

The 340B Drug Pricing Program

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Healthcare Systems Bureau (HSB)

Health Resources and Services Administration (HRSA)



Disclosures

James Morris and Sherry Pontell have no relevant financial or nonfinancial interests to disclose.

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Learning Objectives

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

1. Describe 340B OPAIS enhancements.
2. Describe important tips for registering and completing recertification.
3. Prepare for HRSA's integrity checks.
4. Describe HRSA's 340B Program integrity guiding principles.
5. Describe the audit process.
6. Describe the areas of audit focus.



Obtaining CME/CE Credit

If you would like to receive continuing education credit for this activity, please visit:

<http://ryanwhite.cds.pesgce.com>



Acronyms

340B OPAIS:	340B Office of Pharmacy Affairs Information System
AFI:	Area for Improvement
AO:	Authorizing Official
CAP:	Corrective Action Plan
CE:	Covered Entity
COD:	Covered Outpatient Drug
CP:	Contract Pharmacy
MEF:	HRSA Medicaid Exclusion File
NPI:	National Provider Identifier
PC:	Primary Contact
RW:	Ryan White



340B Drug Pricing Program (340B Program)

- **The 340B Program requires drug manufacturers to provide covered outpatient drugs to eligible covered entities at reduced prices.**
- **Covered entities eligible to participate in 340B are defined in the statute.**
- **Manufacturers that participate in Medicaid are required to participate in the 340B Program.**
- **To participate in the 340B Program, eligible covered entities must register and be enrolled with the 340B Program, and comply with all 340B Program requirements.**



Intent of the 340B Program

Permits eligible safety net providers “to stretch scarce Federal Resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

H.R. Rep. No. 102-384(II), at 12 (1992)



340B Program Eligible Entities

Federal Grantees/Designees	Hospitals
<ul style="list-style-type: none">• Federally qualified health centers• Federally qualified health center look-alikes• Title X Family Planning grantees• Ryan White Care Act recipients (A,B,C,D,F)• Black lung clinics• Hemophilia treatment centers• Native Hawaiian health centers• Urban Indian organizations• Tribal Compacts• STD prevention grantees• TB prevention grantees	<ul style="list-style-type: none">• Disproportionate share hospitals• Children’s hospitals• Critical access hospitals• Free standing cancer hospitals• Rural referral centers• Sole community hospitals



