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Stay Audit-Ready: Unlocking the HRSA FY24 Data Request List

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MEET YOUR PRESENTERS



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Statement of Disclosure

Jennifer and Heidi have no conflicts of interest.

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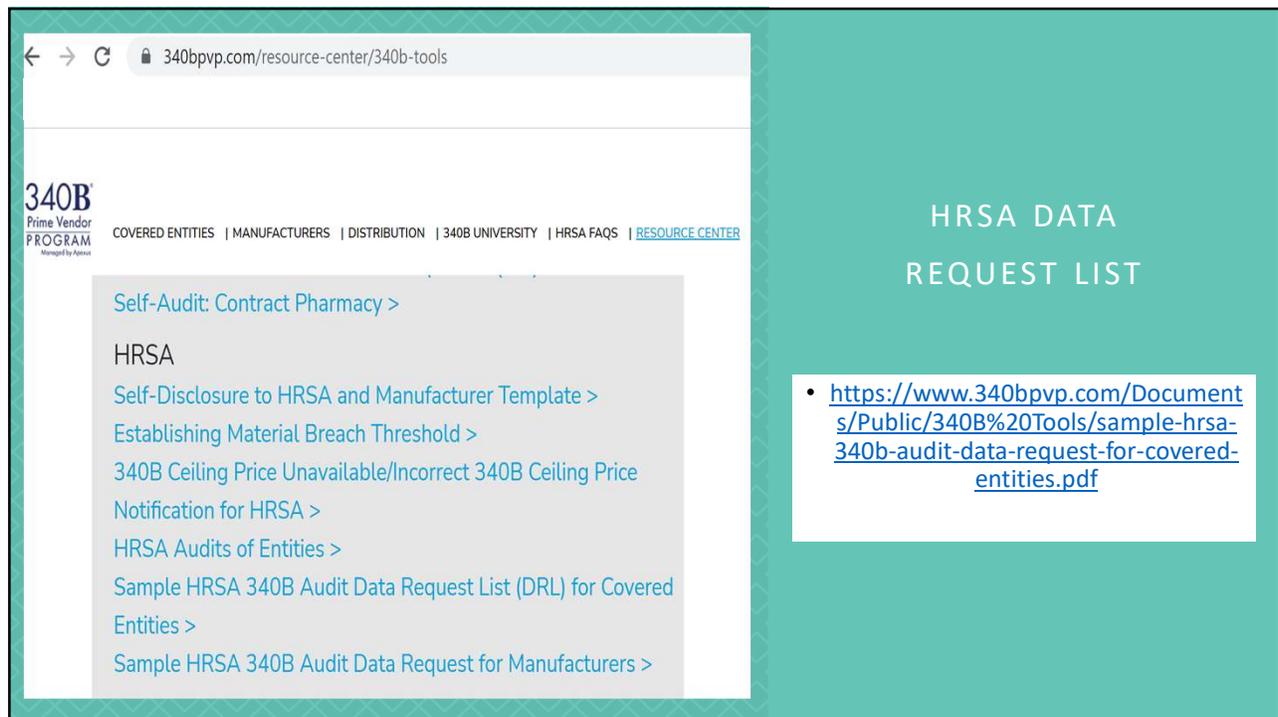
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AGENDA

- + Data Request Review
- + Data Preparation Techniques
- + Audit Readiness Tools



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Prime Vendor
PROGRAM
Managed by Agency

COVERED ENTITIES | MANUFACTURERS | DISTRIBUTION | 340B UNIVERSITY | HRSA FAQs | [RESOURCE CENTER](#)

[Self-Audit: Contract Pharmacy >](#)

