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"You are never wrong, if you do the right thing."

HRSA Audits:
Data Request List (DRL)

07/29/2026

Overview of Today's Discussion

- ✓ What is a Data Request List (DRL)?
- ✓ What Documents are included on a DRL?
- ✓ Key Areas for 340B Policies and Procedures (P&Ps)
- ✓ Covered Entity Hospital Eligibility Documentation
- ✓ Grantee Eligibility Documentation
- ✓ 340B Universe Narrative
- ✓ Provider List
- ✓ Purchasing Documentation
- ✓ Medicaid Billing Documentation
- ✓ Additional Documents
- ✓ Questions

What is a Data Request List (DRL)?

A Data Request List (DRL) is the formal list of documents, reports, policies, and data that the HRSA auditor requires a Covered Entity (CE) to submit as part of a 340B Program Audit.

Purpose: the DRL helps HRSA determine whether a CE is complying with 340B Program requirements, including:

- Prevention of drug diversion
- Prevention of duplicate discounts
- Maintenance of accurate 340B OPAIS records
- Eligibility of registered sites and contract pharmacies
- Proper procurement and inventory management controls
- Oversight and auditing of contract pharmacy arrangements

HRSA typically sends the DRL shortly after notifying the CE that it has been selected for audit, with a specified timeframe by which all data must be submitted.

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What Documents are Requested in a DRL?

1) Policies and Procedures (P&Ps)
2) Covered Entity Eligibility Documentation
3) 340B Universe Narrative
4) Provider List (including proof of employment/relationship with CE)
5) Purchasing Documentation
6) Contract Pharmacy Documentation
7) Documentation for any Non-Registered Location Receiving 340B Drugs
8) Self-Disclosure Documentation
9) Medicaid Billing Documentation
10) Combined Purchasing and Distribution Model (CPDM) Documentation
11) Documentation of the CEs Corrective Action Plan (CAP) from Previous HRSA Audit

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Key Areas for 340B Policies and Procedures

- ✓ CE Registration and Recertification Process
- ✓ Process for Updating 340B OPAIS Record
- ✓ Process for Determining Which Sites are Eligible
- ✓ Description of Procurement Process
- ✓ Prevention of GPO Prohibition Violations
- ✓ Definition for any Exclusions to the Definition of “Covered Outpatient Drug”
- ✓ CE Process for Conducting Oversight of its Contract Pharmacy(ies)
- ✓ 340B Inventory or Accumulation
- ✓ Prevention of Diversion (Mixed-Use and Contract Pharmacies)
- ✓ Prevention of Duplicate Discounts (Mixed-Use and Contract Pharmacies)

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Covered Entity Hospital Eligibility Documentation

- ✓ Listing of Locations where Patient Health Care is Provided
- ✓ Applicable Medicare Cost Report (MCR)
  - Including Encrypted Signature Stamp on Worksheet S
- ✓ Unbundled Trial Balance and Trial Balance Crosswalk
- ✓ Documentation Demonstrating the Hospital is Owned or Operated by State or Local Government
  - Law Creating the Hospital
  - Documentation from State or Local Government Clearly Demonstrating Ownership
  - Hospital Charter
  - By-Laws
  - IRS Documentation Describing the Hospital

Hospital Eligibility Documentation (cont.)

- ✓ Documentation Demonstrating the Hospital is Formally Granted Governmental Powers by a Unit of State or Local Government
  - Law Creating the Hospital
  - Documentation from State or Local Government Demonstrating Ownership
  - Hospital Charter
  - By-Laws
  - IRS Documentation Describing the Hospital
- ✓ Documentation of the Hospital's Private Non-Profit Status
  - 501(c)(3) Certification
  - IRS Form 990

Grantee Eligibility Documentation

- ✓ Listing of Locations where Grantee Provides Health Care Services to Persons for whom the Grantee Deems Itself Responsible for the Health Care Services Provided
- ✓ Tribal Contract / Compact with Indian Health Service
- ✓ Notice of Grant Award or Designation of Look-Alike Status
  - Form 5A
  - Form 5B

340B Universe Narrative

- ✓ Narrative Describing How the Data was Gathered, Including any Limitations, Exclusions, or Inclusions
- ✓ Report of all 340B Drugs Given to Patients from all Sites, Off-Site Facilities / Grant-Associated Sites, and Pharmacies (Entity-Owned and/or Contracted)
  - Drug Name
  - NDC
  - Acquisition Price
  - Drug Purchase Account Type
  - Quantity Issued
  - Patient ID Number
  - Payer
  - Date of Drug Order or Prescription Written
  - Ordering Provider
  - Location
  - Date of Service

Provider List

- ✓ First Name
- ✓ Last Name
- ✓ NPI
- ✓ Employment Status
  - “Exclusive” – provider employed by / prescribes for Covered Entity ONLY
  - “Non-Exclusive” – provider employed by / prescribers for multiple entities (i.e. “moonlights”)
- ✓ Employment Start Date
- ✓ Employment Termination Date (if applicable)

Purchasing Documentation

- ✓ Wholesaler Name
- ✓ Account Number
- ✓ Account Name
- ✓ Pricing Associated with Each Account (340B, GPO, WAC)
- ✓ 340B ID Associated with Account
- ✓ Name and Address of the Location Receiving Drugs from Wholesaler or Manufacturer (Ship-To Location)
- ✓ Description of Location Receiving Drug
- ✓ Is the Account Used in a Controlled Substance Ordering System (CSOS)?
- ✓ Does the Ship-To Location Furnish, Administer, or Dispense the Drugs Directly to Patients In Person or by Mail?
- ✓ If the Ship-To Location that Initially Received the Drugs from the Wholesaler or Manufacturer Redistributes those Drugs to Other Location(s) *[ex: Central Fill Location]*, what is the Name, Address, and 340B ID of the Location(s) to which the Drugs are Redistributed?
- ✓ Provide a Copy of One Wholesaler or Manufacturer Invoice from Each Account Identified
- ✓ Provide a Purchase Report for Specified Timeframe – may be able to utilize Apexus Prime Vendor Program platform to extract this information!

Note: for Non-Hospitals, purchasing documentation must include all Clinic Administered Drugs (CADs)

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Medicaid Billing Documentation

- ✓ Provide Medicaid Fee-For-Service (FFS) Billing Documentation for Each Covered Entity Site and Pharmacy that Carves In Medicaid

Example Table A:

340B ID	State	NPI(s)	State-Assigned Medicaid Number(s)	Medicaid Fee-for-Service Claim Form
123456	MA	1234567890	101112	[Embedded document]
123456	CT	1234567890		[Embedded document]
123456A	MA	1234567890	131415	[Embedded document]
123456A	CT	1234567890		[Embedded document]

Additional Documents (as Applicable)

Contract Pharmacy(ies)

- ✓ All PSAs for Contract Pharmacies Registered on OPAIS
- ✓ Statement from External Auditing Firm that Conducted the Last Mock-HRSA Audit

Self-Disclosure(s)

- ✓ Documentation Provided to the Office of Pharmacy Affairs (OPA)

Corrective Action Plan(s)

- ✓ Description of the Full Scope of Non-Compliance with all Supporting Documentation
- ✓ Letters to Affected Manufacturers and any Additional Correspondence
- ✓ Supporting Documentation of Continuous Monitoring (ex: Internal Audit Documentation)
- ✓ Copy of any Self-Disclosures made to the OPA from the Beginning of the Audit Sample Period through the Date of the On-Site/Remote Audit

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We’re Here to Help!

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