Grantee Breakout Session: Essentials for Clinic Administered Drugs

Chelsea Violette
Chief Operating Officer
FQHC 340B Compliance

Jangus Whitner

340B Policy & Compliance Director

Apexus, 340B Prime Vendor





None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.





At the completion of this activity, the participant will be able to:

- Evaluate 340B inventory options, in light of Medicaid billing, 340B savings opportunities, and oversight workload.
- Determine the best mechanism for tracking medication administration, based on available technology.
- Describe the various resources available for 340B purchasing records.
- Design a process for 340B inventory validation and auditing.

Major 340B Compliance Areas

Covered Entities

- Prevent diversion to ineligible patients
- Medicaid duplicate discount prohibition
- Certain hospitals only
 - Group Purchasing Organization (GPO) Prohibition
 - Orphan Drug Exclusion

Manufacturers

- Offer to sell CODs at 340B ceiling price



Diversion



HRSA Requirements

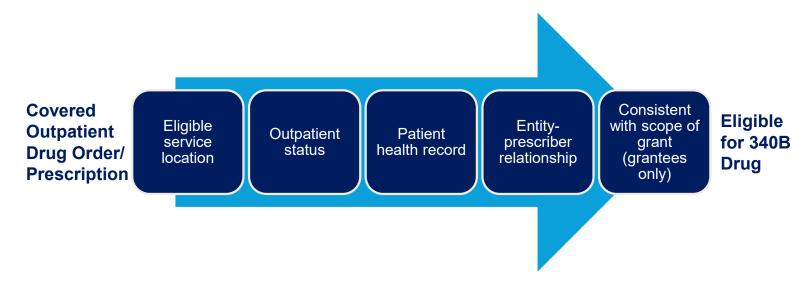
- What is diversion?
 - The reselling or transferring of a 340B drug to a person who is not a patient of the entity
- Covered entities must have processes in place to ensure that only eligible patients receive 340B medications.

Prevent Diversion to Ineligible Patients

- Entities must not resell or transfer 340B drugs to ineligible patients
- Patient Definition:
 - The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
 - The individual receives health care services 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; and
 - The individual receives a health care service or range of services from the covered entity which is consistent
 with the service or range of services for which grant funding or Federally-qualified health center look-alike
 status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.
 - An individual will not be considered a patient of the covered entity if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self-administration or administration in the home setting.
 - Exception: Individuals registered in a State-operated or funded AIDS Drug Assistance Program (ADAP) that
 receives Federal Ryan White funding ARE considered patients of the participant ADAP if so registered as
 eligible by the State program.



Applying Patient Definition in Practice¹



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

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.



Operational Considerations for Diversion Prevention

340B-eligible patient definition (P&P)