HRSA

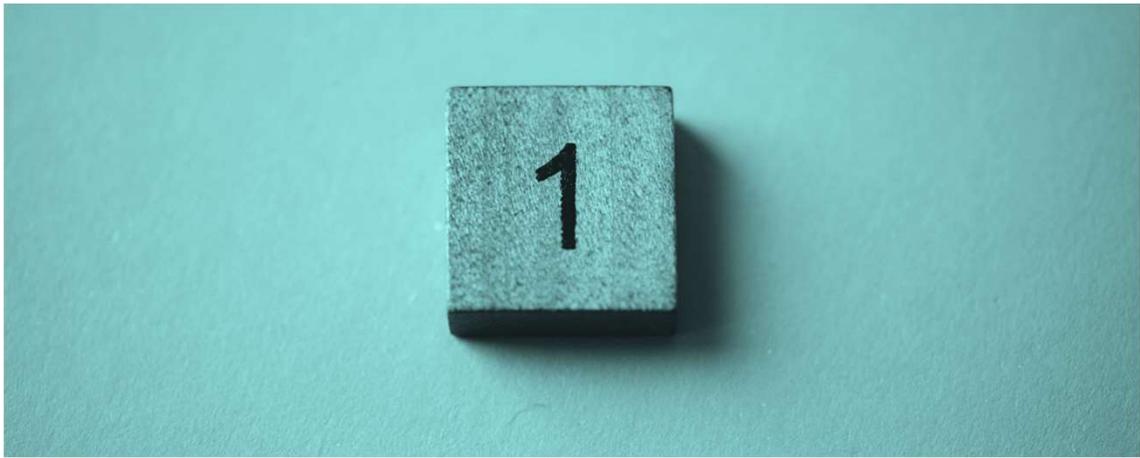
- [Self-Disclosure to HRSA and Manufacturer Template >](#)
- [Establishing Material Breach Threshold >](#)
- [340B Ceiling Price Unavailable/Incorrect 340B Ceiling Price Notification for HRSA >](#)
- [HRSA Audits of Entities >](#)
- [Sample HRSA 340B Audit Data Request List \(DRL\) for Covered Entities >](#)
- [Sample HRSA 340B Audit Data Request for Manufacturers >](#)

HRSA DATA
REQUEST LIST

- <https://www.340bpvp.com/Documents/Public/340B%20Tools/sample-hrsa-340b-audit-data-request-for-covered-entities.pdf>

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1. POLICY AND PROCEDURE



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1. POLICY AND PROCEDURE

Policy Elements

- Registration and Recertification
- Maintenance of OPAIS
- Compliance with registration
- Procurement, and exclusions to the definition of a covered outpatient drug
- Oversight-internal and external audits
- Prevention of Diversion
- Prevention of Duplicate Discounts
- Material Breach and Self Disclosure
- Eligible locations for special circumstances

New for FY24 (1st change):

- Prevention of Diversion and Duplicate Discount at ALL pharmacies

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POLICY SAMPLE

340B Program Policy and Procedure

Responsible Approving Party:	Signature(s):	Effective Date:
Executive/Authorizing Official Approval		Click or tap to enter a date.
Pharmacy/Primary Contact Approval		Click or tap to enter a date.
Review Dates		Click or tap to enter a date.

PURPOSE
This policy and procedure document is intended to ensure that [Covered Entity], which participates in the Health Resources and Services Administration (HRSA) 340B Drug Pricing Program (340B Program), remains compliant with all applicable 340B state and federal laws and regulations. As such, this policy and procedure should not be interpreted or implemented in a manner that would contradict any such law, furthermore, the purpose is to define a systematic approach to protect the integrity of and adherence to the rules and regulations of the HRSA 340B Program.

BACKGROUND
Section 340B of the Public Health Service Act (1962) requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign a pharmaceutical pricing agreement (PPA) with the Secretary of Health and Human Services. This agreement limits the price that manufacturers may charge certain covered entities for covered outpatient drugs. The 340B Program is administered by the Federal Health Resources and Services Administration in the Department of Health and Human Services (DHHS). Upon registration on the HRSA 340B Database/Office of Pharmacy Affairs Information System (OPAIS) as a participant in the 340B Program, 340B covered entities agree to abide by specific statutory requirements and prohibitions to access 340B drugs.

SCOPE
This policy and procedure document is applicable to [Covered Entity]'s participation in the 340B Program, which provides 340B covered outpatient drugs to its patients. This document includes guidelines for managing 340B drug purchasing and compliance at [Covered Entity].

DEFINITIONS
Actual Acquisition Cost (AAC)
Actual prices are paid to acquire marketed drugs, or drugs sold by specific manufacturers, as defined in the [Covered Outpatient Drug Rule](#).
340B Drug Pricing Program (340B Program)
The 340B Program resulted from the enactment of Public Law 102-585, Section 602 of the Veterans Health Care Act of 1992, which is codified as Section 340B of the Public Health Service Act. The 340B Program is managed by the HRSA Office of Pharmacy Affairs (OPA). Section 340B limits the cost of covered outpatient drugs to certain federal grantees, federally qualified health center look-alikes, and qualified hospitals. Participation in the 340B Program can result in significant savings on the cost of pharmaceuticals for safety-net providers. The purpose of the 340B Program is to enable these entities to stretch scarce federal resources, reaching more eligible patients, and providing more comprehensive services.
340B Eligible Location:

340B Referral Prescription

Responsible Approving Party:	Signature(s):	Effective Date:
Executive/Authorizing Official Approval		Click or tap to enter a date.
Pharmacy/Primary Contact Approval		Click or tap to enter a date.
Review Dates		Click or tap to enter a date.

