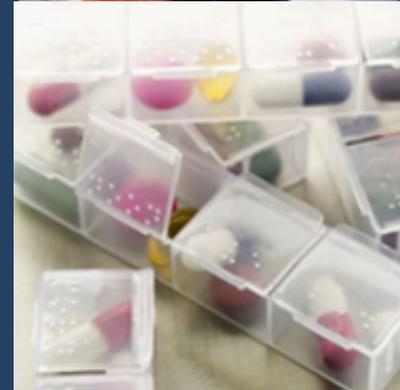


**Becoming Audit Ready:
Understanding HRSA Requirements and
Lessons Learned to Prepare Your Entity**

**14th Annual Health Care Symposium
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340B Overview and Compliance

1



Provide brief overview
of program
requirements

2

Review how Patient
Definition applies to
CHCs

Data and Reporting
Suggestions to become
Audit Ready

broadcast

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340B Program Overview

Program Overview and Requirements

HRSA Intent of 340B Program

To permit covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

Statutory Requirements

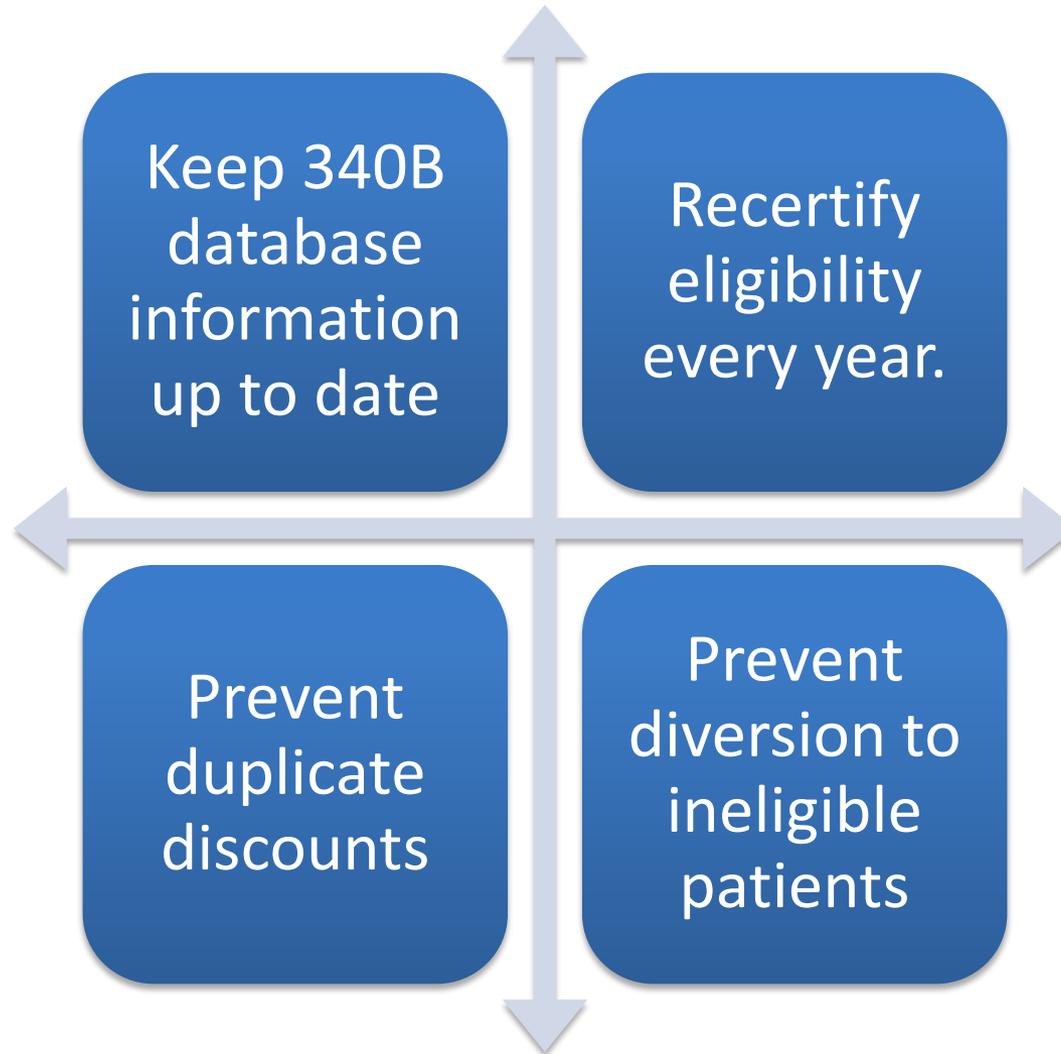
1. Duplicate Discount Prohibition (Medicaid)

