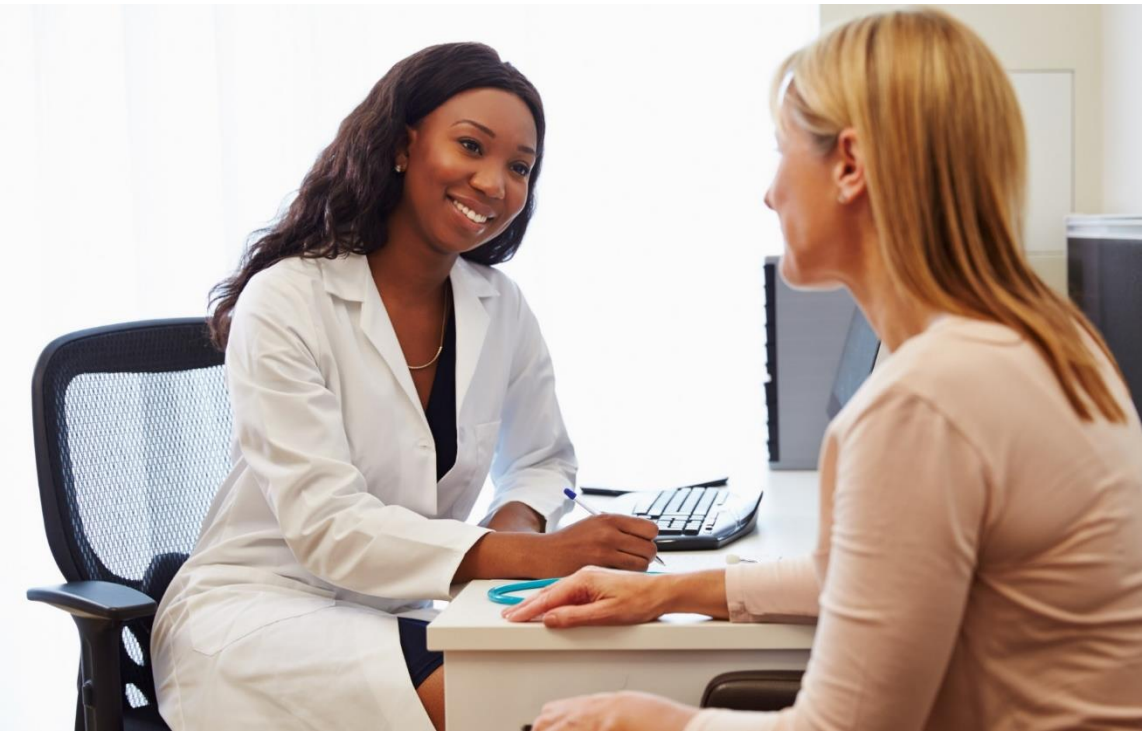

340B Implementation: A Guide for Community Health Centers and Grantees

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340B Policy & Compliance Director

Apexus, 340B Prime Vendor

Disclosure Statement

Jangus Whitner has a financial interest with Pfizer that terminated in 2022 and the relationship has been mitigated through peer review of this presentation. There are no relevant financial relationships with ACPE defined commercial interests for anyone else in control of the content of the activity.

Due to the nature of Apexus' role as HRSA's 340B Prime Vendor, it is a neutral organization that supports all 340B Program stakeholders and will not be discussing political dynamics and legal challenges facing the program.

Pharmacist & Technician Learning Objectives

1. Review 340B compliance considerations important to grantees
2. Discuss available resources for helping maintain a compliant program
3. Review frequently asked questions from grantees and discuss solutions

340B Program Considerations for Grantees

Opening a New Site

Eligibility and Registration

- Sites of grantees administered by HRSA (FQHCs, direct RW or HTC) must be added to the Electronic Handbook (EHB) prior to registration in 340B OPAIS
- Eligibility of other grantees not administered by HRSA will be verified with the granting agency

Multiple sites under same grant

- FQHCs = associated sites
- Other grantees = each site receives a unique 340B ID

What steps need to be taken before the clinic can begin using 340B?

Ensuring Compliant Practices

Inventory management practices

- Physical or virtual replenishment inventory models for clinic-administered, owned pharmacies, and contract pharmacies
- Are all patients treated 340B eligible?
- Pharmacies (and even clinic locations) may hold inventory for multiple 340B grantees

Clinic inventory models

Often not pharmacy managed and harder to maintain auditable records; may require paper logs

Show of Hands

Which inventory model do you use?

