

# HRSA Audit Trends & Best Practices

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340B Midwest Regional Conference & Expo  
September 23 & 24, 2024



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





## LEARNING OBJECTIVES

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

- Review recent audit trends as well as the most recent data request list
- Describe the timeline of an audit and what to expect
- Outline best practices to be prepared before you receive an audit notice





## Does the Idea of a HRSA Audit Make You Feel Like This? You're Not (Home) Alone!

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- HRSA Audits are stressful for even the most prepared and compliant organizations
- Proactively maintaining the auditable records that will be requested for a HRSA audit can make the preparation much less stressful
- Being prepared for the types of questions that will be asked in an audit can facilitate a smoother and more successful audit

# Policies & Procedures



Regularly review P&Ps to ensure they align with present-day practices



Map to DRL elements to save time in HRSA audit prep and streamline Q&A from HRSA auditor



# Eligibility Documentation

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Collect & highlight eligibility documents



If using the Electronic Handbook (EHB), work with team to obtain view access

[https://secure.login.gov/sign\\_up/enter\\_email](https://secure.login.gov/sign_up/enter_email): Create an account, add the entity using the organization's Tax ID, and request permission to view the organization's H80 grant  
CEO will receive a message to approve permissions, where they will select only the "View" checkboxes and approve



Collect pharmacy ownership documentation

Satellite, infusion, retail, etc.

Pharmacy license, insurance, etc.



# Contract Pharmacies

Prepare	Consolidate and highlight all PSAs, including all contract amendments
Maintain	Maintain a perpetual list of contract pharmacies and associated accounts
Review	Perform regular reviews of OPAIS registrations to correct any address inaccuracies and remove unused pharmacies
Plan	Have an action-plan with your contract pharmacy partners to request and obtain hard copy claims in a timely manner

# Provider Documentation

Work with your  
credentialing  
team to build  
user-friendly tools

Residents

Employed vs  
contracted  
documentation

Evidence of  
affiliation with the  
covered entity





# 340B Universe (Utilization Data)

## Clinic/Physician Administered Drugs

- Utilization data from less robust EHRs
- NCODs, reversals, and prescription assistance medications in data

## Contract Pharmacy Prescriptions

- Data from multiple TPA platforms
- Uploading only replenishable claims

## Audit tips

- Staff adept at EHR and TPA navigation
- Pre-audit samples when received
- Set up team for success even if you can't be present



	A	B	C	D	E	F	G	H	I	J	K	L	M	N
	Sample #	Rx #	Date Dispensed/ Administered	Eligible Service?	Eligible Location?	Scope?	Credentialed Provider?	Referral Provider?	Date of Referral Documentation	Location of Documentaion	Date of Visit/Encounter	Visit Type	Intial Start Date Location	Drug on Med List?
1														
2		1												
3		2												
4		3												
5		4												

When pre-auditing selected samples, create a road map for yourself and your team to streamline searching through the medical record on audit day!