1. No Diversion (Patient Definition)

1. Hospitals Only

- Group Purchasing Organization (GPO) Prohibition
- Orphan Drug Exclusion

Participation Requirements



Expected to conduct annual external audits of contract pharmacies

Reflect

I have the most questions about:

- A. Specific questions about patient definition of 340B guidelines?

- A. What kind of record keeping and reporting requirements are part of 340B compliance?

- A. What are the auditors looking for when they audit a 340B entity?

340B Patient Definition

The Entity must:

1. Establish a health care relationship
2. Maintain records of health care
3. Provide services by a health care professional
Who is employed or under contractual arrangements
4. *So that the entity maintains responsibility for care*
5. Provides health care consistent with grant funding
6. Services must be more than dispensing

Established Relationship

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

Services must be more than dispensing

What activities/services may not qualify as a medical service?

Patient
Education

Case
Management

Diabetes
Training

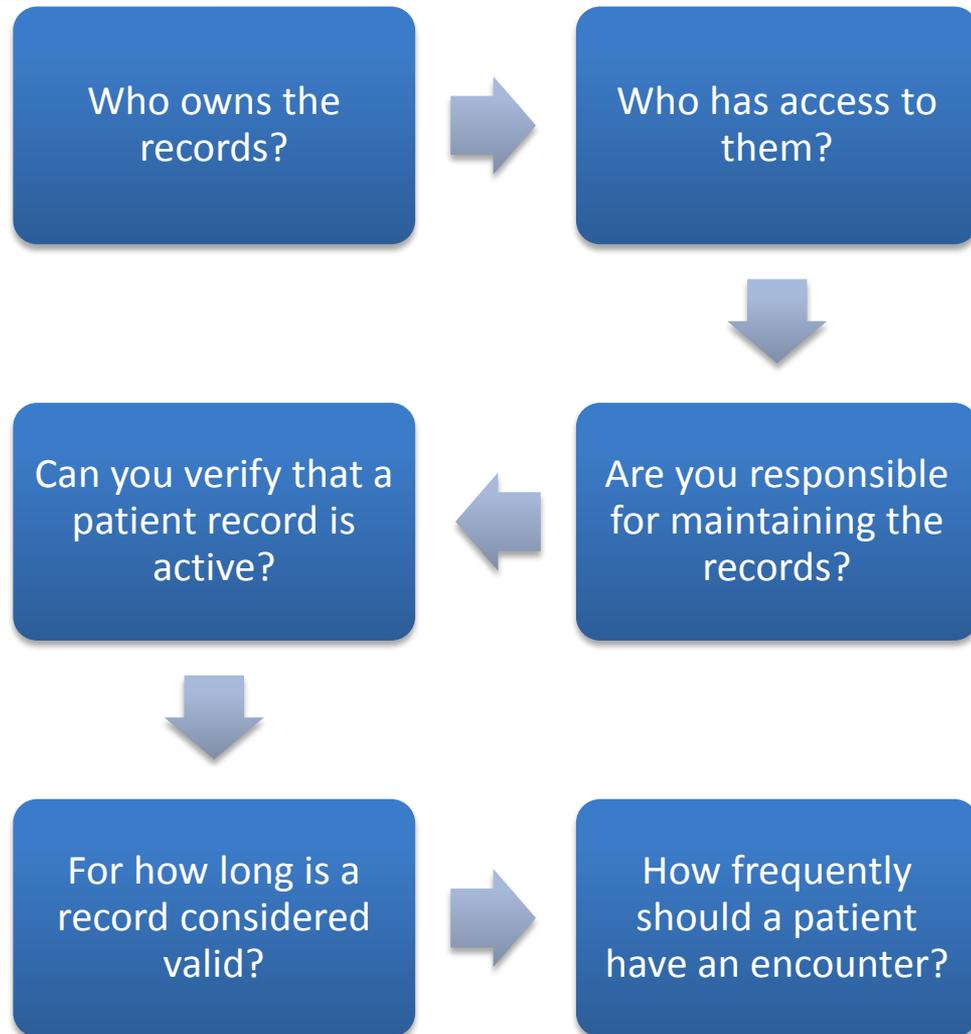
Medication
Management

Social
Services

Community