- Physical inventory
- Neutral/virtual replenishment inventory
- Both

Transferring 340B Inventory

340B purchase alignment with 340B ID

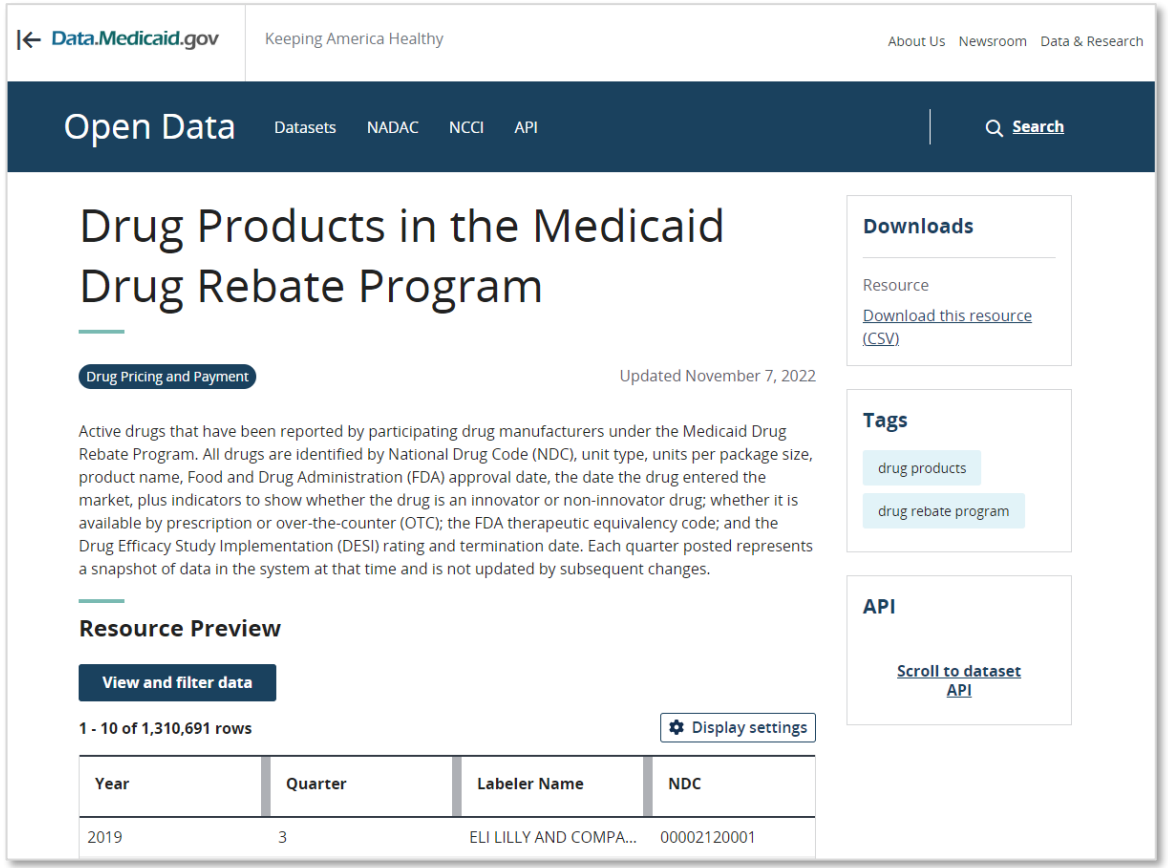
- FQHCs/FQHC-LAs may transfer 340B drugs between the main site and associated sites in 340B OPAIS
- Other grantees (e.g., STD clinics) may be a part of the same organization but individual clinics have different 340B IDs
  - Sites that would like to use a combined purchasing model (all sites under a single grant wanting to purchasing off one 340B account) should contact HRSA for approval
  - Grantee Combined Purchasing and Distribution Request for HRSA
  - Primarily seen in state grantees

Covered Outpatient Drug

- Defined in Section 1927(k)(2) of the Social Security Act
- Document the definition and its operational application in 340B policies and procedures, including any exclusions
- Maintain auditable records and apply policy consistently