Policy Statement
If an eligible patient's [Covered Entity] provider refers them to an outside provider, prescription(s) written by the outside provider will be considered eligible for fill with 340B purchased inventory at [Covered Entity] Pharmacy or eligible for claim capture and replenishment at a [Covered Entity] contract pharmacy with 340B purchased inventory as long as the [Covered Entity] will remain compliant with meeting 340B eligibility requirements related to 340B Referral Prescription.

Definition
Eligible patient
A patient of a covered entity that meets HRSA's definition of a patient. A 340B eligible patient may receive 340B purchased covered outpatient drugs while receiving care as an established patient within the covered entity's scope of services.
o HRSA's definition of a patient requires that (1) The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's healthcare; and (2) the individual receives healthcare services from a healthcare professional who is either employed by the covered entity or provides healthcare under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the health center.
o An individual is not considered a patient if the only service received from the covered entity is the dispensing of drug(s) for self-administration in the home setting.

Referral
Documentation entered by the patient's [Covered Entity] provider demonstrating a referral relationship between the patient, [Covered Entity], and the specialist.
o Referral order entered by the patient's [Covered Entity] provider to a specialist, specialist group or specialty.
o Subsequent referrals made by the specialist.
o Coordination of Care Referral: When a patient has either self-referred or has established care with a specialist prior to establishing care with [Covered Entity], an acknowledgment of specialty care by a [Covered Entity] provider may serve as an endorsement for any existing specialty care for 340B eligibility purposes.

Procedure
1. [Covered Entity] will determine if a prescription qualifies as 340B eligible by verifying the presence of supporting documentation within [Covered Entity]'s electronic health record

Drugs Not Considered Covered Outpatient Drugs For the Hospital/Clinic Administered Drug Universe

1. Vaccines
a. Reason
o Section 1027(k) defines covered outpatient drugs as "... those drugs which are treated as prescribed drugs for purposes of section 1025(a)(2), a drug which may be dispensed only upon prescription (except as provided in paragraph (3)), and—" a biological product, other than a vaccine which—"
o Vaccines are regulated by the FDA as "Vaccines, Blood, and Biologics"—not drugs.

2. No Pharmaceutical Pricing Agreement
a. Reason: Drugs where the manufacturer has not signed a pharmaceutical pricing agreement (PPA) for the specific labeler code for the drug, are by definition not covered outpatient drugs.

3. Medical Devices

4. Biologics
a. Commonly bundled outpatient drugs considered non-covered outpatient drugs:
o Plain IV fluids or diluents (Entity needs to define volume excluded and IV with or without electrolytes)
o Injection solutions
o Normal saline or heparin flushes based on FDA's jurisdictional update referencing section 503(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353(g))
o Contrast media (Entity needs to define the specific type of contrast being excluded (e.g., IV dyes and radiopaque films), but not radiopharmaceuticals (e.g., Xelpro, Lutathera, Avuma, Rhovone, Plavix), Bupropion, pharmacological stress agents (e.g., Lexicon and echocardiography agents (e.g., Definity, billed separately)).
o Anesthesia gases
o Diastolic solutions
o Drugs contained in procedural kits

b. Reason: **[REDACTED]** (regards the definition of covered outpatient drug referenced in the 340B Statute (Social Security Act 1027 (k)) and decides that bundled drugs do not meet this definition, a GPO may be used for drugs that are not covered outpatient drugs. This decision is consistently applied in all areas of the entity, documented in policy/procedures, and notices.
i. Social Security Act 1027(k)(3) Limiting definition—The term "covered outpatient drug" does not include any drug, biological product, or serum provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug):
ii. Inpatient hospital services.
iii. Hospice services.
iv. Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.
v. Physician services.
vi. Outpatient hospital services.
vii. Nursing facility services and services provided by an intermediate care facility for the mentally retarded.
viii. Other laboratory and x-ray services.
ix. Retail delays.
Such items also does not include any such drug or product for which a National Drug Code number is not

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2. Provide Covered Entity Eligibility Documentation



- A list of locations where health care services are provided
- The Medicare Cost Report
 - MCR used at the time of recertification
 - MCR most recently filed to the start of the sample period
 - MCR filed since the start of the sample period

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PROMPTLY UPDATE OPAIS QUALIFICATION INFORMATION

- Beginning April 2023
- Utilize a change request to update MCR information immediately upon filing a new or amended cost report.