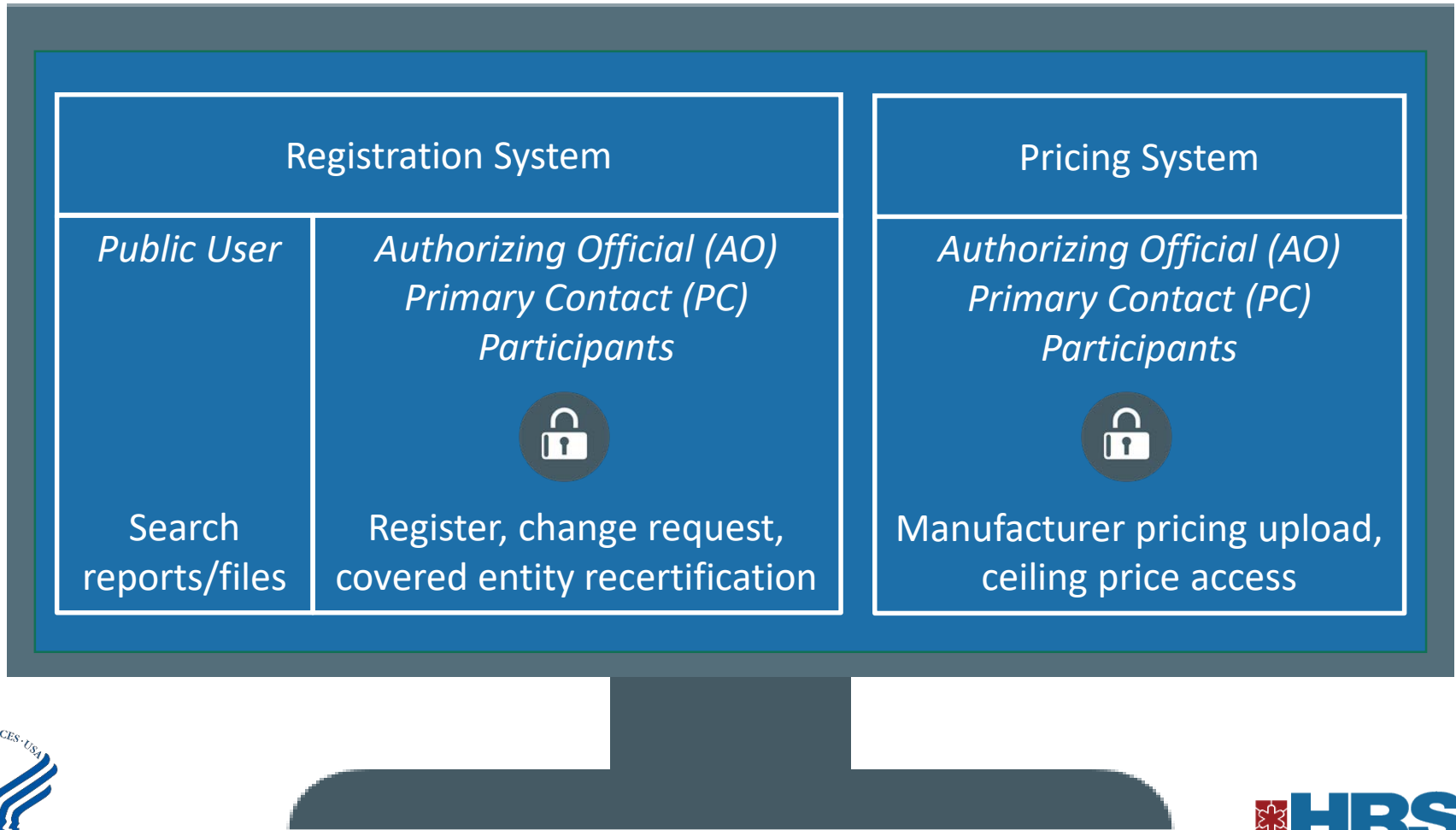
340B OPAIS

- Entities are not eligible for the Program unless listed in the 340B OPAIS.
- The 340B OPAIS is the primary source for covered entities, manufacturers, wholesalers, and OPA.
- Each clinic/site must have a specific 340B ID.
- Wholesalers will not ship discounted drugs unless address is an exact match to the 340B OPAIS.
- Information is updated daily.
- Online registration is available for all applicants at <https://340bopais.hrsa.gov/>



340B OPAIS

An integrated 340B Office of Pharmacy Affairs Information System



340B OPAIS Enhancements

- **340B OPAIS looks different but the requirements and information have not changed.**
- **OPAIS users must have an account.**
 - Accounts can be set up at <https://340bopais.hrsa.gov/>
- **User guides can be accessed via the help menu on the AO's and PC's landing page (after logging into the 340B OPAIS).**
- **AOs and PCs access their tasks via the task page (after logging into the 340B OPAIS).**



340B OPAIS Enhancements (Continued)

- **PCs can now complete the registration and recertification but the AO must attest and submit to OPA.**
- **A registration and a recertification can be sent back to the AO for clarification or correction.**
 - Comments from OPA will be displayed in top left of the "My Tasks "screen.
- **All fields can now be edited by the entity.**
- **The AO and PC cannot be the same person in the 340B OPAIS.**



340B OPAIS Enhancements

- **Communication with HRSA:**
 - Through the registration process.
- **Contract pharmacy representative update:**
 - CE will have the ability to use its profile to search and edit contract pharmacy representative's information associated with its 340B ID.
- **Grant field registration requirements:**
 - CE (excluding Indian Health Service grantees) will be required to submit a grant number with its registration.



340B OPAIS: General Tips

- **General quarterly registration schedule:**
 - 1-15th of January, April, July, and October
- **General annual recertification schedule:**
 - Hospitals: middle of August through middle of September
 - STD, TB, and FP: middle of April through middle of May
 - All other grantees/recipients: middle of January through middle of February
- **AO must have an account setup in order to complete all functions in the 340B OPAIS.**



340B OPAIS: General Tips (Continued)

- Please follow user guide instructions when submitting a registration, recertification, or change request.
- CEs should terminate and stop purchasing 340B drugs the day they become ineligible. Do not wait until recertification to terminate.
- If critical information is changing about your entity, be prepared to answer questions and provide documentation to support the change request (including at recertification).
- Medicaid billing number updates accepted in OPAIS by the 15th of the last month of each quarter, will appear on the MEF as of the first of the next quarter. Accepted changes do not affect the MEF immediately.
- Ensure AO and PC are always up to date for each CE 340B ID.



340B OPAIS: Registration Tips

- System sends automatic emails (task notification) to AO during registration, recertification, or change request until the AO acts on the notification.
- CEs can provide additional information in the comments” section” of the registration or change request. CEs can upload documents.
- If you are trying to reactivate a terminated entity, please choose “reinstate” when registering.
- Please spell out any unclear acronyms in the CE’s name and subdivision name.
- CPs can only be registered by the CE.



340B OPAIS: Registration Tips (Continued)

- **Gather all the needed information:**
 - Grant numbers are now a required field for registrations (except Indian Health Programs).
 - If unsure of grant number, please contact state or federal program manager.
- **The registration page on the HRSA OPA website lists the grant number format for each Non-Hospital entity type.**
- **If a direct grantee, entity must be active in HRSA's Electronic Handbook (EHB).**



340B OPAIS Registration Tips

- Know your Ryan White Federal grant number.

Ryan White Part	Federal Grant Number
Part A	H89HA-----
Part B, direct, rebate	X07HA-----, X08HA-----, X09HA-----
Part C	H76HA-----
Part D	H12HA-----



Eligibility : Accurate 340B OPAIS Information

- All information for each site (340B ID) listed in the 340B OPAIS must be accurate and up to date.

340B ID Non-hospital Name (Status)		Print
Name		Current Program Status
Subdivision Name		Registration Date
Type		Participating Start Date
Site ID		Participating Approval Date
340B ID		Last Recertification Date
Grant Number		Street Address
Employer Identification Number		Billing Address
Authorizing Official Primary Contact		
<input type="text"/>		
Comments	Medicaid Billing	CE Attachments
Contract Pharmacies		Shipping Addresses
History		

For more information 340B OPAIS records see:
<https://www.hrsa.gov/opa/340b-opais/index.html>



340B Recertification

- **Required by Statute.**
- **Ensures 340B Program integrity, compliance, transparency and accountability.**
- **Ensures accuracy of covered entity information in the 340B OPAIS.**
- **Ensures the accuracy of contract pharmacies listed in 340B OPAIS.**



Keys to Successful Recertification

- **Verify AO and PC contact information in the 340B OPAIS prior to recertification.**
 - Update contact information prior to recertification if necessary.
- **Monitor 340B Program webpage and email messages prior to recertification.**
- **Review and print out the OPAIS Recertification User Guide, which is available in the “Help” menu.**
- **Submission of a 340B OPAIS online change request is not the same as recertification.**



Recertification

Lessons Learned and Helpful Hints

- The purpose of recertification is to verify and update CE information and attest to compliance.
- PO Boxes are only authorized for an entity's billing address.
- It is highly recommended that CEs print the Recertification User Guide for assistance.
 - The guide is available from the "Help" menu when logged into the 340B OPAIS.



