340B Compliance Low-Hanging Fruit: Creating an OPAIS Crosswalk

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DISCLOSURE STATEMENT

- Hannah Rowell owns direct stock in NanoViricides (NNVC)

  and

- All of the relevant financial relationships listed for this/these individual(s) have been mitigated.

  and

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

Presenter

Hannah Rowell

Senior 340B Consultant

Hannah is a Senior 340B Consultant on the Draffin Tucker's 340B Services Team and holds the 340B Apexus Certified Expert credential. She brings prior experience in healthcare quality and process improvement in her approach to 340B compliance. Hannah is a nationally recognized expert in the 340B community and is a frequent presenter at national conferences. Hannah has served as Faculty for 340B University in-person training. In her previous role leading the 340B Program for a large FQHC, Hannah oversaw a network of nearly 200 contract pharmacies while maintaining compliance, navigating contract pharmacy restrictions, and guiding the health center through a HRSA audit with zero findings.

About Draffin Tucker

- Founded in 1948

- Regional CPA firm with national presence

- Approximately 70% of our Firm is dedicated to the healthcare industry
  - Audit
  - Reimbursement
  - Advisory
  - 340B

LEARNING OBJECTIVES

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

- Identify how to download 340B data from OPAIS

- Describe how to validate that contract pharmacy agreements match HRSA expectations

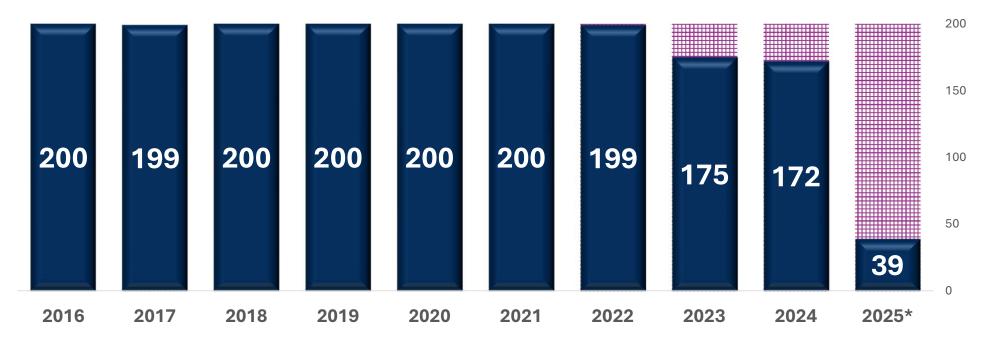- Review how to validate Medicaid Exclusion File (MEF) is accurate.

OPAIS Accuracy

With everything you are juggling, why is it important to maintain accurate records in OPAIS?

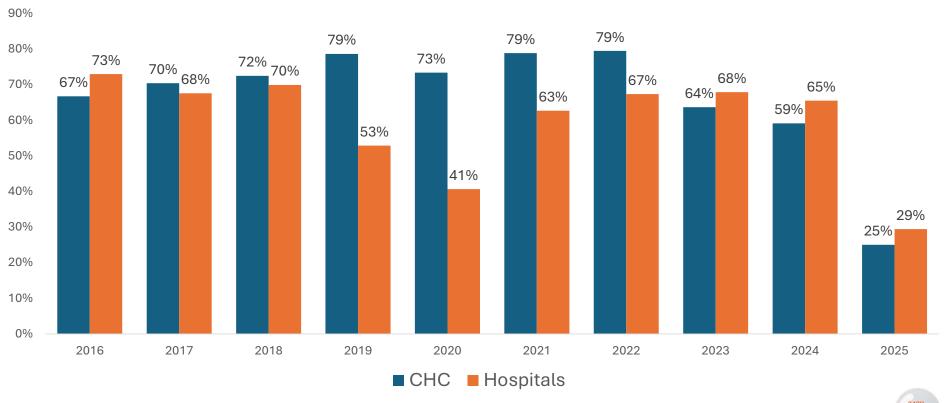Graphic credit: PRESENTERMEDIA

HRSA Audits Since 2016

200	199	200	200	200	200	199	175	172	39
2016	2017	2018	2019	2020	2021	2022	2023	2024	2025*