Shared medical records

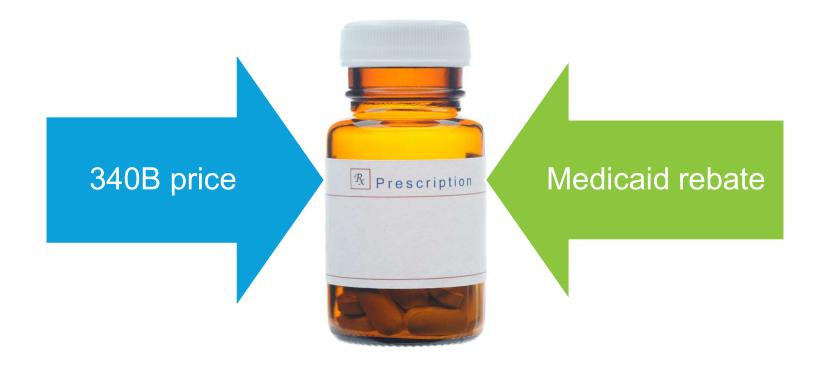
Emergency box medications



Prevention of Duplicate Discounts



Duplicate Discount Prohibition





Carve-In/Carve-Out Decision at Registration

his si	te, will the covered entity bill Medicaid fee-for-service for drugs purchased at 340B prices?
Yes	
) No	
ervice our ho lan to NPI) o	nswer is yes, please provide the state(s) and associated billing number(s) listed on the claims to bill Medicald fee-for-for particular states that you plan to bill for 340B drugs in the space(s) below (this could include numbers for the state espital is located in and any out-of-state Medicaid agencies your hospital plans to bill for 340B drugs). All numbers you use to bill Medicaid fee-for-service should be provided and may include the billing provider's national provider identifier nly, state assigned Medicaid number only, or both the NPI and state assigned Medicaid number. Do not list a state for the covered entity will not bill Medicaid fee-for-service for drugs purchased at 340B prices.
xclusi	exports the Medicaid billing information listed in this site's 340B OPAIS record to generate the quarterly Medicaid on file (MEF). HRSA requires the information on the MEF be accurate and complete for every registered site in the 340B and that covered entities follow any additional state Medicaid requirements in order to prevent duplicate discounts.
	his site may request a change to its 340B OPAIS record at any time, the Medicaid fee-for service billing practice at this just match the quarterly MEF.

OPAIS & Medicaid Exclusion File

- Covered entities choosing to carve in must inform HRSA of their decision by:
 - Answering "yes" to the Medicaid billing question during registration
 - Provide the billing number(s) and the state(s) that is billed in 340B OPAIS
 - National Provider Identifiers (NPIs) and/or Medicaid Provider Numbers (MPNs)
- Medicaid Exclusion File (MEF)
 - A static report populated with 340B OPAIS information
 - Informs state to exclude all claims from listed billing numbers from the rebate file
 - FFS only (not used for MCO claims)
 - MEF is the source of truth for manufacturers, wholesalers, and others

https://www.hrsa.gov/sites/default/files/hrsa/opa/clarification-medicaid-exclusion.pdf



State Requirements

- States often have additional Medicaid carve-in requirements beyond the 340B OPAIS/MEF listing of billing information
- Clinic-administered drug examples can include:

Institutional Claims

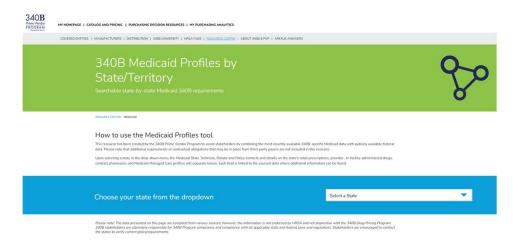
Identifiers

- UD modifier
- U6/U8 modifier
- Medicare JG/TB requirements

Drug cost submission

- 340B actual acquisition cost (AAC)
- Usual and customary rate (U&C)





Duplicate Discount Considerations

- Medicaid billing requirements
 - Does the entity carve-in or carve-out Medicaid?
 - Does the entity bill multiple states' Medicaid plans?
 - Does the state require claim-level modifiers?



CAD Duplicate Discount Considerations

State excludes claims from rebates solely based off the Medicaid Exclusion File (MEF)

- Consistently billing CADs under the Medicaid Billing Numbers (MBNs) and National Provider Identifiers (NPIs) listed in the MEF
- Can be difficult to only carve in select CADs, if all bills are submitted under the same MBN/NPI

State excludes claims from rebates based off claim-level modifiers

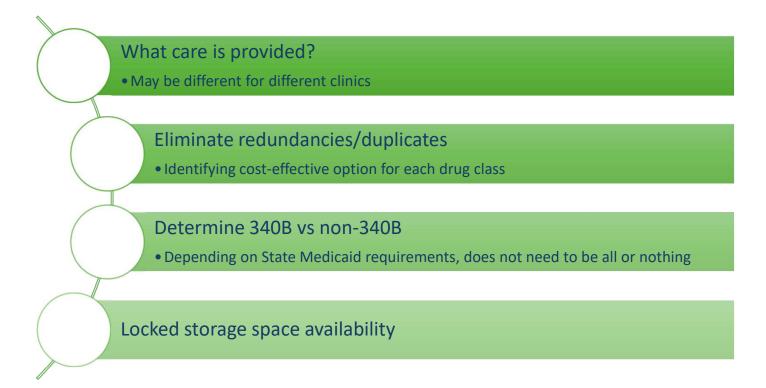
 Important to review if NDC-level data is assigned to the final bill to Medicaid