Recertification

Lessons Learned and Helpful Hints (Continued)

- Be prepared to have your 340B ID available when calling for technical assistance.
- Pharmacies are not authorized to have their own unique 340B ID.
- A CE will not be able to view changes in 340B OPAIS until HRSA OPA has signed off on the CE's certification.
- Failure to perform recertification by the established deadline will result in removal from the 340B Program.



Recertification

Lessons Learned and Helpful Hints (Continued)

- CEs that wait until the last days of recertification period may experience delays in technical assistance.
- Once a CE certifies all of its sites, the CE loses the ability to adjust its record unless the record is returned by OPA for correction.
- If the PC performs a recertification task, the AO must attest to the task before it is sent to HRSA OPA.
- HRSA OPA will only receive recertification tasks once the AO attests to them.



Recertification

Lessons Learned and Helpful Hints (Continued)

- Once the recertification period has started, HRSA OPA will only accept change requests for a change to a CE's AO.
- If a CE determines a site requires termination, the CE must be prepared to provide the following information:
 - The date the termination was effective.
 - A brief description of the facts surrounding the reason for termination and how the effective date was determined.
 - The last day that 340B drugs were or will be purchased under the 340B ID.



Other Integrity Activities

- **Integrity checks completed during the registration process**
 - Contract pharmacy agreement
 - Signatures, dates, name and address of pharmacies
 - Pharmacy agreements signed prior to participation
- **Operational site visit questions**
 - Correct 340B ID
 - Correct HAB grant number
 - Have knowledgeable person to answer 340B questions
- **Loss of eligibility**
 - Become ineligible when grant is lost
 - Stop purchasing on the ineligible date
 - Do not wait until recertification to terminate
- **Termination request**
 - CE's responsibility
 - Complete all questions



Program Integrity

- **Guiding Principles:**

- Maximize oversight reach
- Manage compliance risks
 - Strategies:
 - CE and CP registration
 - CE annual recertification
 - CE evaluation and self-disclosure
 - HRSA recipient site-visits
 - HRSA 340B Drug Pricing Program audit



Audits of Covered Entities

Audits of Covered Entities

340B Drug Pricing Program covered entities must ensure program integrity and maintain accurate records documenting compliance with all 340B Program requirements.

HRSA has the authority to audit covered entities for compliance with 340B Drug Pricing Program (340B Program) requirements (42 USC 256b(a)(5)(C)):

Covered entities are subject to audit by the manufacturer or the federal government. Failure to comply may make the 340B covered entity liable to manufacturers for refunds of discounts or cause the covered entity to be removed from the 340B Program.

+ Audit Number, Duration & Scope

+ Audit Process

+ Audit Standards

Audits of Covered Entity Results

[FY 2018 Audit Results](#)
(updated 9/10/18)

[FY 2017 Audit Results](#)
(updated 9/10/18)

[FY 2016 Audit Results](#)
(updated 9/10/18)

[FY 2015 Audit Results](#)
(updated 9/10/18)

[FY 2014 Audit Results](#)
(updated 8/8/18)

[FY 2013 Audit Results](#)
(updated 5/30/18)

[FY 2012 Audit Results](#)
(updated 7/14/17)

<https://www.hrsa.gov/opa/program-integrity/index.html>



HRSA Audits by the Numbers

As of December 10, 2018

	FY12	FY13	FY14	FY15	FY16	FY17	FY18	FY19	TOTAL
Number of covered entities audited	51	94	99	200	200	200	200	51	1095
Outpatient facilities/sub grantees	410	718	1476	2720	4011	2046	3279	526	15186
Contract pharmacies	860	1937	4028	4443	3531	4052	3290	842	22983
Number of finalized reports	51	94	99	200	200	199	101	0	1005