Percentage of Entities with Adverse Findings

Year	CHC	Hospitals
2016	67%	73%
2017	70%	68%
2018	72%	70%
2019	79%	53%
2020	73%	41%
2021	79%	63%
2022	79%	67%
2023	64%	68%
2024	59%	65%
2025	25%	29%

■ CHC ■ Hospitals

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Audience Participation: What do you think is the most common type of audit finding?

a)   Diversion Findings

b)   Duplicate Discounts

c)   Incorrect or incomplete MEF

d)   Incorrect OPAIS

e)   GPO Violation

Findings Details – All CE Types

	2016	2017	2018	2019	2020	2021	2022	2023*	2024*
Diversion Findings	92	85	70	31	15	19	23	20	20
Duplicate Discounts	57	48	68	60	42	38	40	43	28
Incorrect or incomplete MEF	9	11	14	7	13	23	20	13	15
Incorrect OPAIS	56	61	63	52	50	100	118	71	86
GPO Violation	9	6	2	5	1	3	1	5	0
Other	14	15	8	3	1	0	5	4	1

Partial results.

A note about Diversion Findings...

	2016	2017	2018	2019	2020	2021	2022	2023*	2024*
Diversion Findings	92	85	70	31	15	19	23	20	20
Duplicate Discounts	57	48	68	60	42	38	40	43	28
Incorrect or incomplete MEF	9	11	14	7	13	23	20	13	15
Incorrect OPAIS	56	61	63	52	50	100	118	71	86
GPO Violation	9	6	2	5	1	3	1	5	0
Other	14	15	8	3	1	0	5	4	1

Partial results. 25 results outstanding in 2023, 28 outstanding in 2024

2024 OPA Update

340B Program Compliance

In January 2024, HRSA created a new webpage to provide in one place the resources available to covered entities regarding HRSA audits to ensure compliance with 340B Program requirements. As HRSA noted on the webpage, **HRSA Patient Definition Guidelines** (PDF - 31 KB)**, published 25 years ago, contain HRSA's interpretation of key statutory requirements and continue to guide HRSA's audit activities**. In the coming weeks and months, HRSA will be sending a series of audit findings to covered entities where we have identified potential areas of non-compliance with statutory requirements. Once complete, HRSA will post audit results on our public website.

(2024, August). *340B Drug Pricing Program*. Health Resources & Services Administration. https://www.hrsa.gov/opa

340B Patient Definition Compliance Resources

Program integrity is a top priority for the 340B Program. Section 340B(a)(5)(C) of the Public Health Service Act (PHSA) (PDF - 39 KB) authorizes HRSA to conduct audits of covered entities to ensure compliance with 340B Program requirements. In accordance with section 340B(d)(2), HRSA also carries out covered entity oversight activities. HRSA's 340B Program audits review covered entity compliance with several statutory provisions, including eligibility status, duplicate discounts, and diversion in accordance with sections 340B(a)(4), (5)(A) and (B) of the PHSA.

Since the beginning of HRSA's audit program in 2012, HRSA has communicated its approach for implementing this audit authority to stakeholders through program policies, guidance documents, and regulations. **More than 25 years ago, HRSA published Patient Definition Guidelines (PDF - 31 KB), which contain HRSA's interpretation of several key statutory requirements and which continue to guide HRSA's audit activities.** To further assist covered entities with 340B Program compliance activities, HRSA has compiled existing resources on how it conducts audits and determines non-compliance to ensure compliance with the 340B statutory prohibition against diversion:

*HRSA notes that the decision in *Genesis Health Care, Inc., v. Becerra, Civ. 4:19-cv-01531-RBH (D.S.C. November 3, 2023)*, is applicable solely to Genesis Health Care.