Inventory Models



Selecting Your CAD Formulary





Sample Formulary List

Drug Name	J Code
etonogestrel SUBDERM IMPLANT 68 mg (NEXPLANON)	J7307
copper (PARAGARD) IUD KIT	J7300
levonorgestrel MIRENA IUD KIT 52 mg	J7298
levonorgestrel LILETTA IUD KIT 52 mg	J7297
medroxyprogesterone acetate (Depo Provera)	J1050
Skyla IUD	J7301
Kyleena IUD	J7296
penicillin G benzathine INJ 1,200,000 Units / 2 mL	J0561
Ceftriaxone Sodium 250 mg	J0696
KETOROLAC (TORADOL) INJ 60MG/ML	J1885
cyanocobalamin (vitamin B-12) To 1000 MCG	J3420
denosumab SubQ SYRINGE 60 mg/mL (PROLIA)	J0897
penicillin G benzathine INJ 600,000 Units / 1 mL	J0561
EPINEPHrine AUTO-INJ 0.3 mg	J0171
methylPREDNISolone succinate INJ AOV 125 mg/2 mL	J2930
methylPREDNISolone acetate INJ SDV 40 mg/1 mL	J1030
EPINEPHrine JR AUTO-INJ 0.15 mg	J0171
diphenhydramine HCl	J1200
ketorolac tromethamine	J1885
albuterol sulfate	J7611
Injection, Penicillin g benzathine, 100,	J0561
PPD APLISOL, VL 5TU/0.1ML 1ML(10TEST/VL)/TUBERCULIN PUR PRO D(TUBERSOL) 0.1ML	86580
DEXAMETHASONE(DECADRON)INJ MDV 4MG/ML	J1100
METHYLPRED (SOLU-MEDROL)IN	J2920
LIDOCAINE HCL 1%(XYLOCAINE)MDV	J2001
GLUCAGON HUMAN EMERGENCY KIT 1MG	J1610
DEXAMETHASONE(DECADRON)INJ MDV 4MG/ML	J1100
Levalbuterol Hydrochloride Inhalation Solution (Xopenex®)	J7614
Albuterol sulfate .083%/ml	J7620
ALBUTEROL TO 2.5 MG IPT TO 0.5 MG	J7620
INJ MEDRXYPRGESTRON CNTRACPT 150 MG (SubCut)	J1055



Physical Inventory

- Physically separate inventory
 - 340B and/or non-340B inventory kept physically separate
 - More common in 340B-only areas
 - Example 340B-only area: "closed-door" retail pharmacies, grantee clinic carving in Medicaid
- HRSA expects covered entities to describe how 340B inventory is accounted for to
 - Maintain auditable records
 - Prevent diversion
- Inventory adjustments (purchases, administrations, waste, etc.)
- Medicaid carve-in/carve-out decision impact

Virtual Replenishment Inventory Process

- One neutral inventory used for both 340B eligible and ineligible patients
- New 11-digit NDCs are first purchased on the non-340B account to establish the neutral inventory
- Product is administered to patient, 11-digit NDC captured
 - Patient eligibility verified and tallied as an accumulation in the appropriate bucket (340B or non-340B)

Non-340B

340B

Virtual Replenishment Inventory Process

- Purchase order generated to replace product taken off the shelf
 - Product ordered on 340B or non-340B account based on accumulations
 - Non-340B is used whenever the quantity needed exceeds the 340B accruals available
- Replenishment product arrives and is placed on shelf, re-establishing the neutral inventory

Non-340B

340B

Auditable Records



Auditable Records

- Maintaining auditable records is a requirement of covered entities participating in the 340B Program to ensure compliance with the 340B requirements
- Covered entities should consider how they may maintain inventory records in such a way that they can be retrieved in the event of an audit



HRSA Covered Entity Data Request List

Sample HRSA 340B Audit Data Request List (DRL) for Covered Entities



Purpose: This tool provides an example data request list (DRL) for a HRSA 340B audit. This is only a sample and may differ from an actual HRSA data request.