Comments	Medicaid Billing	Qualification Info	Cost Center	CE Attachments	Shipping Addresses	Contract Pharmacies	Parent/Child	History
Entity is a Disproportionate Share Hospital defined by section 1886(d)(1)(D) of the Social Security Act, and this status is recognized by CMS								
Disproportionate Share Adjustment Percentage			42.66					
Control Type per HCRIS (Worksheet S-2, Line 21)			9 - Governmental, County			Cost Reporting Period		1/1/2022 12/31/2022
Hospital Classification			Public or Private Non-Profit Hospital Granted Governmental Powers			Filing Date		5/31/2023
Has the provider changed ownership during or since the end of the above cost reporting period?			No					

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2.C TRIAL BALANCE CROSSWALK: NEW-PROVIDE THE UNBUNDLED TRIAL BALANCE

BEGAN IN FY21 - ITEM G. ADDED IN FY22

- A. The 340B ID
- B. Name of each offsite outpatient facility as identified on OPAIS
- C. Address of the off-site outpatient facility
- D. Worksheets A & C: Line Number and Cost Center Description
- E. Trial balance name and department code/account (cost center)
- F. The location code or shorthand used to identify the site in the electronic health record (EHR)
- G. Indicate if 340B drugs are utilized during encounters at the site

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(2.D-F) HOSPITAL ELIGIBILITY DOCUMENTATION:

- **2.E. Hospital Types 1 & 2 Requiring Contract with State or Local Government**
 - As of FY22 must highlight the following in the contract:
 - Provision whereby indigent care provided by Hospital
 - Name of Hospital and Government Agency
 - Signatures of Hospital and Government Agency
 - Effective Dates of the Contract

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(2.D-F) HOSPITAL ELIGIBILITY DOCUMENTATION CONT:

- **All hospitals must prove non-profit status.**
 - Auditors will request the entire IRS Form 990 as it is the preferred document to demonstrate non-profit status.

3. PROVIDE A 340B UNIVERSE FOR SAMPLE PERIOD



3. 340B PROGRAM NARRATIVE

- 3.A: **Not New** - Include a narrative describing the methodology and system or software used to gather the data: noting any limitations, exclusions, and inclusions (e.g., reversals, direct purchases, etc.)

Universe	Methodology/System /Software	Report Name(s)	Notes
Mixed Use	Mixed Use TPA		Includes Reversals and direct purchases, explain limitations, or any exclusions
Child Site	EHR or TPA		
In-House Rx	TPA		
Contract Rx	TPA		

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3.B. COLUMN HEADER CROSSWALK

Universe	TPA	Report Name	Required Element	Header Field Name	Header Description	Note
Mixed			Drug			
Mixed			NDC			
Mixed			Acquisition Price			
Mixed			Type of account and associated 340B ID			Not included in data
Mixed			Quantity			
Mixed			Patient ID (Medical Record number)			
Mixed			Payer to tertiary			
Mixed			Date of Drug Order			
Mixed			Ordering Provider			
Mixed			Location ordered			
Mixed			Date of administration or			
Clean			Drug			

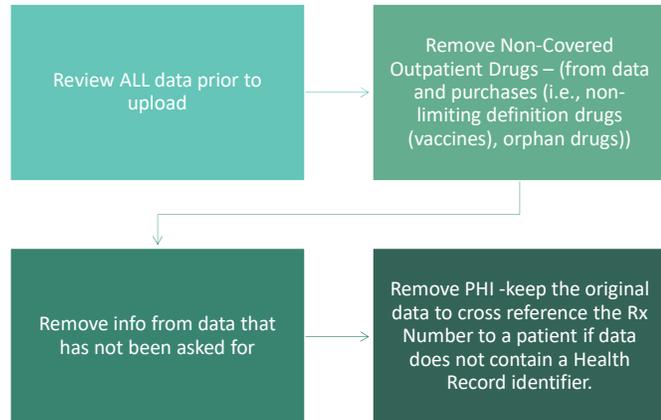
Provider Administered
 In-House Pharmacy
 Contract Pharmacy
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3C. SAMPLE TIPS



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4. PROVIDER LIST

Include Name and NPI

Indicate if employed or contracted

Start and Term dates of employment/contract

Instance of auditor giving CE 24 hours for this info to be included on provider list.

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5. PURCHASING DOCUMENTATION – CREATE CROSSWALK OF ACCOUNTS TO INVOICES

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Crosswalk Goal:
List all 340B, GPO, WAC, and CSOS accounts by name for each universe.