Date Last Reviewed: January 2024

https://www.hrsa.gov/opa/educational-resources/patient-definition-resources

Reminder: 1996 Patient Definition

(C) Definition of a Patient

An individual is a "patient" of a covered entity (with the exception of State-operated or funded AIDS drug purchasing assistance programs) only if:

1. the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and

2. 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

3. 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 entity for purposes of 340B 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.

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.

Health Resources and Services Administration

[0905–ZA92]

Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility

AGENCY: Health Resources and Services Administration, HHS.
ACTION: Final Notice.

61 Fed. Reg. 55156, October 24, 1996

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2024 HRSA Audit Findings

CHC

- To be validated as part of the [covered entity], a **site must first be listed** as an approved service site **on Form 5B** in the HRSA electronic handbooks.

- However, the [#] prescriptions were issued from sites that were **not listed** as approved service sites **on Form 5B** in the HRSA electronic handbooks. Therefore, **the sites are not a part** of the **[covered entity]** for purposes of the 340B Program.

HOSPITAL

- To be validated as part of a covered entity, a **site must first be listed as reimbursable** with associated outpatient costs and charges on the **most recently filed** Medicare cost report. A covered entity may be part of a health care system; however, the inclusion of a covered entity within a larger organization does not make the entire organization eligible for the 340B Program."

2024 HRSA Audit Findings, cont.

- An individual is not considered a patient of a covered entity when the healthcare service was provided to the individual **outside of** an **employment, contractual**, or other arrangement (e.g., **referral** for consultation) with the covered entity.

- [CE]'s provision of health care services to the individuals at other points in time **unrelated to the** [#] sampled **340B prescriptions** and sharing of medical records with providers at sites not able to be registered in [CE]'s 340B Program, is not sufficient to demonstrate that the **responsibility for care provided remained with [CE].**

What's next in Patient Definition?

- HRSA appears to be **doubling down on its 1996 Patient Definition** and the enforcement of it's pre-2019 patient definition with the "initiation requirements".

- HRSA lost its case with Genesis, which involved the initiation requirements, but the ruling was limited to Genesis.

- Covered Entities started receiving these new diversion findings in June/July 2024, and many appeals have been filed. Not aware of any appeal results.
  - It may take HRSA many months to review appeals

- If HRSA leaves the findings, will a covered entity sue HRSA like Genesis did?

Creating an OPAIS Crosswalk

Graphic credit: PRESENTERMEDIA

Document organization

First things first...

- Preparing for an **audit** requires gathering a tremendous number of documents. Having these **items carefully organized and waiting** will go a long way towards being continuously audit ready.

- Best practices include clear and concise folder labels and file names. It is wise to keep these important files in a shared location, and more than one team member should know where they are and how to access them if needed.

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Organizing contract pharmacy amendments

An auditor will likely ask to see historical amendments dating back to when each new pharmacy location was added to a pharmacy services agreement. It is best to gather and store those in a user-friendly format.

File names are your friend! Utilize the file name as an element of the organizational strategy.

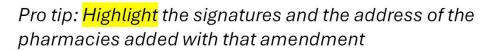- Example Pharmacy Amendment – OPAIS additions 2018-07 July – Executed 4.12.2018
- Example Pharmacy Amendment – OPAIS additions 2018-04 April – Executed 12.20.2017
- Example Pharmacy Amendment – OPAIS additions 2017-10 Oct – Executed 7.1.2017
- Example Pharmacy Amendment – OPAIS additions 2017-07 July – Executed 4.6.2017
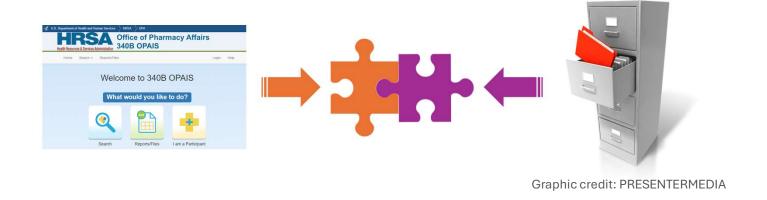
Stores become active   **When contract signed**

Pro tip: <mark>Highlight</mark> *the signatures and the address of the pharmacies added with that amendment*

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What is an OPAIS crosswalk?

