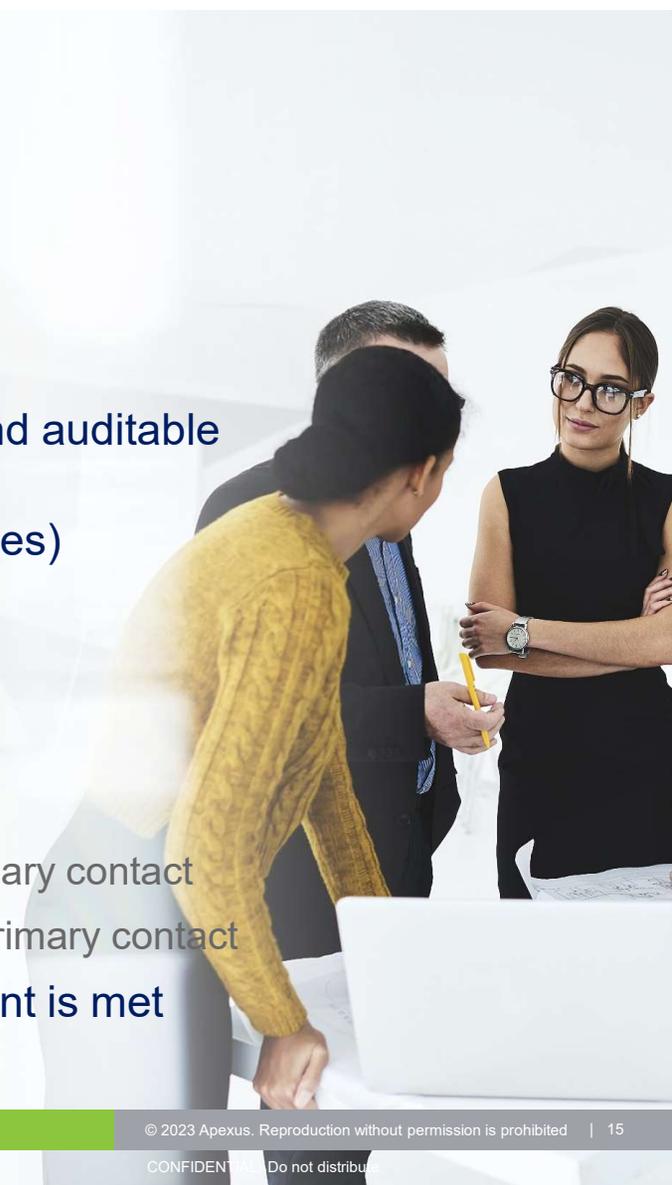
## 3. Secure buy-in

- Central site (340B ID on the account) will assume responsibility for all medications purchased on that account
- AOs from each site will need to sign off on proposal

# Crafting The Proposal

## Three core components

1. Description of model including purchasing, inventory tracking, and auditable records
2. List of sites participating (covered entities and contract pharmacies)
  - Each site participating in the model and its role
    - Purchaser: site responsible for 340B purchases in its 340B ID
    - Receiver: receiving 340B purchases from main identified 340B ID
  - Relationship between sites selected for model
    - Same grant number, ownership and same authorizing official/primary contact
    - Same grant number, ownership and different authorizing official/primary contact
3. Policies and procedures describing how each compliance element is met



# Understanding Compliance Elements

- **Drug inventory should align with account under which the drugs were purchased**

May result in multiple inventories at each site with multiple grants (centrally obtained vs. locally ordered)

- **Tracking NDC from purchase to administration**

Best practice for ensuring that no diversion occurs

- **Access to records at each site**

- **Impact of Medicaid carve-in/-out decision**

Ensure proper listing on Medicaid Exclusion File for each site and impact on contract pharmacies

# Other Elements of Proposal



Signed attestation from participating site AOs



Ordering entity acknowledgment of responsibility and entity accountability



Process for updating policies and procedures and alerting HRSA when proposal elements are updated (e.g., new site added/terminated)

# Tips for Submitting Proposal

- **Prior to submitting the proposal**
  - Ensure that OPAIS is up to date prior to submission
  - Obtain AO approval from each site
- **Lessons from the field**
  - Ensure accountability structure in place
  - Develop experts and keep documentation
  - Weigh benefit and breadth