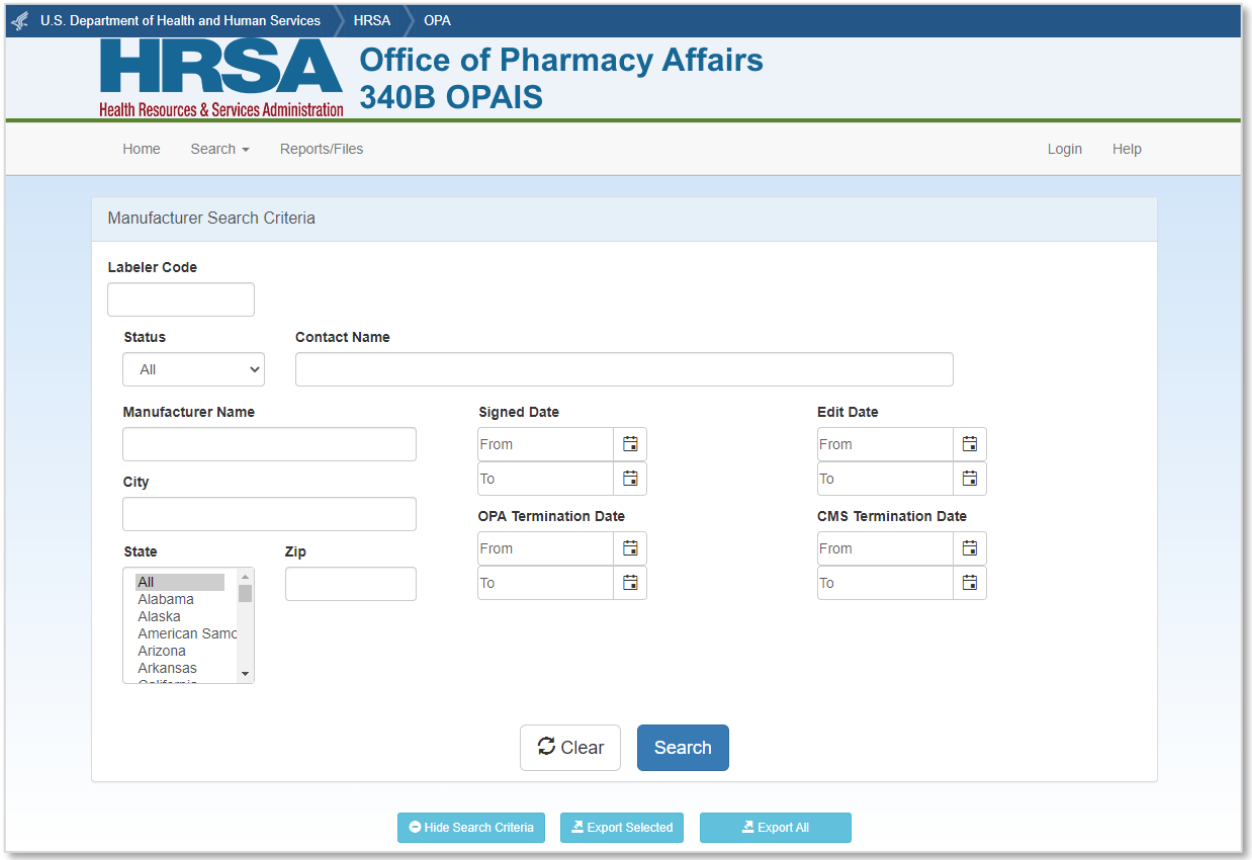
Covered Outpatient Drug Resources

MDRP Product List



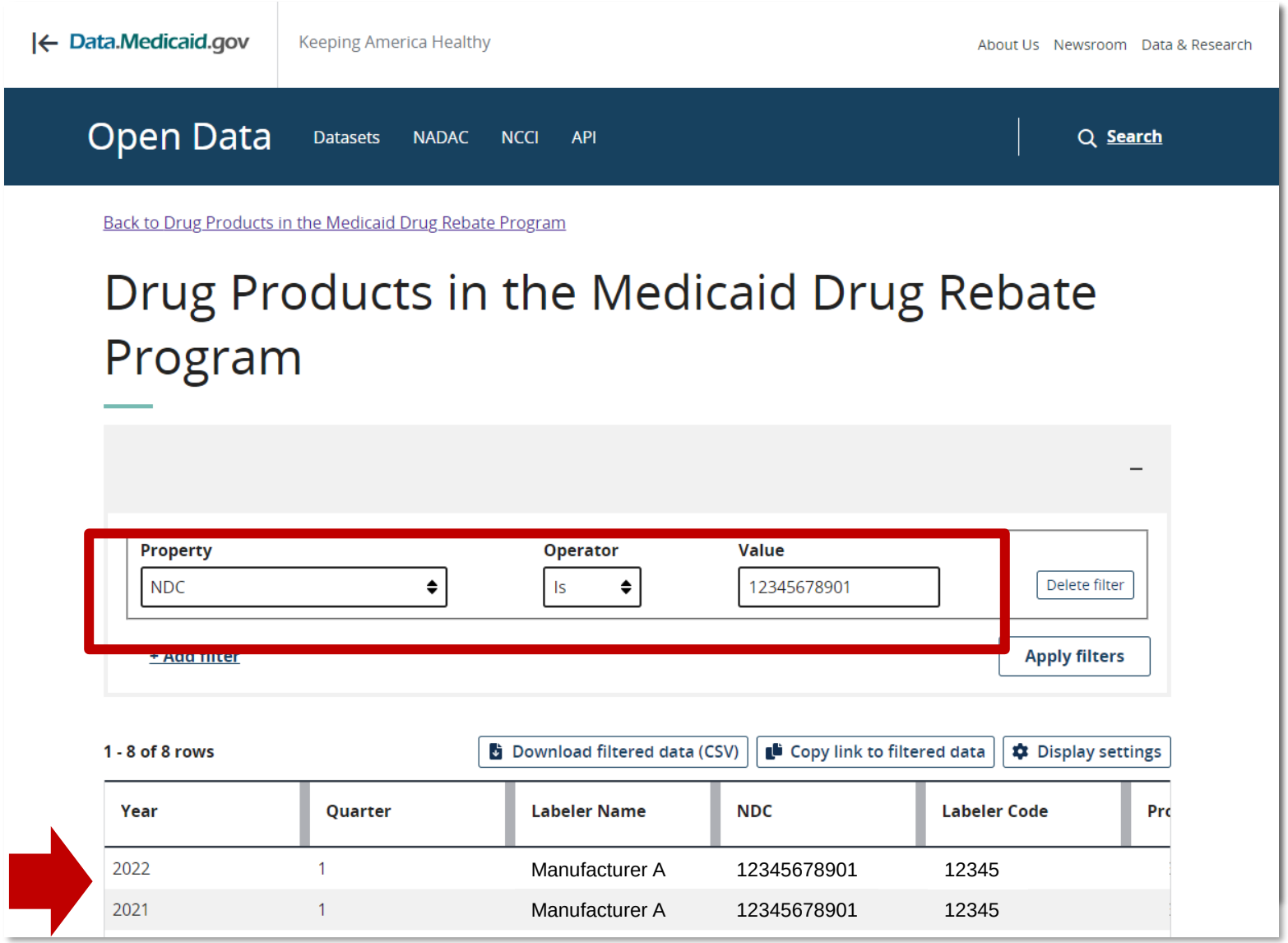
https://data.medicaid.gov/dataset/0ad65fe5-3ad3-5d79-a3f9-7893ded7963a