- A crosswalk helps you tie your data in OPAIS to valid sources of truth for your 340B program.

- A crosswalk is a helpful tool to **spot variation between sources** of data, and ensure that OPAIS is accurately reflecting your NPIs, Medicaid Billing Numbers (MBNs), addresses, pharmacies and more.

- Having a current crosswalk on hand makes **recertification a breeze**.

Graphic credit: PRESENTERMEDIA

Step one: Gathering the internal data

- You will need the following items for your crosswalk:
  - ✓ Accurate list of Medicaid Billing Numbers (MBNs) and National Provider Identifiers (NPIs) used by each CE location
  - ✓ Grantees need a current copy of their grant eligibility and Site ID numbers.
    - For FQHCs, this is your EHB Form 5B
  - ✓ Medicare Provider Numbers, if applicable to your CE type
  - ✓ Contract Pharmacy addresses, pulled directly from your current Pharmacy Services Agreement(s)
  - ✓ Official addresses of each 340B eligible location

- This data should be **collected fresh each time** you complete the crosswalk. Getting a new document from the primary stakeholder is important as sometimes changes occur, and no one thinks to notify the 340B team.

Step two: Pulling your data from OPAIS

- https://340bopais.hrsa.gov/home

Note:
You don't need to be logged in as AO or PC to download your data.

Search for your Covered Entity

OPAIS will return a list of the various CEs with that name

Page |« ‹ 1 of 1 › »| Record 1 to 12 of 12   Page Size: 20 ▼

☐	340B ID ↑	Entity Type ▽	Name	Sub Name	Address	City	State ▽	Dates		
								Start ▽	Term ▽	Edited ▽
○	○		○	○	○	○				
☐	CH096040	CH	COMMUNITY CLINIC OF MAUI	Community Clinic of Maui	1881 Nani St	Wailuku	HI	4/1/2004		2/25/2025
☐	CH09604A	CH	COMMUNITY CLINIC OF MAUI, INC.	Community Clinic of Maui KHAO Satellite Clinic	670A WAIALE ROAD	WAILUKU	HI	4/1/2004		2/25/2025
☐	CH09604C	CH	COMMUNITY CLINIC OF MAUI	Community Clinic of Maui NHOW Satellite Clinic	15 IPU AUMAKUA LN	LAHAINA	HI	4/1/2004	4/1/2024	2/23/2024
☐	CH09604D	CH	COMMUNITY CLINIC OF MAUI	Temporary Site - Lahaina Satellite	1830 Honoapiilani Hwy	Lahaina	HI	10/4/2023	10/1/2024	7/12/2024

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Please select fields to export   Cancel

Covered Entity Export Options

☐ Select/Deselect all   ⚠ * - These fields will be included in the export in separate worksheets.   ☐ Use old export format   **Export**

☐ Covered Entity Details

☐ Grant Number
☐ Site ID
☐ Medicare Provider Number
☐ Outpatient Facility Provider Number
☐ 340B ID
☐ Current Program Status
☐ Entity Type
☐ Registration Date
☐ Participating
☐ Participating Start Date
☐ Participating Approval Date
☐ Termination Code
☐ Termination Date
☐ Last Recertification Date
☐ CE ID
☐ Parent CE ID
☐ NOFO Number
☐ Assistance Received From Date
☐ Assistance Received To Date
☐ Entity Name
☐ Entity Sub-Division Name