Covered Entity Data Request



HRSA Covered Entity Data Request—Inventory

Policies and procedures

- Description of purchasing process (including all pharmacies, if applicable) (1D)
- How the covered entity accounts for 340B inventory or accumulation in a physical or virtual replenishment inventory (1H)
- Prevention of diversion at covered entity and all pharmacies (1I, J)
 - Site eligibility location
 - Referral/responsibility of care remained with covered entity
 - Medical/patient health record
 - Patient eligibility (including status change)
 - Provider eligibility (relationship)
 - Service in the scope of grant (if applicable/non-hospital)
 - Documenting and accounting for wastage of a drug not administered



HRSA Covered Entity Data Request—Inventory

Documentation

- Provide a listing of all 340B drugs that were administered or prescribed to patients from the parent site, offsite facilities/child sites, and pharmacies(contracted or entity-owned) during the sample period (3C)
- List all accounts (wholesaler, direct, and consignment) used to purchase drugs for the parent, off-site facilities/grant-associated sites, and all pharmacies (entity-owned and contracted) (5A)
- Provide a copy of one invoice for each account (5B)

Considerations for Operationalizing HRSA's Expectations



Drug Purchase Records

PVP purchase history reports Secondary and tertiary wholesalers or distributors



Drug Utilization Records

Medical record reports

Manual logs (paper or electronic)

Drug waste (patient-specific or expired stock)

Barcode scanning



Inventory Reconciliation Records

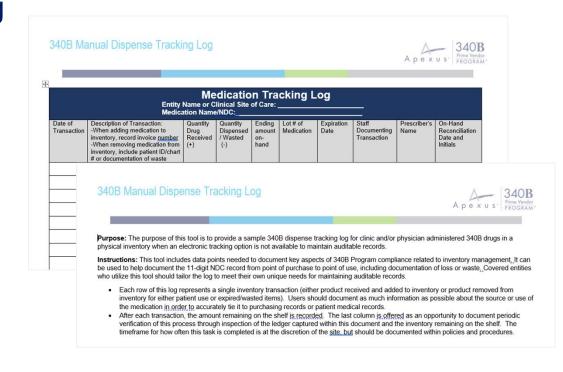
Cycle counts

Monthly or quarterly purchase vs utilization analysis



Tracking Dispensations

- Determine method for ensuring only eligible patients receive 340B medications
- Must be able to provide records of all dispensations
- Maintain tracking system that captures all HRSArequired data elements
- Must be able to account for all 340B purchased inventory



Tracking CAD Inventory: Drug Utilization Records



Medical Record Reports

• Discrete fields for drug administrations



Manual Logs

• Paper or electronic



Drug Waste

Patient-specific or expired stock



Barcode Scanning

Management of missed scans



340B Manual Dispense Tracking Log



- Single NDC per page
- Includes additions and reductions to inventory
- Identifies individuals who have handled the product
- Product count is reconciled at each transaction