340B OPAIS Manufacturer Search



https://340bopais.hrsa.gov/manufacturersearch

Medicaid Drug Rebate Program Search



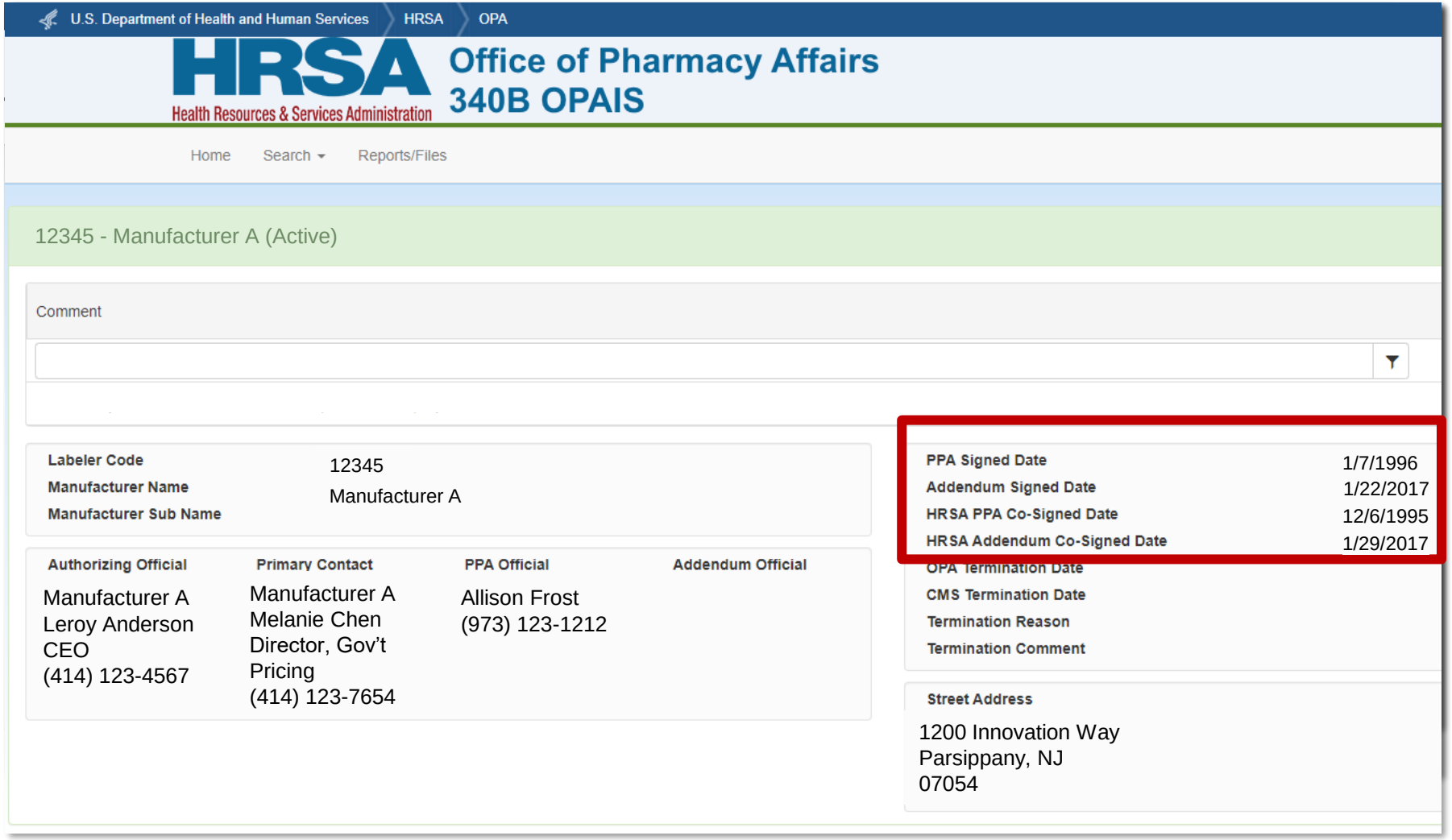
MDRP website

→Program Data

→Drug Product Data

Direct link available in HRSA FAQ #2583

340B OPAIS Manufacturer Search



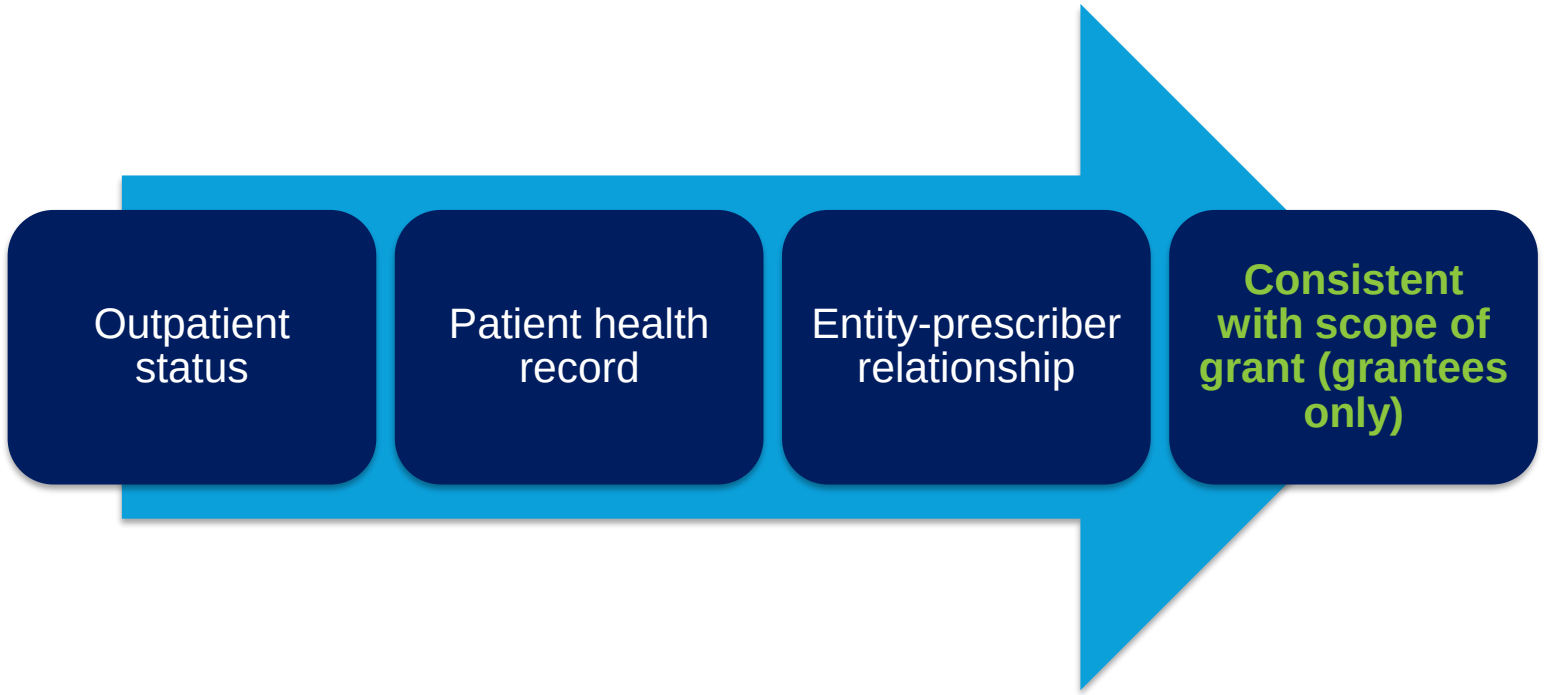
340B OPAIS website

→ Search

→ Manufacturers

Applying Patient Definition in Practice[1]

Covered outpatient drug order/ prescription



Eligible for 340B drug

Covered entities carving out Medicaid must ensure that 340B drugs are not billed to Medicaid fee-for-service

[1] An individual registered in a state-operated or -funded AIDS drug purchasing assistance program receiving financial assistance under title XXVI of the PHS Act will be considered a "patient" of the covered entity for purposes of this definition if so registered as eligible by the state program.