Types of Audits

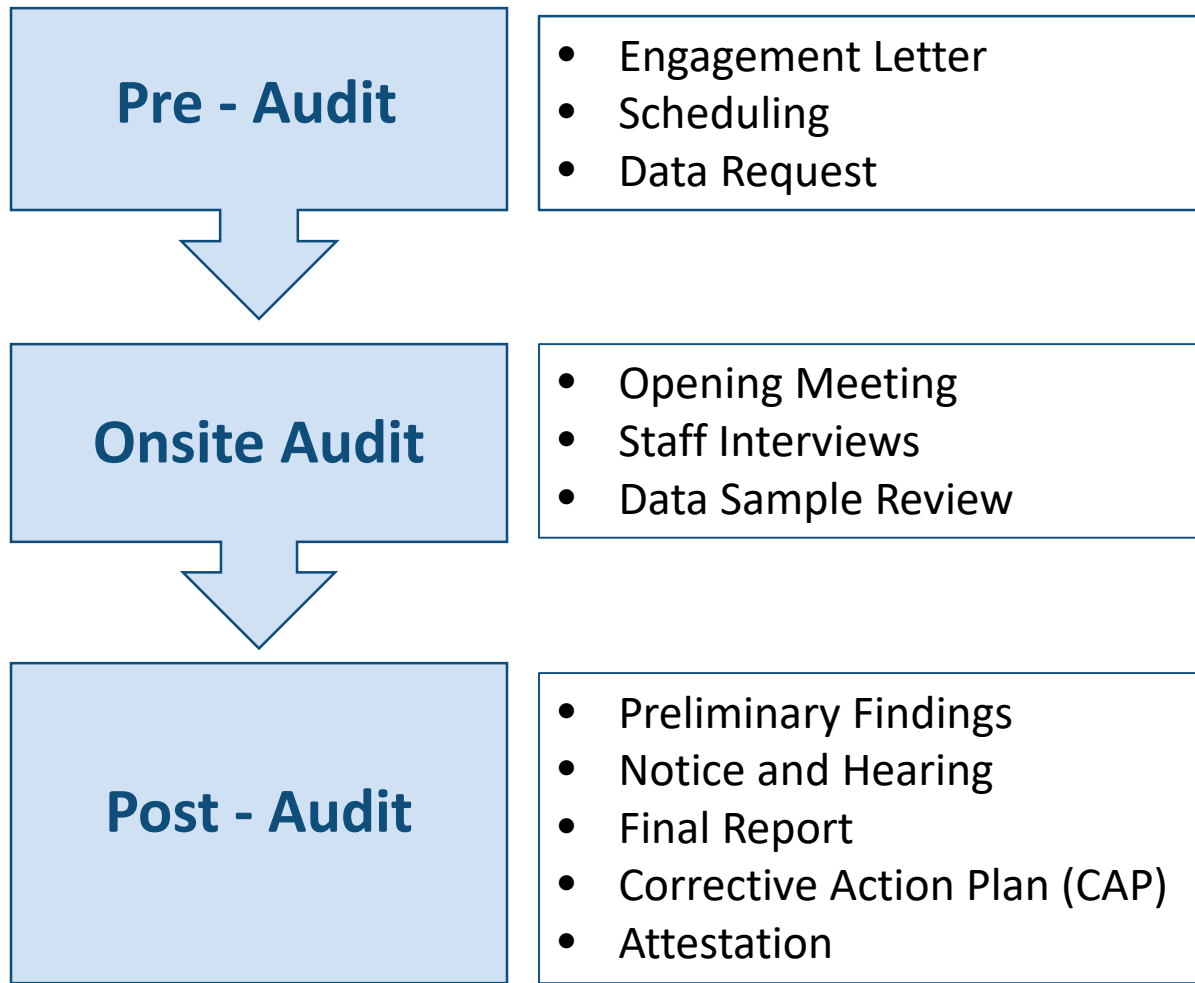
Risk Based

- Number of CE sites
- Number of CPs
- Complexity of program
- Volume of purchases

Target Based

- Reported non-compliance
- Follow up on CE's corrective action for a previous HRSA audit finding(s)

Audit Process



Areas of Audit Focus

- **Eligibility**
 - Keep 340B OPAIS information accurate and up to date
 - Maintain auditable records
 - Provide Contract pharmacy oversight
 - Comply with GPO prohibition*
- **Diversion**
 - Prevent diversion to ineligible patients
- **Duplicate**
- **Discounts**
 - Prevent duplicate discounts

** Only disproportionate share hospital (DSH), children's hospital (PED), and free-standing cancer hospital (CAN) types are subject to the Group Purchasing Organization (GPO) prohibition.*



Audit Trends Findings

- **Eligibility**
 - Incorrect 340B OPAIS record.
- **Diversions**
 - Prescriptions originating from ineligible sites.
- **Duplicate discounts**
 - Incorrect or incomplete Medicaid Exclusion File (MEF).



Audit Trends

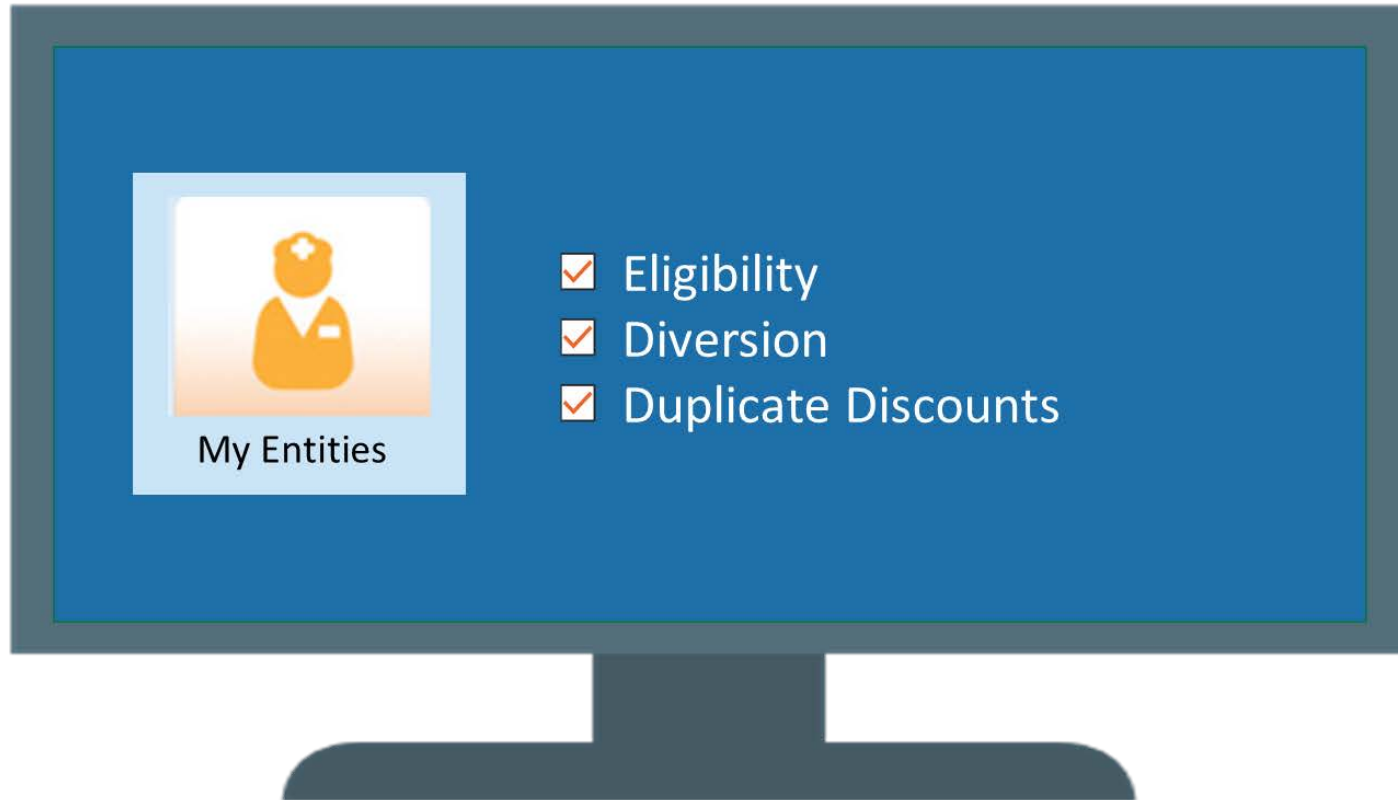
Area for Improvement (AFI)