Sample Medication Log

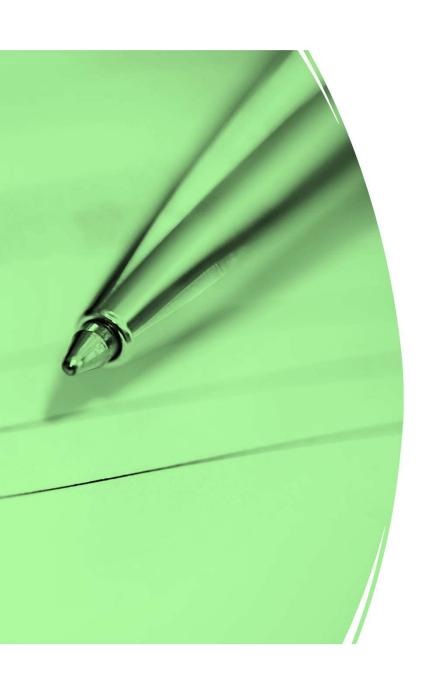
Drug Name: Mirena 52mg IUD		11-Digit NDC:		50419-0412-01		Inventory Type:		340B			
	Date	Inventory Received	Expired/ Wasted Inventory	Patient First and Last Name	DOB	Lot	Exp Date	Qty Administered	Ending Balance	Staff Name	Notes
1	6/26/2023	10				TU01BPE	8/31/2025			Pharmacy Tech Bob	Starting Inventory
2	6/28/2023			Helen Parr	2/5/1998	TU01BPE	8/31/2025	1	9	Dr. Stephen Strange	
3	7/1/2023			Princess Jasmine	7/16/2004	TU01BPE	8/31/2025	1	8	Dr. Christina Yang	
4	7/1/2023			Elsa of Arendelle	3/3/1993	TU01BPE	8/31/2025	1	7	Dr. Stephen Strange	
5	7/6/2023							0	7	Nurse Carla Espinosa	Inventory Audit
6	7/9/2023			Cat Woman	11/15/1996	TU01BPE	8/31/2025	1	6	Nurse Anne Perkins	
7	7/10/2023			Lola Bunny	4/30/2001	TU01BPE	8/31/2025	1	5	Dr. Christina Yang	
8	7/15/2023			Snow White	9/20/2003	TU01BPE	8/31/2025	1	4	Dr. Christina Yang	
9	7/16/2023		1	Fiona Shrek	1/1/1999	TU01BPE	8/31/2025		3	Dr. Stephen Strange	Failed Insertion
10	7/17/2023			Kim Possible	5/27/2005	TU01BPE	8/31/2025	1	2	Nurse Anne Perkins	
11	7/22/2023	10				LG64TRA	10/31/2025		12	Pharmacy Tech Bob	McKesson Invoice #12345
12	7/23/2023			Carmen SanDiego	4/7/2000	TU01BPE	8/31/2025	1	11	Nurse Anne Perkins	
13	7/25/2023			Sandy Cheeks	7/3/1997	TU01BPE	8/31/2025	1	10	Dr. Stephen Strange	
14	7/27/2023			Edna Mode	12/22/1994	LG64TRA	10/31/2025	1	9	Dr. Christina Yang	
15	7/30/2023			Wonder Woman	5/9/1998	LG64TRA	10/31/2025	1	8	Dr. Stephen Strange	
16	8/2/2023			Penny Lane	6/29/2001	LG64TRA	10/31/2025	1	7	Nurse Anne Perkins	
17	8/4/2023			Eleanor Rigby	10/3/1995	LG64TRA	10/31/2025	1	6	Dr. Christina Yang	
18	8/5/2023								6	Nurse Carla Espinosa	Inventory Audit
19	8/8/2023			Velma Dinkley	2/16/1992	LG64TRA	10/31/2025	1	5	Nurse Anne Perkins	
20	8/9/2023			Hannah Banana	1/28/2003	LG64TRA	10/31/2025	1	4	Dr. Stephen Strange	
21											
22											
23											
24											
25											



Electronic Log? Turn It Into An Inventory Snapshot!

Drug Name	NDC	Current Qty On Hand	Min Stock Threshold	Qty to Order
IUD	11111-1111-88	4	10	6
Drug 2	22222-222-01	4	5	1
Drug 3	33333-3333-33	0		0
Drug 4	44444-4444-44	0		0
Drug 5	55555-5555-55	0		0
Drug 6	66666-6666-66	0		0
Drug 7	77777-7777-77	0		0
Drug 8	88888-8888	0		0
Drug 9	99999-9999-99	0		0
Drug 10	10101-0101-01	0		0
Drug 1 Overstock	11111-1111-11	0		0
Drug 7 Overstock	77777-7777-77	0		0





Quality of Medical Record Documentation

- Evaluation of current state can help identify items with accurate and reliable EMR documentation, and thus more readily pulled into reports
- EMR documentation is often more robust for:
 - Drugs administered (Depo, Bicillin, etc.)
 - Single-dose vials (easier to track than MDV waste)
 - Drugs documented by a nurse of medical assistant (as opposed to a medical provider)



Considerations for CAD Purchasing Auditable Records

- PVP purchase history reports
- Secondary and tertiary wholesalers or distributors



Historical Purchases

Download historical purchasing information at the invoice level for products purchased on 340B or WAC accounts through PVP contracted distributors. This report may not include information for products purchased directly from a manufacturer or through non-centracted distributors. Run tips report for specific critis belief codes,

Entity:	All			•
Select One:	By NDC	O By Labeler Code	O By Manufacturer	O By Date
NDC: *		or more NDCs to b nultiple values	e Exported. Use a co	omma (',') to
Labeler Code:				- A
Manufacturer:	Select one	•		
Date Range:	01/01/2022	2 - 12/31/2022		
Export	Reset Fields			

The data provided were purchases reported to Apexus by our Authorized Distributors. The data may not reflect all purchases for any given search due to factors such as manufacturer direct purchases or utilization of a non-contracted distributor.

For assistance, contact Apexus Answers by calling (888) 340-2787 or email apexusanswers@340Bpvp.com.