Entity–Prescriber Relationship

Eligible providers who are “floaters”

Covered entity maintains a list of providers who could prescribe from non-covered entity

Pharmacy should have means to verify patient is a patient of the covered entity

- Provider alone may not be enough
- Ensure additional screening

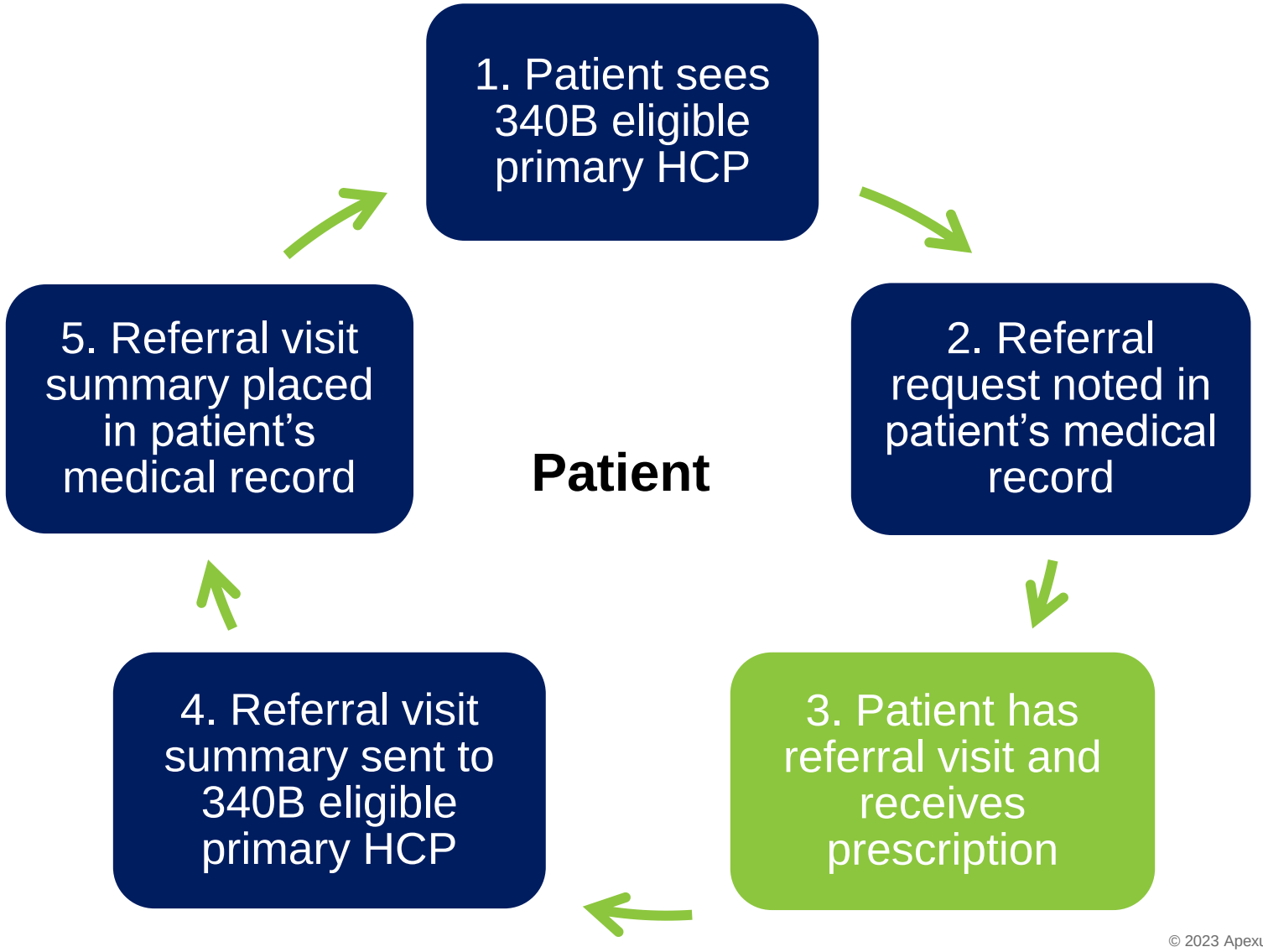
340B Eligibility via Referral

Q. If we refer a patient to an outside clinic, can we fill the patient's prescriptions from our 340B clinic?

A. A covered entity may refer an individual for consultation to an outside clinic not registered for the 340B Program and consider that patient 340B eligible only if the individual receives health care from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity (61 Fed. Reg. 55156 (October 24, 1996). If the covered entity can document that it retained responsibility for the health care services provided to the referred individual, then that individual may be eligible to receive 340B drugs from the covered entity. How a covered entity counts referrals under the 340B Program should be addressed in its written policies and procedures.

FAQ: 1493

Best Practice Referral Documentation



Medicaid: Should We Carve In or Out?

Case: FQHC has a clinic setting where all patients seen are eligible. It is having trouble meeting the state Medicaid fee-for-service (FFS) billing requirements for 340B claims. What should it do?