Include column for:

- Wholesaler name
- Account number
- Account name
- Location name
- 340B ID
- Account Type

Include:

- Dispense location
- Receiving (ship to)
- Bill to

(to assist in OPAIS address verification)

Provide an Invoice example for each account

Embed, link, or list corresponding file name.

Ensure the invoice contains an appropriate covered outpatient drug.

Update on a rolling 6-month basis to be in HRSA audit ready state

Wholesaler Name	Account Number	Account Name	Location Name	Receiving Location	Dispensing Location	Account Type	340B ID	Billing Address	Invoice Name	Notes
Add Supplier	1234556	HSP MAIN PHS	Inpatient Pharmacy	123 HOSPITAL ST, CITY, AL 123456	123 HOSPITAL ST, CITY, AL 123456	340B	DSH123456	123 HOSPITAL ST, CITY, AL 123456	5.B. HRSA ID Invoice 7805XXX	

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6.A.B. CONTRACT PHARMACY DOCUMENTATION

CREATE CONTRACT PHARMACY CROSSWALK

RUN AN OPAIS EXTRACT OF ALL CONTRACT PHARMACIES

Minimize Columns to: 340B ID, Pharmacy Name, Address, Contract Approval Date

Add columns: TPA, Utilized/Not Utilized, Originating Contract File Name, Notes

Key Take Aways:
Update on a rolling 6-month basis to remain audit ready

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CONTRACT PHARMACY CROSSWALK EXAMPLE

340B ID	Pharmacy Name	Address	Contract Approval Date	TPA	Active	Contract Name	Notes
HRSA ID	Uptown Drug Store	N Bus hwy	date from extract	Macro	Utilized	List contract file name when first registered or embedd copy	
HRSA ID	Downtown Drug Store	E Hickory	date from extract	Macro	Utilized	List contract file name when first registered	
HRSA ID	Walgreens #0XYZ	S BLVD	date from extract	Walgreens	Utilized	List contract file name when first registered	
HRSA ID	PHY	S Jefferson	date from extract	ScriptPro	Utilized	List contract file name when first registered	
HRSA ID	Walmart 001	Grand Ave	date from extract	Macro	Utilized	List contract file name when first registered	
HRSA ID	Walmart 005	Range RD	date from extract	Macro	Not Utilized	List contract file name when first registered, if not list term date or NA	Central fill

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6B. CONTRACT PHARMACY SERVICE AGREEMENTS CONT.

- Added in FY21
- **Highlight** the following required elements in the contract prior to upload:
 - Signatures including dates of both parties executing the contract
 - Name and address for each contract pharmacy location participating in the contract pharmacy arrangement
 - Each CE location by name and address or a general statement that inclusively identifies the parent and all CE location(s) participating in the contract pharmacy agreement (a.k.a., child site language)

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6.C-D. CONTRACT PHARMACY DOCUMENTATION



6.C. Provide last Independent Audit of Contract Pharmacies



6.D. Provide supporting documentation of internal contract pharmacy audits during start of sample period through date of audit.

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6. CONTRACT PHARMACIES &
7. IN-HOUSE PHARMACIES
(3RD CHANGE FOR FY24)

Provide a list of all
Medicaid fee-for-
service BIN and PCN
numbers that are
carved-out

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8. SELF-DISCLOSURE DOCUMENTATION



Provide any self-disclosures made to OPA since start of sample period through date of audit



In Q1 FY23 at least two instances of auditor requesting attestation of no self-disclosure.

9. MEDICAID DOCUMENTATION – 5TH AREA OF CHANGE

For Each 340B ID AND Pharmacy that Carves-In

Medicaid Crosswalk

Provide one FFS Medicaid Claim and screen shot of retail billing (if applicable)

For each state carved in, for each 340B ID, list the NPIs and MPNs, and state requirements to prevent duplicate discount

340B ID/ Pharmacy	State	State Requirements	NPI(s)	State assigned Medicaid number(s)	Medicaid FFS Claim Form
CAH12345-00	MN	UD	123456	XYZ	[Embedded document]
CAH12345-01	MN	UD	123456	XYZ	[Embedded document]
In-House Rx	MN	SCC 20	123456, 123457	XYZ	[Embedded document]

REVIEW KEY TOOLS
[HTTPS://WWW.SPENDMEND.COM/RESOURCES/](https://www.spendmend.com/resources/)

- 340B Program Narrative, with data methodology table
- Column header crosswalk
- Location/Trial Balance Crosswalk
- Purchasing Crosswalk
- Contract Pharmacy Crosswalk
- Entity Owned Pharmacy Listing
- Medicaid Crosswalk




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Q&A

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