# Purchasing Data



Secondary  
(and tertiary)  
wholesalers



PVP purchase  
history report



Med-surg accounts  
for grantees



On-going account  
list maintenance



Sample invoices



Hospital clean site  
inventory



Review NDCs with  
utilization without  
purchases and  
vice versa



Practice tracing  
claims through TPA  
to replenishment



Inventory  
monitoring/  
reconciliation  
records

Begin Date	Wholesaler	Address	Account #	GLN #	Vawd Accrediation	Termination Date	TPA
10/1/2021	McKesson	1995 McKesson St. Suite 101 Aurora, IL 60502		20083 50428480670		5/24/2022	Wellpartner
10/1/2021	McKesson	Tri States Distribution Center 1 John Henry Drive Robbinsville, NJ 08691		20092		3/24/2020	Wellpartner
10/1/2021	Cardinal	71 MIL-Acres Drive , Wheeling,WV 26003-4042	2150410801	78742029925			Wellpartner
10/1/2021	McKesson	Tri States Distribution Center 1 John Henry Drive Robbinsville, NJ 08691		20047		3/24/2020	Wellpartner
10/1/2021	McKesson	Clear Lake Distribution Center 2101 12th Ave S, Clear Lake, IA 50428		20041 50428017029	In process		Wellpartner
10/1/2021	McKesson	SoCal Distribution Center 9501 Norwalk Blvd Santa Fe Springs, CA 90670		20042		6/19/2020	Wellpartner
10/1/2021	McKesson	Birmingham DC 6775 Jefferson Metro Parkway,McCalla, AL 35111		20029			Wellpartner
10/1/2021	McKesson	Honolulu Distribution Center 80 Sand Island Access Road Honolulu, HI 96819		20038			Wellpartner
10/1/2021	McKesson	2798 New Butler Rd. New Castle, PA 16101		20001 50428029213		8/15/2020	Wellpartner
10/1/2021	McKesson	Atlanta DC 8148		20007			Wellpartner
10/1/2021	McKesson	2975 Evergreen Drive,Duluth, GA 30096		20038			Wellpartner
10/1/2021	McKesson	Chicagoland Distribution Center 8144		20051 50428480311			Wellpartner
10/1/2021	McKesson	1995 McKesson Street, Suite 101		20043		5/24/2022	Wellpartner
10/1/2021	McKesson	Mason Rd. Siute 100 LaVergne, TN 37086		20046 50428480403	- 9/17/2021 - 6/15/2021		Wellpartner
10/1/2021	McKesson	Aurora, IL 60502		20048		5/24/2022	Wellpartner
10/1/2021	McKesson	Memphis Distribution Center 4836 Southridge Blvd Memphis, TN 38141		20058		1/12/2021	Wellpartner
10/1/2021	McKesson	4012 South Purdue Oklahoma City, OK 731		20093			Wellpartner
10/1/2021	McKesson	4836 Southridge Blvd, Memphis, TN 38141		20098 1100009998441		9/17/2021	Wellpartner
11/10/2021	McKesson	Central Fill Only	Central Fill Location No Acct#				Nuvm
11/10/2021	McKesson	Central Fill Only	Central Fill Location No Acct#				Nuvm
11/10/2021	McKesson	8200 Bluegrass Blvd. Jeffersonville, OH 43128		29574 78742019925			Nuvm
11/10/2021	Cardinal	Central Fill Only		2150411284 840162206588			Nuvm
11/10/2021	Cardinal	71 MIL-Acres Dr, Wheeling , WV 26003-5024		2150411278 840162277373			Nuvm
11/10/2021	Cardinal	2353 Prospect Dr, Aurora, IL 60502		2150264350			Nuvm
11/10/2021	Cardinal			2150415387			Equiscripts
11/10/2021	Cardinal			2150415384			Equiscripts
11/10/2021	Cardinal	No invoice		2150415385			Equiscripts
11/10/2021	Cardinal	No invoice		2150415386			Equiscripts
11/10/2021	Cardinal	No invoice		2150415333			Equiscripts
11/10/2021	Cardinal	340B250 Commercial St Ste 2012 Manchester, NH, 03101-1118		2150416282			Equiscripts

Example



# Self-Audit Templates

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



**Compliance Element: Prevention of Diversion**

*Section 340B of the Public Health Service Act prohibits the resale, or other transfer, of a 340B drug to a person who is not a patient of the entity. Covered entities are responsible for maintaining an accurate patient eligibility determination system, including tracking and accounting all of 340B drugs at the covered entity to ensure that diversion has not occurred.*

**PATIENT ELIGIBILITY VERIFICATION**

**Table 1**

- For each of the 20 administrations/dispenses selected in step 2c of the instructions (page 1) and for the date range selected in step 1 of the instructions, verify patient eligibility by validating the dispense/administration record against the entity's health care record
- Validate that the prescription/drug order is the result of a health care service included in the scope of grant and was provided to a covered entity patient at an eligible site by an eligible provider such that the covered entity documents its responsibility for care in its health care record

**Table 1**  
340B Eligibility Determination Verification Table  
Time period tested: begin date \_\_\_\_\_ to end date \_\_\_\_\_  
(attach actual data to substantiate eligibility for each sample)

(1) Sample ID (prescription number or dispense tracking number)	(2) Date dispensed/ administered	(3) Drug dispensed/ administered/ prescribed based on eligible CE service?		(4) Drug dispensed/ administered/ prescribed from location with a 340B ID?		(5) Drug dispensed/ administered as a result of a service included in the scope of grant?		(6) ELIGIBLE Provider				(7) DRUG and VISIT documented in covered entity's health care record?			
		YES	NO	YES	NO	YES	NO	(A) Employed/ contracted?		(B) Documented referral?		YES	NO		
								YES	NO	YES	NO				