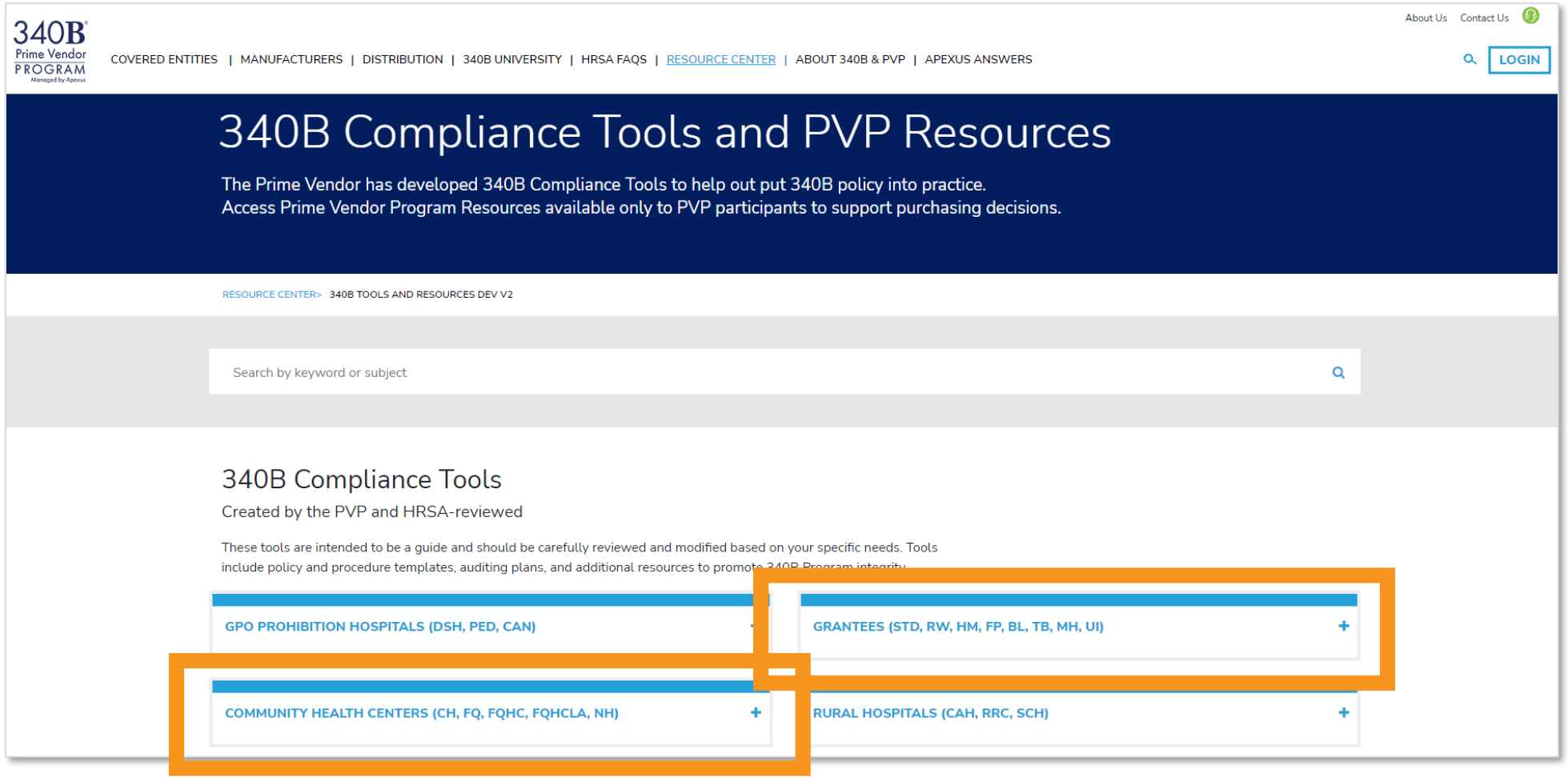
- Choose to carve out?
  - Maintaining a non-340B inventory for Medicaid FFS patients
  - How many medications are used in this setting?
- What if we just don't bill for the medications used?
  - If Medicaid FFS is billed at an all-inclusive rate, entity should answer "yes" to Medicaid billing question (carve in)
  - If Medicaid FFS is not billed at all, entity should answer "no" to the Medicaid billing question (carve out)

Multiple Eligibility Types

- A single site may register as more than one grantee type
- Each registered entity must continue to meet eligibility and compliance requirements
  - What is additional benefit from registering as more than one?
  - What additional recordkeeping/compliance requirements would apply?

Establishing and Maintaining Compliance

Where to Find Help

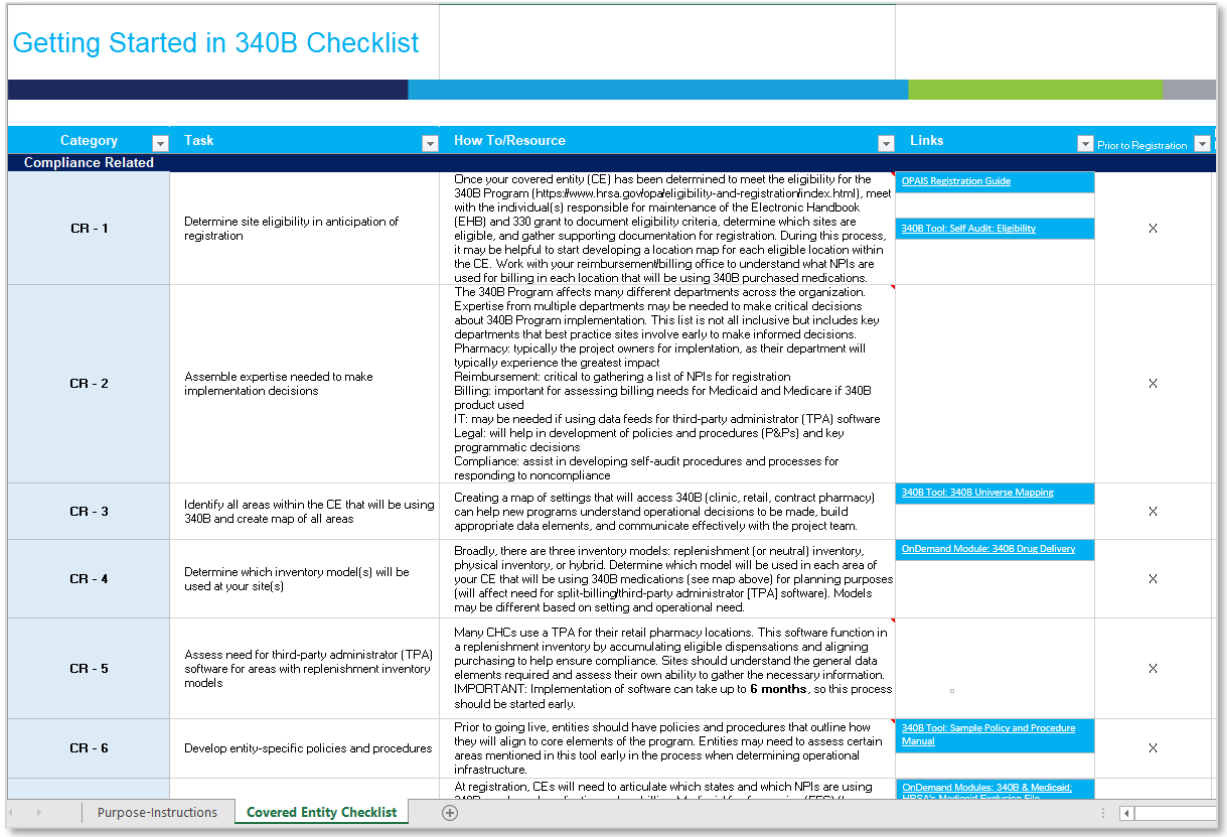


340Bpvp.com/Tools

Finding the Tools for You

- New to the program?
  - Glossary of 340B terms
  - Getting started in 340B checklist
  - Policy and procedure templates
  - Dispense tracking log example
- Looking for additional resources to support a compliant program?
  - Self-audit tools (policy and procedure, eligibility, diversion, duplicate discount, contract pharmacy)
  - Split-billing software configuration considerations
  - HRSA and manufacturer disclosure examples