- **Policies and procedures that address:**
 - Registration/recertification process
 - Accurate 340B OPAIS record
 - Procurement process
 - CP oversight
 - Eligibility of sites
 - Prevention of diversion (CE, CP)
 - Prevention of duplicate discounts (CE, CP)
 - Self-disclosure of non-compliance (CE, CP)

HRSA expects a CE's policies and procedures to reflect the CE's actual practice.



Areas of Audit Focus



Eligibility: Register Sites in 340B OPAIS

- Ryan White eligibility requirements are defined in statute.
- Section 340B(a)(4) of the Public Health Service Act.

(D) An entity receiving a grant under subpart II of part C of title XXVI (relating to categorical grants for outpatient early intervention services for HIV disease).

(E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under title XXVI.

(J) Any entity receiving assistance under title XXVI (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).

A CE must register all sites that purchase, dispense, administer or otherwise generate 340B eligible prescriptions.



Grant Number Format

Entity Type	Federal Grant Number Format	Note
Health Centers (CH)	H80CS-----	Site ID=BPS-H80-----
FQHCLA (LAL)	LALCS-----	Site ID=BPS-LAL-----
Hemophilia Treatment Centers (HTC)	H30MC-----	
Ryan White A (RWI)	H89HA-----	
Ryan White B (RWII), (RWIIR), (RWIID)	X07HA-----, X08HA-----, X09HA-----	
Ryan White C (HV)	H76HA-----	
Ryan White D (RW4)	H12HA-----	
Family Planning (FP)	FPHPA-----	
Tuberculosis Prevention Clinics (TB)	1U52PS-----	This is not the same as the funding opportunity number
Sexually Transmitted Disease Prevention Clinics (STD)	1H25PS-----	This is not the same as the funding opportunity number
Black Lung Clinics (BL)	H37RH-----	
Tribal Compacts/Contracts (FQHC638)	N/A	
Urban Indian (UI)	N/A	
Native Hawaiian (NH)	H1CCS-----	

Eligibility and Auditable Records

- Eligibility records (e.g., notice of grant award)
- Contract pharmacy records (e.g., CP contracts and records to demonstrate CP oversight)
- Purchase records
- Inventory records (physical inventory and virtual inventory)
- Patient health records
- Provider records
- Dispensation / administration records (e.g., orders in electronic health record and hard copy prescriptions)
- Billing records
- Policies and procedures (that reflect actual practices)



Eligibility and Contract Pharmacy Guidelines

- **HRSA contract pharmacy guidelines (75 Fed. Reg. 10272 (Mar. 5, 2010)):**
 - A CE must have a written contract in place between itself and a CP, specifying each location that will dispense 340B drugs.
 - A CE must provide oversight of each CP arrangement utilized.
 - A CE must ensure against diversion and duplicate discounts of CE's 340B drugs.

CPs must register for the 340B Program and be listed on the 340B OPAIS prior to dispensing 340B drugs on a CE's behalf.



Eligibility and Contract Pharmacy Contracts

- **Contract Pharmacy Service Contracts**
 - HRSA expects all CP locations to be identified by name and address.
 - The DEA information feeds OPAIS and the information in OPAIS should match that of the written contract.
 - HRSA expects all CE locations participating in the CP arrangement to be identified.
 - List each CE location name and address or include an inclusive statement.

Each RW 340B ID must register each CP it has an arrangement with.



Eligibility Case Study

Scenario

- Integrity Project Inc. has two grant associated sites registered in the 340B OPAIS:
 - Main Street Clinic, 1 Main Street, Big City, VA (340B ID: RWI123456)
 - Side Street Clinic, 1 Side Street, Big City, VA (340B ID: RWI12345A)
- Integrity Project Inc. has a contract pharmacy contract with Big City Pharmacy.
- The Big City Pharmacy is registered as a contract pharmacy to the Main Street Clinic 340B ID on the 340B OPAIS.
- The Main Street Clinic and the Side Street Clinic send prescriptions to the Big City Pharmacy that are deemed 340B eligible.