☐ Covered Entity Address

☐ Address 1
☐ Address 2
☐ Address 3
☐ City
☐ State
☐ Zip
☐ Second Zip

☐ Billing Information

☐ Billing Organization
☐ Address 1
☐ Address 2
☐ Address 3
☐ City
☐ State
☐ Zip
☐ Second Zip

☐ Shipping Information ⚠

☐ Shipping Organization
☐ Address 1

☐ Primary Contact Information

☐ Primary Contact Name
☐ Primary Contact Title
☐ Primary Contact Telephone
☐ Primary Contact Extension

☐ Authorizing Official Information

☐ Authorizing Official Name
☐ Authorizing Official Title
☐ Authorizing Official Telephone
☐ Authorizing Official Extension

☐ Signed By Information

☐ Signed By Name
☐ Signed By Title
☐ Signed By Date
☐ Signed By Telephone
☐ Signed By Extension

☐ Medicaid Billing

☐ Medicaid Number
☐ NPI

☐ Nature Of Support ⚠

☐ Nature Of Support
☐ InKind Support Description
☐ Support Received From Date
☐ Support Received To Date

☐ Misc.

☐ Rural
☐ Public Comments
☐ Edit Date

☐ Contract Pharmacy Details ⚠

☐ Pharmacy Name
☐ Address 1
☐ Address 2
☐ Address 3
☐ City
☐ State
☐ Zip
☐ Second Zip
☐ Contract ID
☐ Contract Begin Date
☐ Contract Approval Date
☐ Contract Term Date
☐ Pharmacy Comments
☐ Pharmacy ID
☐ Medicaid Billing
☐ Carve-In Effective Date
☐ Carve-In End Date

☐ Contract Pharmacy Rep Information ⚠

☐ Contract Pharmacy Rep Name
☐ Contract Pharmacy Rep Title

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OPAIS will export the data in this format:

	Grant Number	Site ID	Medicare Provider Number	Outpatient Facility MPN	340B ID	Organization Status	Entity Type	Registration Date	Participating
1									
2	Exported On:	7/28/2025 15:05	**Covered Entity List Export**						
3	Exported By:	anonymous							
4	Covered Entity Details								
5	Grant Number	Site ID	Medicare Provider Number	Outpatient Facility MPN	340B ID	Organization Status	Entity Type	Registration Date	Participating
6	H80CS00722	BPS-H80-008908			CH096040	Active	CH	4/1/2004	True
7	H80CS00722	BPS-H80-005024			CH09604A	Active	CH	4/1/2004	True
8	H80CS00722	BPS-H80-001943			CH09604C	Terminated	CH	4/1/2004	False
9	H80CS00722	BPS-H80-037111			CH09604D	Terminated	CH	10/2/2023	False
10	H80CS00722	BPS-H80-038203			CH09604E	Active	CH	7/10/2024	True
11	H80CS00722	BPS-H80-038692			CH09604F	Active	CH	10/3/2024	True
12	FPHPA090326				FP967322	Terminated	FP	1/1/1998	False
13	FPHPA090326				FP967611	Terminated	FP	1/1/1998	False
14	FPHPA090326				FP96793	Terminated	FP	4/1/2004	False
15	H76HA00642				HV96732	Terminated	HV	4/1/2004	False

Covered Entity Details | Contract Pharmacy Details | Shipping Address Details | Nature Of Support Details | +
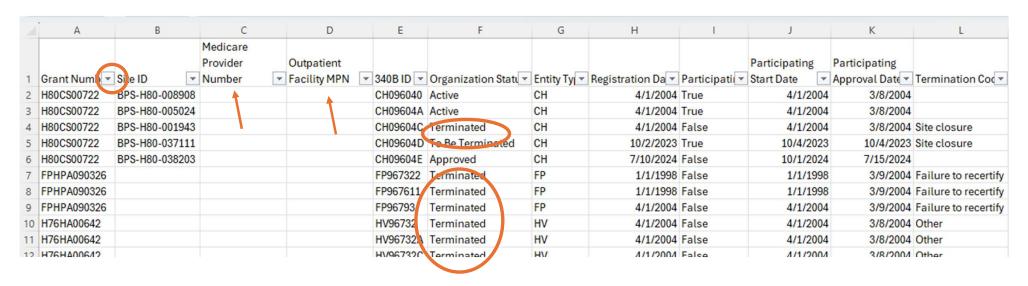
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Audience Participation: Who can download OPAIS data in Excel format?