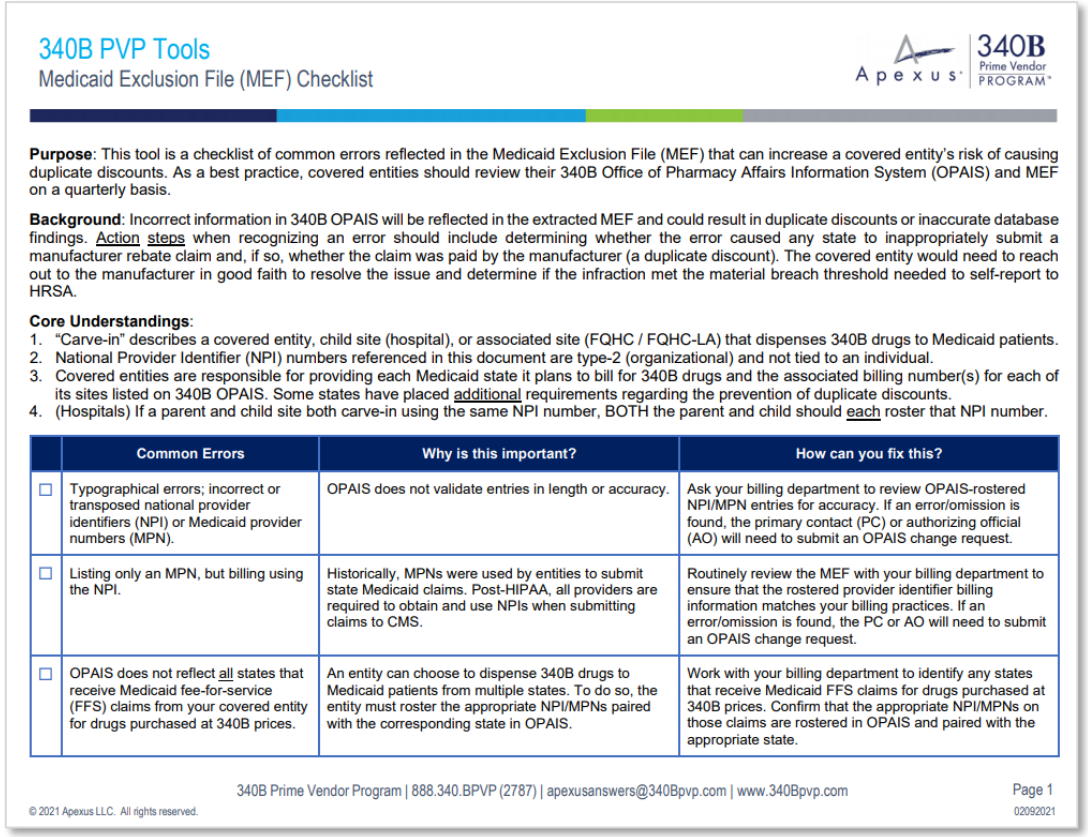
Tools Spotlight



Getting Started in 340B Checklist

Category	Task	How To/Resource	Links	Prior to Registration
Compliance Related				
CR - 1	Determine site eligibility in anticipation of registration	Once your covered entity (CE) has been determined to meet the eligibility for the 340B Program (https://www.hrsa.gov/opa/eligibility-and-registration/index.html), meet with the individual(s) responsible for maintenance of the Electronic Handbook (EHB) and 330 grant to document eligibility criteria, determine which sites are eligible, and gather supporting documentation for registration. During this process, it may be helpful to start developing a location map for each eligible location within the CE. Work with your reimbursement/billing office to understand what NPIs are used for billing in each location that will be using 340B purchased medications.	OPAIS Registration Guide 340B Tool: Self Audit: Eligibility	X
CR - 2	Assemble expertise needed to make implementation decisions	The 340B Program affects many different departments across the organization. Expertise from multiple departments may be needed to make critical decisions about 340B Program implementation. This list is not all inclusive but includes key departments that best practice sites involve early to make informed decisions. Pharmacy: typically the project owners for implentation, as their department will typically experience the greatest impact Reimbursement: critical to gathering a list of NPIs for registration Billing: important for assessing billing needs for Medicaid and Medicare if 340B product used IT: may be needed if using data feeds for third-party administrator (TPA) software Legal: will help in development of policies and procedures (P&Ps) and key programmatic decisions Compliance: assist in developing self-audit procedures and processes for responding to noncompliance		X
CR - 3	Identify all areas within the CE that will be using 340B and create map of all areas	Creating a map of settings that will access 340B (clinic, retail, contract pharmacy) can help new programs understand operational decisions to be made, build appropriate data elements, and communicate effectively with the project team.	340B Tool: 340B Universe Mapping	X
CR - 4	Determine which inventory model(s) will be used at your site(s)	Broadly, there are three inventory models: replenishment (or neutral) inventory, physical inventory, or hybrid. Determine which model will be used in each area of your CE that will be using 340B medications (see map above) for planning purposes (will affect need for split-billing/third-party administrator [TPA] software). Models may be different based on setting and operational need.	OnDemand Module: 340B Drug Delivery	X
CR - 5	Assess need for third-party administrator (TPA) software for areas with replenishment inventory models	Many CHCs use a TPA for their retail pharmacy locations. This software function in a replenishment inventory by accumulating eligible dispensations and aligning purchasing to help ensure compliance. Sites should understand the general data elements required and assess their own ability to gather the necessary information. IMPORTANT: Implementation of software can take up to **6 months**, so this process should be started early.		X
CR - 6	Develop entity-specific policies and procedures	Prior to going live, entities should have policies and procedures that outline how they will align to core elements of the program. Entities may need to assess certain areas mentioned in this tool early in the process when determining operational infrastructure.	340B Tool: Sample Policy and Procedure Manual	X
		At registration, CEs will need to articulate which states and which NPIs are using	OnDemand Modules: 340B & Medicaid;	

Purpose-Instructions | Covered Entity Checklist



340B PVP Tools

Medicaid Exclusion File (MEF) Checklist

Apexus | 340B Prime Vendor PROGRAM

Purpose: This tool is a checklist of common errors reflected in the Medicaid Exclusion File (MEF) that can increase a covered entity's risk of causing duplicate discounts. As a best practice, covered entities should review their 340B Office of Pharmacy Affairs Information System (OPAIS) and MEF on a quarterly basis.