Eligibility Case Study

Questions to consider:

- Does the Big City contract pharmacy contract list the name and address of the Main Street Clinic and the Side Street Clinic?
- Does the Side Street Clinic have its own contract pharmacy contract with Big City Pharmacy?

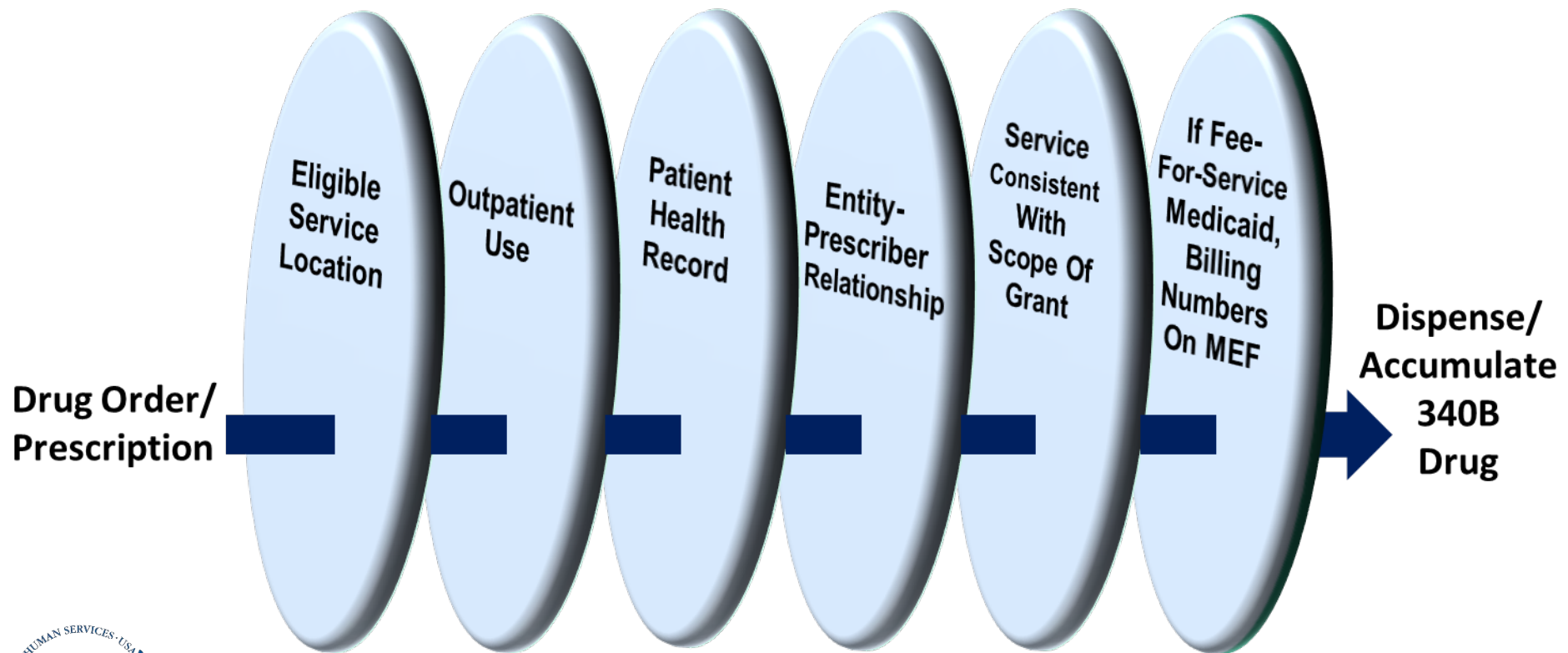
Diversion

- **Covered entities are prohibited by section 340B(a)(5)(B) of the PHSA from reselling or otherwise transferring a 340B drug to a person who is not a patient of the entity.**
- **Patient eligibility requirements are defined in guidelines (61 Fed. Reg. 55156 (Oct. 24, 1996)).**
 - CE has established a relationship with the individual, such that the CE maintains records of the individual's health care;
 - 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 CE;
 - the individual receives a health care service or range of services from the CE 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.
- **All sites that purchase and use 340B drugs for their eligible patients must be listed in the 340B OPAIS.**



Applying Patient Definition In Practice

(Excludes ADAP, scope of grant applies to recipients only and CEs carving out Medicaid must ensure 340B CODs are not provided to Medicaid patients)



Diversion: Improper Accumulation

- **If a CE uses a replenishment model, it must ensure that accumulation on the 340B account is tied to an exact 11-digit National Drug Code (NDC) match that was originally dispensed to a 340B-eligible patient to ensure 340B inventory is appropriately controlled and integrity of 340B purchases is maintained.**
 - A CE cannot dispense one COD to a patient and replenish with a different manufacturer's COD.
 - A CE's replenishment system must properly count the COD doses dispensed/administered to each 340B eligible patient to prevent over-accumulation and over purchase.
 - A covered entity must have auditable records to demonstrate proper accumulation in a replenishment model.



Diversion Case Study

Scenario:

- Integrity Project Inc. (340B ID: RWI123456) operates an entity-owned retail pharmacy.
 - The pharmacy has one 340B purchasing account and it was set up with the wholesaler using 340B ID: RWI123456.
- Integrity Project works closely with a small, short staffed and underfunded family planning clinic in the city.
 - The family planning clinic has its own grant and 340B ID.
 - The family planning clinic really appreciates that they can order intrauterine devices (IUDs) at the 340B price from the Integrity Project Pharmacy.



Diversion Case Study

Question to consider:

- Can Integrity Project Pharmacy use its 340B wholesaler account to purchase IUDs for the family planning clinic?