a) AO

b) PC

c) AO and PC

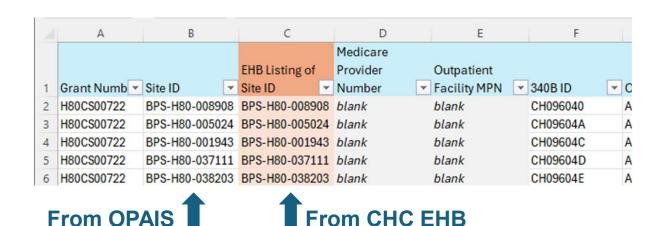d) AO and PC, only during quarterly registration periods

e) Anyone

Step three: Organizing the OPAIS data

- Add filters to the column headers

- Take the data related to terminated sites and move that to a separate tab.

- You can delete columns that don't apply to your CE or make a note that they are correctly blank fields.

Step four: Adding in the external data

From OPAIS ↑   ↑ **From CHC EHB**

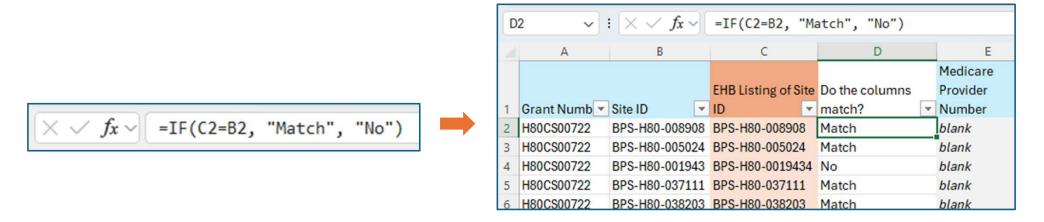This is just one example of a validated field, but I recommend this process for:

- Addresses
- MBNs
- NPIs

- Adjacent to each field you plan to validate, insert a new column.
- Carefully type or paste the value from your grant documents, billing records, or contracts.
- Optional: color coding can help clarify which data came from OPAIS vs. from CE records.

Step five: Cross-checking the data

- You can either visually review the columns, or an easier way is to use an Excel formula to tell you whether the two columns match.

`=IF(C2=B2, "Match", "No")`

D2		=IF(C2=B2, "Match", "No")		
	A	B	C	D	E
1	Grant Numb	Site ID	EHB Listing of Site ID	Do the columns match?	Medicare Provider Number
2	H80CS00722	BPS-H80-008908	BPS-H80-008908	Match	blank
3	H80CS00722	BPS-H80-005024	BPS-H80-005024	Match	blank
4	H80CS00722	BPS-H80-001943	BPS-H80-0019434	No	blank
5	H80CS00722	BPS-H80-037111	BPS-H80-037111	Match	blank
6	H80CS00722	BPS-H80-038203	BPS-H80-038203	Match	blank

Medicaid Exclusion File (MEF) considerations

- For covered entities that carve-in Medicaid, on a quarterly basis, your OPAIS records get captured and become the HRSA Medicaid Exclusion File (MEF).

"340B OPAIS takes a snapshot of carve-in decisions at 12:01am ET on the 16th day of the month prior to the start of each quarter, irrespective of weekends or holidays."