Background: Incorrect information in 340B OPAIS will be reflected in the extracted MEF and could result in duplicate discounts or inaccurate database findings. Action steps when recognizing an error should include determining whether the error caused any state to inappropriately submit a manufacturer rebate claim and, if so, whether the claim was paid by the manufacturer (a duplicate discount). The covered entity would need to reach out to the manufacturer in good faith to resolve the issue and determine if the infraction met the material breach threshold needed to self-report to HRSA.

Core Understandings:

1. "Carve-in" describes a covered entity, child site (hospital), or associated site (FQHC / FQHC-LA) that dispenses 340B drugs to Medicaid patients.
2. National Provider Identifier (NPI) numbers referenced in this document are type-2 (organizational) and not tied to an individual.
3. Covered entities are responsible for providing each Medicaid state it plans to bill for 340B drugs and the associated billing number(s) for each of its sites listed on 340B OPAIS. Some states have placed additional requirements regarding the prevention of duplicate discounts.
4. (Hospitals) If a parent and child site both carve-in using the same NPI number, BOTH the parent and child should each roster that NPI number.

	Common Errors	Why is this important?	How can you fix this?
☐	Typographical errors; incorrect or transposed national provider identifiers (NPI) or Medicaid provider numbers (MPN).	OPAIS does not validate entries in length or accuracy.	Ask your billing department to review OPAIS-rostered NPI/MPN entries for accuracy. If an error/omission is found, the primary contact (PC) or authorizing official (AO) will need to submit an OPAIS change request.
☐	Listing only an MPN, but billing using the NPI.	Historically, MPNs were used by entities to submit state Medicaid claims. Post-HIPAA, all providers are required to obtain and use NPIs when submitting claims to CMS.	Routinely review the MEF with your billing department to ensure that the rostered provider identifier billing information matches your billing practices. If an error/omission is found, the PC or AO will need to submit an OPAIS change request.
☐	OPAIS does not reflect all states that receive Medicaid fee-for-service (FFS) claims from your covered entity for drugs purchased at 340B prices.	An entity can choose to dispense 340B drugs to Medicaid patients from multiple states. To do so, the entity must roster the appropriate NPI/MPNs paired with the corresponding state in OPAIS.	Work with your billing department to identify any states that receive Medicaid FFS claims for drugs purchased at 340B prices. Confirm that the appropriate NPI/MPNs on those claims are rostered in OPAIS and paired with the appropriate state.

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Program Oversight and Support

- Multidisciplinary oversight responsibility
  - Responsible for operational and strategic decision making to ensure integrity of the program
  - Ensure adequate resources to maintain 340B Program compliance and optimization goals
  - Create accountability for compliance measures including auditing and program maintenance
- Ensuring adequate resources to support the program

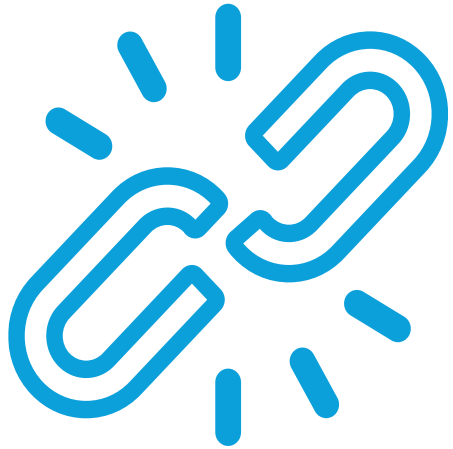
Case: Developing Self-Auditing Strategies

I just got back from to my organization and realized that we need to put a self-audit plan in place—where do I start?

- Create audit plan/calendar based on key compliance areas and locations where 340B is used
- Share with oversight team
- Use tools on 340Bpvp.com as templates
- Define material breach and process for reporting to manufacturers +/- HRSA for repayment
- Repeat audits on regular schedule

Reporting Noncompliance—Material Breach

- X% of total 340B purchases or impact to any one manufacturer
- $X (fixed amount), based on total outpatient or 340B spend, or impact to any one manufacturer
- X% of total 340B inventory (units)
- X% of audit sample
- X% of prescription volume/prescription sample



Grantee Frequently Asked Questions

Are community outreach mobile services or pop-up clinics eligible for 340B?

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Mobile Clinics and Outreach Services

Ensure that 340B drugs are provided only to eligible patients of the covered entity

- What kind of patient health record is kept by the CE? Is it auditable?
- Is the service consistent with the scope of grant?
- How is inventory maintained?

Is a prescription written for a patient's partner considered 340B compliant?

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Partner Treatment

- Patient definition and challenges
  - Who is the patient being treated?
  - Scope of grant
  - Auditable records
- Emergency contraception: OTCs ineligible without a prescription

Our entity recently lost its 340B eligibility. How do we handle 340B inventory on the shelf?

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Terminated Covered Entity Inventory

- 340B physical inventory should be returned, destroyed according to state law, or credit/rebilled with manufacturer
- Inventory cannot be transferred from one 340B grantee/covered entity to another 340B grantee/covered entity
- Entities with extenuating circumstances should contact HRSA directly for possible alternatives to this approach

Which types of covered entities can purchase PrEP on 340B?

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Managed by Apexus

PrEP

- Patient definition and challenges

  Scope of grant

- Grantee purchasing medication should be able to meet eligibility requirements

Takeaways

- Grantees have unique needs in complying with the 340B Program – ensure understanding of scope of grant
- 340Bpvp.com contains resources specific to grantee types that can help establish or maintain compliance
- An important step to ensuring compliance is defining practices in policies and procedures

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Submit Questions!

340B Implementation:
A Guide for Community Health Centers and Grantees

Claim CE by August 18, 2023