Duplicate Discounts

- **Duplicate discounts are prohibited by section 340B(a)(5)(A) of the PHSA.**
 - A drug purchase shall not be subject to both a discount under section 340B and a Medicaid rebate under section 1927 of the Social Security Act.
- **340B Drug Pricing Program Notice December 12, 2014.**
 - HRSA has created the Medicaid Exclusion File (MEF) as a mechanism for CEs to comply with the duplicate discount prohibition.
 - It is a CE's responsibility to ensure that it is appropriately listed on the HRSA MEF and follow any additional state Medicaid laws.

If a site (340B ID) will provide 340B CODs to its Medicaid patients, the 340B ID and its Medicaid billing numbers must be listed on the MEF.



Definition of a Duplicate Discount

A duplicate discount occurs when the same drug is:



Purchased with an
up-front
340B discount

AND



Credited with a
back-end
transaction
Medicaid rebate

- Covered entities are responsible for prevention of duplicate discount.
- A duplicate discount can occur when Medicaid is primary, secondary or tertiary payer.

The MEF is the Official Data Source

- The MEF is created from the 340B OPAIS quarterly.
- The 340B ID carves-out:
 - Will use non-340B drugs for its Medicaid patients and will not be listed on the MEF.
- The 340B ID carves-in:
 - Will use 340B drugs for its Medicaid patients and will be listed on the MEF.

The inclusion or exclusion of claims level data by a CE for drug charges or the Medicaid reimbursement received by the CE, does not relieve the CE of its obligation to ensure its information on the HRSA MEF is accurate.

Carve-Out Medicaid

Medicaid Billing

Will you bill Medicaid for drugs purchased at 340B prices?

Yes

No

If your entity bills Medicaid for drugs purchased at 340B prices that may be subject to a payment of a Medicaid rebate to a state, you must answer 'Yes' and submit to OPA the Medicaid Provider Number (MPN) and/or the National Provider Identifier (NPI) which is used to bill Medicaid for outpatient drugs. If you are unsure of your Medicaid Provider Number and/or NPI, please check with your State Medicaid agency. It is important that your Medicaid billing status is accurately reflected in the 340B database Medicaid Exclusion File to prevent Medicaid rebates on drugs that were purchased at 340B prices and to ensure that the state Medicaid Agency has accurate information for those drugs not purchased under the 340B Program. You must notify OPA prior to any change in your Medicaid billing status.

- The Medicaid billing question must be answered for each 340B ID in the 340B OPAIS.
- Answer “no” to the Medicaid billing question in the 340B OPAIS, 340B ID will NOT appear on the next quarterly MEF.

Carve- In Medicaid

Medicaid Billing

Will you bill Medicaid for drugs purchased at 340B prices? Yes No

If your entity bills Medicaid for drugs purchased at 340B prices that may be subject to a payment of a Medicaid rebate to a state, you must answer 'Yes' and submit to OPA the Medicaid Provider Number (MPN) and/or the National Provider Identifier (NPI) which is used to bill Medicaid for outpatient drugs. If you are unsure of your Medicaid Provider Number and/or NPI, please check with your State Medicaid agency. It is important that your Medicaid billing status is accurately reflected in the 340B database Medicaid Exclusion File to prevent Medicaid rebates on drugs that were purchased at 340B prices and to ensure that the state Medicaid Agency has accurate information for those drugs not purchased under the 340B Program. You must notify OPA prior to any change in your Medicaid billing status. Visit the [Medicaid Exclusion Tutorial](#) for more information.

Medicaid Number	State
No records to display.	
<input type="button" value="+ Add new record"/>	

NPI Number
No records to display.
<input type="button" value="+ Add new record"/>

- The Medicaid billing question must be answered for each 340B ID in the 340B OPAIS.
- Answer “yes” to the Medicaid billing question in the 340B OPAIS, add Medicaid number(s) and State(s) and NPI(s) used to bill Medicaid.
- 340B ID and billing number will appear on the next quarterly MEF.

340B OPAIS → MEF

A change to a 340B ID OPAIS record during this period ...



...is captured at this time...



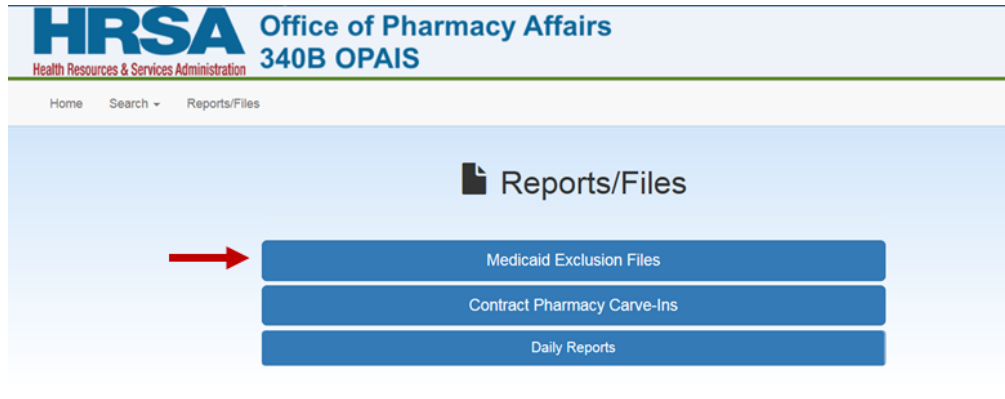
... and applies to this entire MEF period