Referrals

Records of Care

The covered entity
... maintains
records of the
individual's
health care;



Provider Relationship

Health care services from a 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;

How can you document provider employment?

Does provider provide services on behalf of CHC (contractor)?

What if a provider has more than one office?

Is a result of a referral to an outside provider?

Does CHC have responsibility for care provided?

HRSA Referral Policy

Q: If we refer a patient to an outside clinic, can we fill their prescriptions from our 340B clinic?

A covered entity may send a patient to an outside clinic not registered with 340B and consider that patient 340B eligible only if the 340B patient receives health care 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 (61 Fed. Reg. 55156 (October 24, 1996)). If the covered entity can document that it retained responsibility for the health care services provided to the patient, then that individual may be eligible to receive 340B drugs from the covered entity.

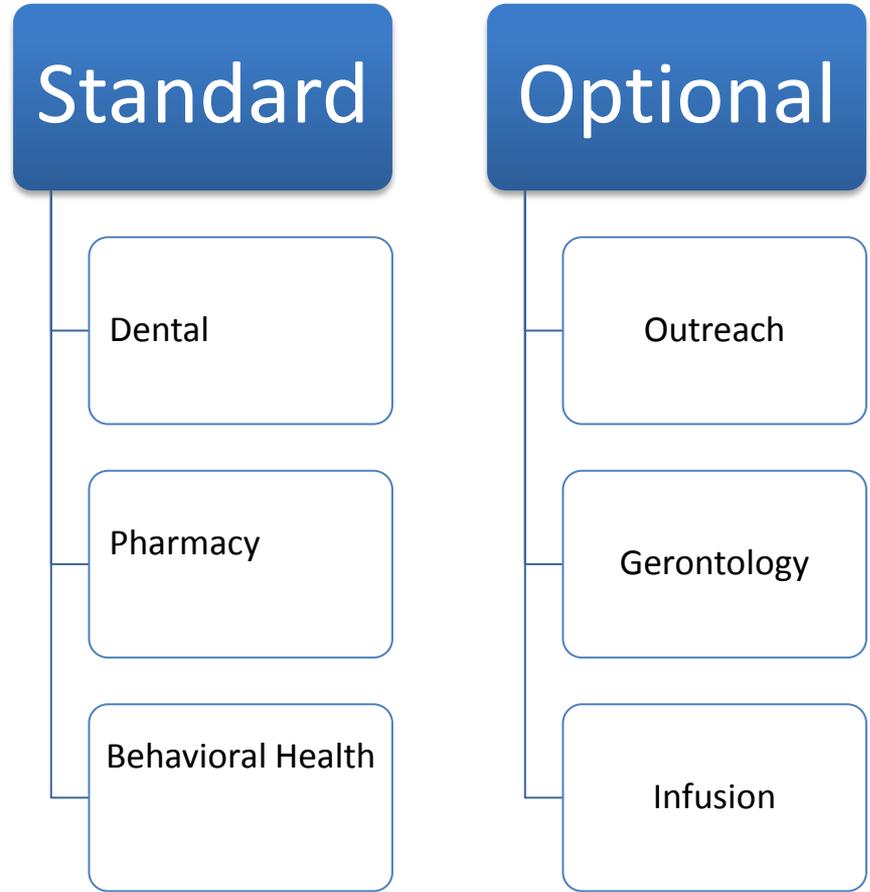
Q: What would be an example of an auditable record for a 340B prescription resulting from a referral?