Tracking Inventory Adjustments

- Must be able to identify and track all inventory adjustments that affect 340B inventory
 - Purchases
 - Administrations
 - Administration waste
 - Expired medications
 - Broken pills
 - Employee use
 - Samples
- Must be able to account for all inventory changes in an inventory reconciliation process



Oversight of your Clinical Administered Drug Inventory



Policies and Procedures

- Your policies and procedures are expected to describe your process for purchasing, tracking, and managing 340B inventory
- Carving in or carving out Medicaid?
 - If carving out, your policies and procedures should also address the process for ensuring that 340B drugs are not dispensed or administered to Medicaid patients
- Policies and procedures should be maintained regularly

Sample Policies and Procedures Manual

Sample Policy and Procedure Manual
Community Health Centers (CH/FQ/FQHC/FQHCLA/NH)



Purpose: This document contains the written policies and procedures that [Entity] uses to oversee 340B Program operations, provide oversight of contract pharmacies, and maintain a compliant 340B Program.

Background: Section 340R of the Public Health Service Act (1992), requires drug manufacturers participating le Secretary of

Sample Policy and Procedure Manual
Community Health Centers (CH/FQ/FQHC/FQHCLA/NH)



ed entities for

n (HRSA) in

Ith Service Act dicaid, and the ent of the

Releases).

	Inventory Management		
		Revision History	
		Effective Date:	xx-xx-xx
Departments Affected:		Original Issue Date:	xx-xx-xx
		Last Reviewed:	XX-XX-XX
		Last Revision:	XX-XX-XX XX-XX-XX

Policy: Covered entities must be able to track and account for all 340B drugs to ensure the prevention of diversion.

Purpose: Ensure the proper procurement and inventory management of 340B drugs.

Background:

340B inventory is procured and managed in the following settings:

- Clinic site administration
- In-house pharmacy
- Contract pharmacy

Inventory methods for each of the above areas within the entity shall be described within the inventory management policy and procedure.

- Policy and Procedure Manuals customized for each covered entity type
- Covered entity must customize the manual to match their actual operations
- Inventory section covers all three practice settings:
 - Clinic site administrations
 - In-house pharmacy
 - Contract Pharmacy





Self-Auditing

Best Practices

- Inventory process is outlined from the receipt of the medication to the dispensation/administration of the medication
- Routine inventory counts
- Reconcile inventory counts with inventory system
- Adjusting and reconciling variances (including documentation of outcome)

Self Audit: Prevention of Diversion
Community Health Centers (CH/FQ/FQHC/FQHCLA/NH)



lo 2

As a best practice, this table can be used for both physically separate inventory and virtual inventory
models. The covered entity should have inventory management procedures in place to prevent diversion of
340B drugs to ineligible patients, which may involve a different process than this table based on the entity.

INVENTORY PURCHASE AND DISPENSE RECONCILIATION

- Best Practices
 - Inventory process is outlined from the receipt of the medication to the dispensation/administration
 of the medication
- Routine inventory counts
 - · Reconcile inventory counts with inventory system
 - · Adjusting and reconciling variances (including documentation of outcome)
- In this example, for each of the 20 drug audit samples selected in step 2b of the instructions (page 1) and for the date range in step 1 of the instructions, use purchasing, dispensing, and inventory records to reconcile inventory units
 - Note that "dispensed units" refers to either dispensed units (if entity charges upon dispense) or administered units (if entity charges upon administration)
 - For physically separate inventory: Note that "inventory units" refers to the number of units in stock (actually on the shelves)
 - For virtual inventory: Note that "inventory units" refers to the number of units in the accumulator
 Any identified variance will need to be resolved and documented to demonstrate that the 340B drug was not diverted

(1) 340B drug name and strength	(2) NDC	(3) Date range selected through today's	(4) Beginnin g inventory (units)	(5) (-) Dispensed (units)	(6) (+) Purchased (units)	(7) (=) Ending inventory	Inve		(9) Variance Resolved ?	
- 15		date		2		(units)	Yes	No	Yes	No
		0 7	5	2 2			a 8		5 8	\vdash



340B Tools

Self Auditing: Administration Records

Auditing samples of administration documentation within the EMR or manual logs

• Often health centers incorrectly assume that their clinic inventories need not be audited

Sample Audit Procedure

- On a monthly basis, select X medication admins and assess:
- Associated with an eligible patient
- Associated with an eligible location and provider
- Does not present a duplicate discount risk