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

Contract pharmacy considerations

- If you look closely, the pharmacy addresses in OPAIS might not exactly match your pharmacy contract
    - OPAIS is fixed and based on DEA listing
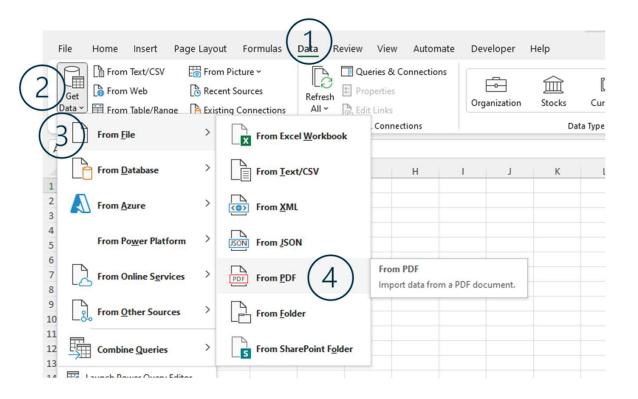   - Ask your contract pharmacy to update your contract to reflect the DEA/OPAIS address

OPAIS Address	Pharmacy Services Agreement Address
34 SOUTH ROUTE 12	34 S US HIGHWAY 12
225 E JONES AVE, STE 03110	225 E JONES AVE
201 N. ELM STREET, SUITE 01-210	201 N ELM ST
3245 N GROVER ST. SUITE 101	3245 N GROVER ST

Contract pharmacy considerations, cont.

- Tip for getting amendment addresses into Excel format:

While you are reviewing your agreements...

- If you have multiple sites and contract pharmacies, review your agreements to ensure that either they:

    a) Include a list of all applicable CE locations, identical to OPAIS listing.

    -or-

    b) Contain language that the underlying agreement applies to all 340B locations eligible and listed in OPAIS.

- Older contracts might only reference the parent site. Work with your contract pharmacy to get an amendment or revision.

More Info:
Apexus FAQ ID: 2507

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Crosswalk: Ongoing monitoring

Graphic credit: PRESENTERMEDIA

- Schedule regular check-ins with your billing team to review the MBNs and NPIs your organization is currently using.

- Ask to look at a sample of billing forms (e.g., HCFA-1500 forms for FQHC clinic-admin drugs) and validate that the billing numbers match your 340B records and thus match your 340B Crosswalk.

- Getting current data is critical to making your Crosswalk a useful compliance exercise.
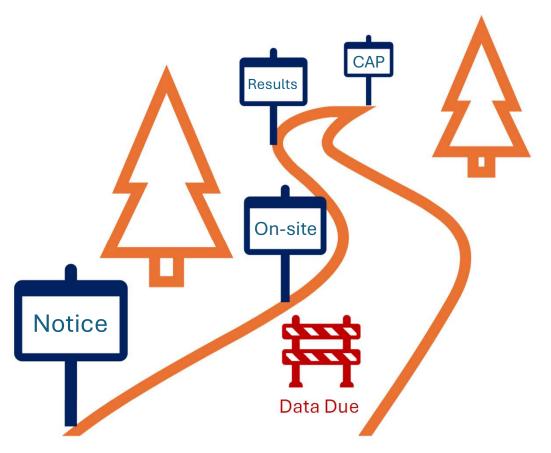
HRSA 340B Audits

What is the experience like?

Graphic credit: PRESENTERMEDIA

So, you received a HRSA audit notification…

Email Notification, and immediate next steps

Notification email goes to AO and PC – they must know to flag you immediately about this.

First steps:

- Panic! (just kidding)
- Within 3 business days – schedule a Welcome Call
- **Tell key folks** – leadership, credentialing, billing, TPAs, contract pharmacies, wholesalers, external auditor
- **Read the Data Request List** carefully and prepare questions for the Welcome Call
- Get organized, start a **project plan**

Collaborating with your External Partners

TPA/Contract pharmacy

- Pharmacy will need to pull hard copies of each audited claim, during a short time frame before the on-site portion.
- TPA reports will be needed to create your "universe" of all 340B claims during the audit period.