The 340B entity should maintain documentation in the entity's record of health care that justifies the 340B entity had responsibility for the health care resulting in the 340B referral prescription. The entity should be able to produce documentation of the **both the request for referral, as well as a summary of the referral visit**, is accessible in the patient's medical record.

Scope of Grant Requirements

Scope of Grant Requirements

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...



340B Program Compliance

Data and Reporting Suggestions
to become Audit Ready

Data and Reporting

Data and Reporting Questions to become Audit Ready

1. How would your organization prepare for an upcoming audit in terms of Process, Records, and Policies & Procedures?
2. What areas of your practice should be reviewed or updated in preparation of a potential audit?
1. Is your organization prepared for the 340B supplemental questions in your upcoming Operational Site Visit? (OSV)

Know your data: Focus on Patient Definition

Compliance Questions:	Data Elements to review:
Are all your facilities registered on the EHB also in the HRSA (OPA) database?	Review HRSA database regularly for up-to-date info.
Do you have clear ways to identify eligible patients?	Compare patient name/DOB to EMR records to prescriptions/dispensations.
Are any prescriptions filled for provider outside entity?	Are the outgoing referral and specialist notes accessible in patient record for referral prescriptions?
Do you perform a regular review of prescription data?	Weekly, monthly reviews; annual external audit for CP.
Can you describe and locate data sources and process used to verify compliance?	Review eligible locations, Patient identifier, NPI, Referral documents
Do your billing records reflect the correct NDCs being billed and replenished?	Review NDCs purchased, dispensed and replenished.

Know your data:

Focus on Duplicate Discounts

Compliance Questions:	Policy Requirements:	Data Elements to review:
Do you use 340B drugs for Medicaid; how are you listed on database?	Review your entity's listing in the HRSA database.	HRSA Database listing
What are your state rules for billing Medicaid FFS (MediCal)?	Previously AAC + \$7.75 required for all In-house - legal challenge.	Pharmacy billing systems for 340B cost + \$7.75
What are state rules for billing Medicaid Managed Care?	Defer to MCO or COH for direction on how to identify 340B claims. May bill via contract pharmacy.	Usually add NCPDP ID of 08, or 20 in each 340B claim
Do you bill Medicaid from a contract pharmacy?	HRSA requires an agreement with state and HRSA notification to bill via contract pharmacy.	Notification to HRSA with 340B ID, state citations/Communications, and contract pharmacy addresses.
What data do you review to make sure there is no duplicate discounts?	Review all Medicaid patients to make sure proper billing is followed.	Patient ID, payer source

Strategies for Covered Entity to Ensure Eligibility

Appoint staff to verify eligibility:

- Patient eligibility via Name, DOB, Record number
- Provider eligibility via NPI, name, and address

For referral:

- Develop systems so pharmacy can determine referral prescription prior to filling prescription.
- Flag referral prescriptions filled at pharmacy to ensure summary notes are received.
- Complete monthly documentation verification for referral prescriptions.