Changes to 340B OPAIS Records	Snap Shot Of OPAIS Taken To Create The Next MEF	Quarterly MEF Period
September 16 th - December 15 th	12:01 a.m. December 16 th	January 1 st – March 31 st
December 16 th – March 15 th	12:01 a.m. March 16 th	April 1 st – June 30 th
March 16 th – June 15 th	12:01 a.m. June 16 th	July 1 st – September 30 th
June 16 th – September 15 th	12:01 a.m. September 16 th	October 1 st – December 31 st



Access and Download the MEF



The MEF excel spread sheet lists details for the 340B IDs that carve-in



Exported By: System
Exported On: Date

MEF Export

Program Code	340B ID	CE ID	Medicaid Number	Medicaid State	NPI Number	Entity Name	Entity SubDivision Name	Street Address	City	State	Zip	Start Date	Term Date
ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC
ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC
ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC	ABC

MedicaidExclusion_Date



Medicaid Managed Care: 340B Drug Pricing Program Notice December 12, 2014

All covered entities are expected to have written policies and procedures pertaining to the prevention of duplicate discounts and ensure their database listing is consistent with actual practice. Medicaid drug rebates were previously limited to MFSS drugs, section 2501(c) of the Patient Protection and Affordable Care Act (Public Law 111-148) amended the Social Security Act (SSA), extending Medicaid drug rebate eligibility to certain Medicaid managed care covered outpatient drugs, effective March 23, 2010. Section 2501(c) further amended the SSA to specify that covered outpatient drugs covered by a Medicaid Managed Care Organization (MCO) are not subject to a rebate if also subject to a discount under section 340B of the PHSA.

This policy release does not apply to the prevention of duplicate discounts that may occur under MCOs. HRSA recognizes the need to address covered entities' role in preventing duplicate discounts under Medicaid managed care, and is working with CMS to develop policy in this regard. We are aware that some covered entities have already worked with MCOs and state partners to develop models for the prevention of duplicate discounts. Some covered entities report using a variety of methods including, but not limited to, Bank Identification Numbers and/or Processor Control Numbers to identify patients of MCOs, National Council for Prescription Drug Programs (NCPDP) codes at the individual claim level for claims submitted through a point of sale (POS) system at a retail or clinic pharmacy (contract pharmacy), and UD Modifiers for physician administered claims or drug costs submitted as part of a bundled or capitated rate. In some cases, states may place certain requirements on covered entities regarding the prevention of duplicate discounts, HRSA encourages 340B covered entities to work with their state to develop strategies to prevent duplicate discounts on drugs reimbursed through MCO's.



Contract Pharmacy Carve-in Report

HRSA Office of Pharmacy Affairs
Health Resources & Services Administration 340B OPAIS

Home Search ▾ Reports/Files

Reports/Files

- Medicaid Exclusion Files
- Contract Pharmacy Carve-Ins**
- Daily Reports



Page: 1 of 256 Go Page size: 2 Change Item 1 to 2 of 512

<input type="checkbox"/>	Contract Detail	340B ID	Entity Name	Entity City	Entity State	Pharmacy Name	Pharmacy Address	Pharmacy City	Pharmacy State	Pharmacy Zip	Start Date	Term Date	Carve-In Effective Date
<input type="checkbox"/>	Contract Detail										04/01/2016		07/01/2016
<input type="checkbox"/>	Contract Detail										12/31/2012		04/01/2018

Page: 1 of 256 Go Page size: 2 Change Item 1 to 2 of 512



Duplicate Discount Case Study

Scenario:

- Integrity Project Inc. has two grant associated sites registered in the 340B OPAIS (340B IDs: RWI123456 and RWI12345A). In addition Integrity Project Inc. has an entity-owned retail pharmacy.
- Both sites administer 340B drugs to Medicaid patients during office visits.
- Both sites send prescriptions for Medicaid patients to the retail pharmacy and the retail pharmacy provides 340B drugs to eligible Medicaid patients.
- The billing numbers used and current MEF listing are as follows:

Site	Billing Number Used	MEF 10/01/18 – 12/31/18
RWI123456	NPI 1234567890 and MA 23456	NPI 1234567890
RWI12345A	NPI 9101112130 and MA 23456A	NPI 9101112130
Retail Pharmacy	NPI 1234567890	

Duplicate Discount Case Study

Questions to consider:

- Does each 340B ID list the billing numbers used on the MEF?
- Have duplicate discounts occurred?
 - What is the full scope of any potential duplicate discount violation?
- Does the State Medicaid agency have specific requirements for the prevention of duplicate discounts?
 - For drugs administered during outpatient visits?
 - For drugs dispensed from the retail pharmacy?

Service Location	Billing Number Used	MEF 10/01/18 – 12/31/18
RWI123456	NPI 1234567890 and MA 23456	NPI 1234567890
RWI12345A	NPI 9101112130 and MA 23456A	NPI 9101112130
Retail Pharmacy	NPI 1234567890	

Program Requirements: Best Practices

- Learn how to determine each site's eligibility to participate in the Program.
- Understand and map your 340B drug operations environment.
 - Identify the locations in which 340B drugs are provided within your CE and where and how 340B drugs are purchased.
 - Include all locations, in-house pharmacies and contract pharmacies.
 - Document inventory type, method and system used to track the purchase, dispensation and administration of drugs at each location.
 - Document Medicaid billing and NPI numbers used to bill 340B drugs and non-340B drugs to state Medicaid agencies at each location.
- Self-audit each drug operations environment for compliance with program requirements for eligibility, prevention of diversion and duplicate discounts.

For 340B tools and resources see:

<https://www.340bpvp.com/education/340b-tools/>



Questions ?



Questions

Contact the 340B Prime Vendor Program

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Email: ApexusAnswers@340bpvp.com

Web: <https://www.340bpvp.com/controller.html>



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