Wholesaler(s)

- Need a report of all 340B purchases during the audit period.
- Will need to pull one example invoice for each purchasing account during the audit period – warning: this can be very tedious

DRL Highlights: Purchasing Accounts

You will be providing a list of all your purchase accounts:

- Wholesaler name
- Account number
- Account name
- Location that receives the drug (easy)
- Location that dispenses the drug
  - **FYI:** *For contract pharmacies with a chain replenishment model, this is something you will need to determine and do some fancy Excel work*
- Type of account
- 340B ID associated with the account

Your "Universe" of Claims

- Our DRL asked for "all 340B drugs that were **administered or dispensed**" during the audit period
  - NOTE: This is <u>not</u> asking what was *captured* during the period

- Everything you upload needs to **exclude patient name**, DOB, address, etc.

- Asked for the location **dispensed** *and* the location **written**

- DRL asks for very specific items – only need to provide the data requested

- Your universe asks for **340B** admins/dispenses
  - Consider whether you have non-340B items (vaccines, test strips, etc.) in your dataset

Audience Participation: Which elements should be **included** in your "universe" of claims for a HRSA 340B audit?

	Include?	Exclude?
Patient Name & DOB		
Non-covered outpatient drugs, such as test strips and lancets		
Location the drug was dispensed		

not a comprehensive list of the data elements

DRL Highlights: Medicaid Billing Documents

- List of each clinic and pharmacy billing Medicaid FFS, with corresponding NPIs and Medicaid Billing Numbers (MBNs) per state.

- DRL asks for **one Medicaid FFS claim form for each clinic** and/or pharmacy, per state billed.

- Once the samples are selected, be ready to produce Medicaid billing forms for those sample claims, too.

DRL Highlights: Provider List

Excel format:
- First Name
- Last Name
- NPI
- Employed/contracted
- Start Date
- Term Date

*Think about any provider who could have written a script that got **filled** during the audit period, so not just providers eligible during the audit period, may need to go back a bit further.*

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Create a project plan

- There are many pieces of audit prep – staying organized is key

- Utilize smart naming conventions for your files

- Once you upload something to the official portal, cannot take down

Simple Project Plan:

DRL #	Item	Status	Owner	Notes
1A	P&P	Done!		
2A	Location list	On target		
2B	Grant docs	Problem		
Etc…		Not started		

File Name Structure:

- Example CHC. DRL 1A. 340B P&P – Policy
- Example CHC. DRL 1A. 340B P&P – Procedure
- Example CHC. DRL 2A. List of CE locations
- Example CHC. DRL 2B. Notice of Grant Award – Full
- Example CHC. DRL 2B. Notice of Grant Award – EHB 5A
- Example CHC. DRL 2B. Notice of Grant Award – EHB 5B
- Example CHC. DRL 3A. Program Narrative
- Example CHC. DRL 3B. Crosswalk of Column Headers

Day of the onsite audit

- Set the stage for the auditor to see you as the high-functioning, professional health center that you are.
  - Backup tech support, and options for displaying EMR info

- Consider having folks on location, but not in the audit room all day.
  - Can call in people as they were needed
  - Need someone very skilled in navigating your EHR

- Plan to take the auditor on a clinic tour and show CAD storage.

- The HRSA/Bizzell may ask for additional documents onsite. **Be ready to roll with day of requests.**

What can make HRSA audit prep way less stressful?

- Having your **policies & procedures** (P&Ps) updated and accurately describing what you do is a huge help.

- **Contract Pharmacy agreements** and amendments collected, organized, and highlighted.

- Investing time in **regular** checks of your 340B records, using the **OPAIS crosswalk methodology** described today.

Audience Participation: When is the best time to organize all of your 340B records and contract pharmacy agreements?

a) Yesterday

b) Today

c) Tomorrow

d) Wait until you receive a HRSA audit notification email

NEED MORE INFORMATION?

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