Review Medicaid patient prescriptions

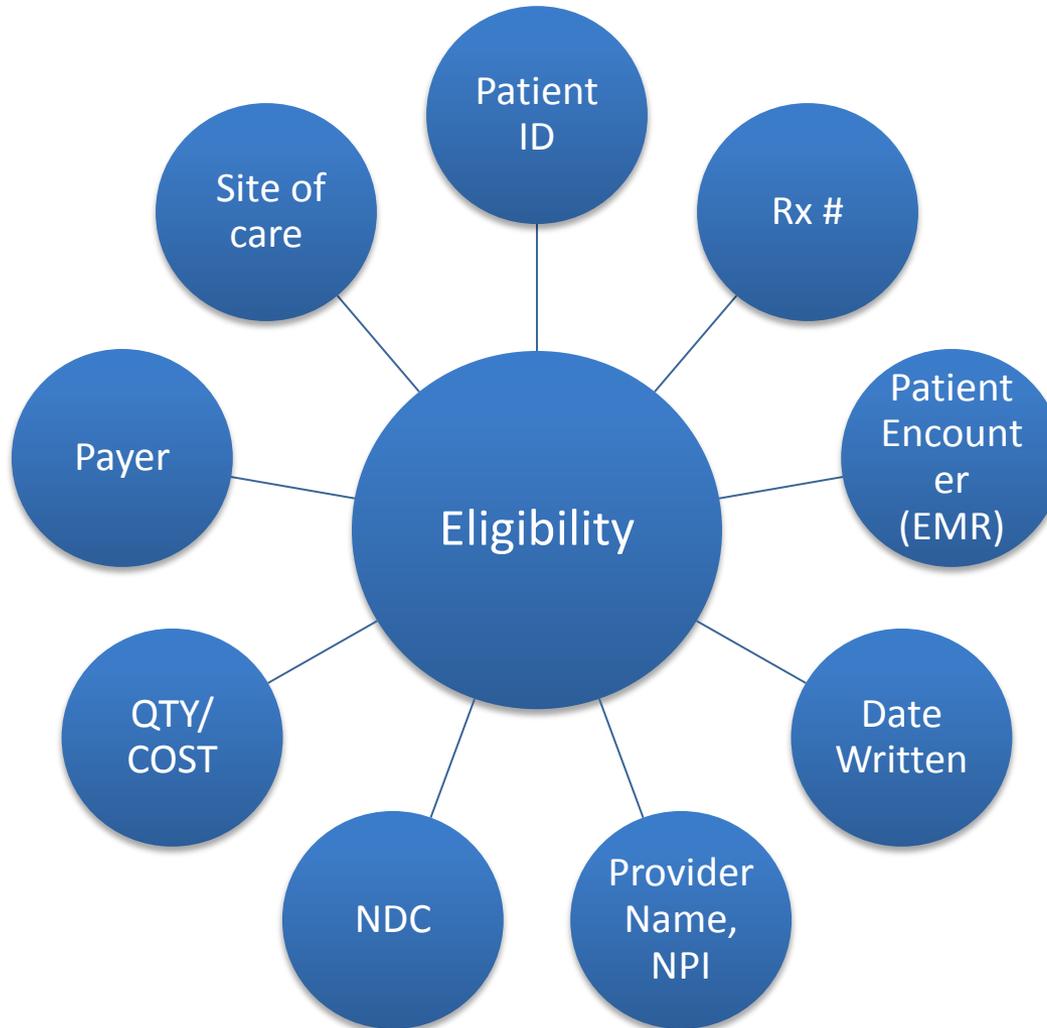
- Submit notification to HRSA
- Make sure you are following state/MCO billing requirements

Review purchasing records and replenishment.

Monthly Reporting

- Select as many claims as feasible for random sample to review monthly based on volume of pharmacy.
- Make sure claims from non-employed providers are included (higher likelihood of error).
- Identify any additional high risk areas that should be included (provider administered, referrals, uninsured patients, emergent care).
- Keep documentation of review for audits.

Data Elements to Review



Self Audit Check List

Patient Y/N	Encnter Date	NPI Y/N	Site Y/N	Referral& Notes Y/N	Medicaid	Rplnsh Y/N	Results OK/ Review
Patient Name /DOB/ ID match Rx	Date on or prior to Rx	IF No Then review referral criteria	All sites on OPA database	Outgoing referral AND incoming notes	Adjust based on Medicaid status	11 digit NDC replenishment	

Preparation for for an upcoming audit

Review OPA database listing and update if needed.