Self Auditing: Duplicate Discounts

- Download the MEF from OPAIS
- For a sample of your Medicaid CAD records, request the billing form (HCFA-1500 or UB-04) from your billing dept
- Confirm that all CADs were billed to Medicaid under billing numbers listed in the active MEF, with the necessary modifiers (if required)





Inventory Management Self-Auditing

- Have process in place to reconcile inventory on a routine basis
 - Cycle counting
 - Spot audits
- Have policies in place regarding adjustments of inventory
- Look at records of inventory adjustments
- Document your inventory reconciliation processes and frequency



Self Auditing: Inventory Reconciliation

- Cycle counts
- Monthly or quarterly purchase vs utilization analysis
 - Patient administration/dispense records coming directly from EMR data often provide great evidence of eligible and compliant use of 340B
 - Beyond just having EMR records (not always an easy task), you are also responsible for monitoring that there are an appropriate quantity of patient records to match the quantity of drug purchased



	Clinic Inventory Re	econcilliation A	Audit Log					Cli	nic Name:											
	Start Date:								End Date:											Confe
Sample	Item Description	NDC	Starting Coun	+	Quantity Recieved	-	Quantity Expired	+	Quantity Wasted	+	Ultilzations	=	Calculated End Count	-	Actual End Count	=	Variance	Reconcilliation Notes:	Auditing Personnel	
1	Mirena 52mg IUD	50419-0412-01	5	+		-		+		+	3	=	4	-	3	=	1	Sample: Example note - "Identified a wasted drug that wasn't documented in log. Corrected in log."	Pharmacy Tech Bob	
2				+		-		+		+		=	0	-		=	0			
3				+		-		+		+		=	0	-		=	0			

Next Steps

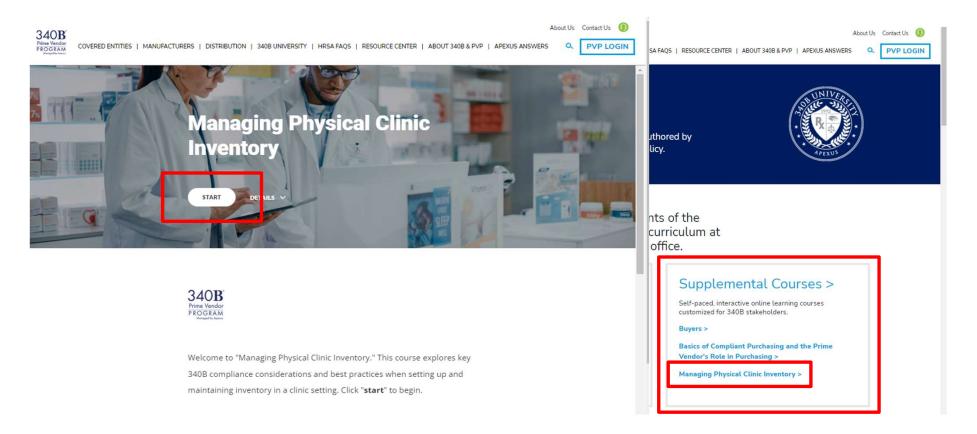


Where to Find Help – 340Bpvp.com



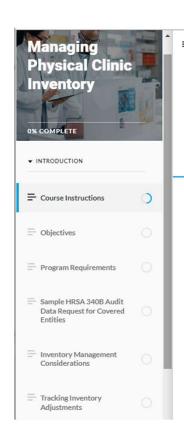


OnDemand Training Module





OnDemand Training Module (Cont'd)



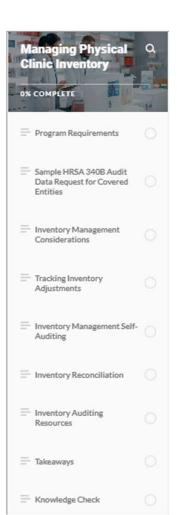
Lesson 1 of 12

Course Instructions

How to view the course

The course navigation moves in a vertical direction. Select the gray scroll bar on the right and move it down so the "continue" button is visible to advance to the next section. You can also click the navigation menu bar on the left to move forward or back to view a particular topic. If you are ready, click the continue button below to advance to the next section in the course.









NEED MORE INFORMATION?

- Chelsea Violette
 - Chelsea@fqhc340b.com
- Jangus Whitner
 - apexusanswers@340bpvp.com