## Self-Audit: Prevention of Duplicate Discounts Community Health Centers (CH/FQ/FQHC/FQHCLA/NH)



**CARVE-IN BILLING VERIFICATION**

**Table 3**

- For each of the 20 340B drug administration/dispenses selected in step 2b of the instructions (page 1) and for the date range selected, verify that the covered entity's carve-in practice is consistent with its listing in the MEF and state Medicaid agency's billing requirements to complete columns 1-5
- Verify that the MPNs and NPIs used to bill Medicaid are those listed in the Medicaid Exclusion File (MEF) to complete column 6
- Review mechanisms required by each state Medicaid agency to identify a drug as 340B when it is billed as part of an outpatient medical encounter (e.g. UD modifier on UB-04 claim form) and from a retail pharmacy (e.g. defined NCPDP code)
- Verify that the state Medicaid billing practice is being followed, and complete column 7
- Attach actual data to substantiate Medicaid billing for each 340B drug administration/dispense

**Table 3**  
Carve-In Billing Verification Table  
Time period tested: begin date \_\_\_\_\_ to end date \_\_\_\_\_

(1) Sample ID (prescription number or dispense tracking number)	(2) Date of dispense	(3) Name of 340B drug dispensed or administered	(4) Name of main or associated site(s) that administered/dispensed the drug, or entity owned retail pharmacy that dispensed the drug	(5) Medicaid provider number (MPN) and National Provider Identifier (NPI) number(s) used to bill Medicaid	(6) Are MPNs and NPIs used to bill Medicaid consistent with those listed on the MEF?		(7) State Medicaid 340B billing requirements followed?	
					YES	NO	YES	NO

**Clinic Inventory Reconciliation Audit Log** Clinic Name: \_\_\_\_\_

Start Date: \_\_\_\_\_ End Date: \_\_\_\_\_

Sample	Item Description	NDC	Starting Count	+	Quantity Relieved	-	Quantity Expired	+	Quantity Wasted	+	Utilizations	=	Calculated End Count	-	Actual End Count	=	Variance	Reconciliation Notes:	Auditing Personnel
1	Mirena 52mg IUD	50419-0412-01	5	+	2	-		+		+	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		



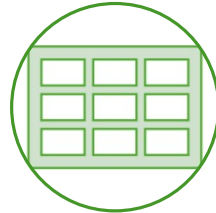
# Medicaid Billing



FFS vs MCO



Billing forms from  
each site and each  
state



FFS BINs & PCNs  
carved out at each  
entity-owned and  
contract retail  
pharmacy



Embedded  
document  
functionality



State billing  
requirements and  
source documents



# Preparing for the Day of the Audit

## Know your team!

- Identify partners and helpers and foster those relationships ahead of time
- Establish expectation with C-suite that a HRSA audit will trump other priorities

## Practice auditor interview questions with relevant staff

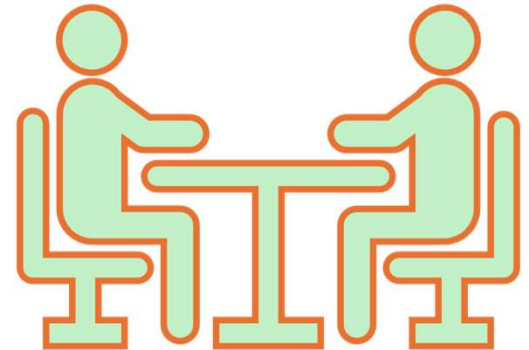
## Practice sample navigation

- Back-up person and device for sample navigation
- Non-sampling individual who can dig for additional information while sampling proceeds

## Essential participants in the room or on the call

## DO NOT plan on being done the day after the audit

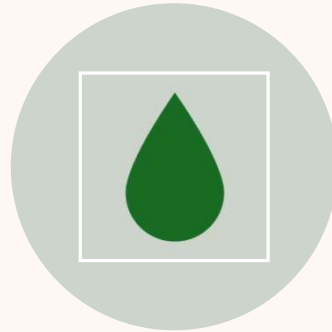
- Plan for additional 3 days for any necessary follow-up



# Most Important!



**SNACKS!**



**WATER!**



**CAFFEINE!**



Questions?



## NEED MORE INFORMATION?

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