Conduct a Compliance Assessment/External Audit to determine areas for improvement.

Review reports of purchased, dispensed, administered 340B/Non-340B medications.

Develop and/or review Policy & Procedures.

Identify potential problem areas in your facility and address them.

Reach out to your Medicaid office to ensure proper billing.

Questions?

Discussion

Feedback



Apply Tools to your Entity

- Policies and Procedures
- Medicaid One-Page Summary

PVP Tools and Resources

- Contract Pharmacy Compliance
- Data and Transactions Tool
- FAQ search page

BPHC 340B Supplemental Questions for Operational Site Visits

On all OSV starting 10/2014

- The clinical consultant will ask the 340B questions and verify appropriate documents.
- Five Question Check List.
- 340B information is forwarded to HRSA/OPA.



OSV 340B Supplement

2. Does the entity have written 340B P&P, or other documents?

3 Do the policies address all 340B requirements: patient definition, duplicate discounts and scope of grant?

1. Does the entity participate in 340B ?

4. Does the health center dispense 340B drugs to patients through a contract pharmacy services model?

Does the entity attest that it provides oversight (e.g., annual audit or other mechanism) of the 340B drugs dispensed by the contract pharmacy?

OSV 340B Supplement

1. Does the entity participate in 340B ?



2. Does the entity have written 340B P&P, or other documents?

3. Do the policies address the following areas?

The health center has an **established relationship with the individual,**

Documented by the health center maintaining records of the **individual's health care?**

The individual receives health care services from a provider **who is employed or under contract or other arrangements (e.g., referral for consultation)** and maintains responsibility for care provided

340B prescriptions are only for patients that receive services provided directly by the health center **or via formal written referral arrangements** consistent with the scope of project?

The prevention of **Duplicate Discounts** under Medicaid?

4. Contract Pharmacy

Does the health center dispense 340B drugs to patients through a contract pharmacy services model? If so:

A written contract exists between the health center and contract pharmacy(ies)?

Does it have written policies and procedures, how the contract pharmacy will ensure against diversion?

Does it have how the contract pharmacy will ensure against duplicate discounts?

5. Oversight and Auditing

Does the health center attest that it provides oversight (e.g., annual audit or other mechanism) of the 340B drugs dispensed by the contract pharmacy?

Appendix I

HRSA Contract Pharmacy Requirements

Focus on Contract Pharmacy Requirements

- The CE **purchases and owns the drugs**. A “ship to, bill to” arrangement must be established.
- The agreement between the CE and contract pharmacy will specify the **responsibility of the parties** to provide comprehensive pharmacy services (e.g. dispensing, record keeping, formulary maintenance, clinical services, etc.)
- The CE will inform the patient of his or her **freedom to choose** a pharmacy provider.
- The contract pharmacy and the CE will **adhere to all Federal, state, and local laws and requirements**.
- The contract pharmacy will provide the CE **with reports consistent with customary business practices**.

HRSA Contract Pharmacy Requirements cont.

Focus on Contract Pharmacy Requirements

- The CE and contract pharmacy will **establish and maintain a tracking system** suitable to prevent diversion of 340B drugs.
- The CE and contract pharmacy will develop a **system to verify patient eligibility**, as defined by HRSA guidelines. Drugs purchased at 340B prices will only be sold to eligible patients of the CE.
- 340B drugs will **not be subject to duplicate discounts**.
- Pertinent documentation will be compiled and made available for **periodic independent audits performed by the CE**.
- Records from both the CE and contract pharmacy that directly pertain to the entity's compliance with the drug resale or transfer prohibition and the prohibition against duplicate discounts are **subject to audits by outside parties**.
- Upon written request to the CE, a copy of the contract pharmacy service agreement will be provided to a participating 340B manufacturers Please view the guidelines found on this page: <http://www.hrsa.gov/opa/federalregister.htm>.