Wyoming Department of Health: Communicable Disease Unit (CDU)

340B, Retail, and EPT Medications Guidance

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Introduction

The Wyoming Department of Health (WDH) Communicable Disease Unit (CDU) oversees the use, distribution, and compliance of medications provided under the Unit's Tuberculosis (TB) and Sexually Transmitted Disease (STD) grant designations in the 340B Drug Pricing Program, as well as the unit's Retail and Expedited Partner Therapy (EPT) medications. This guidance outlines eligibility, enrollment, compliance procedures, audit requirements, and medication handling protocols.

Note: This guidance is subject to routine review and updates for compliance with HRSA and CDC regulations. All participating entities are responsible for adherence to current protocols.

Contact

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Definitions

- **340B Covered Entity:** A facility or program eligible to purchase drugs under the CDU's 340B designation and listed in the OPAIS database.
- **Outpatient Drugs include:** FDA-approved prescription drugs, certain OTC drugs prescribed by a provider, and some biological products (excluding vaccines).
- **Duplicate Discount:** This is a prohibited scenario in which a 340B discount and Medicaid rebate are received for the same drug.
- **Medicaid Carve-Out:** A covered entity's decision not to use 340B drugs for Medicaid patients to avoid duplicate discounts.
- **Medicaid Exclusion File:** A file maintained by HRSA to help prevent duplicate discounts by identifying providers who dispense 340B drugs to Medicaid patients.
- **National Drug Code (NDC): The** Federal Drug Administration's (FDA) NDC Directory contains information about finished drug products, unfinished drugs, and compounded drug products.
- **National Provider Identifier (NPI):** NPI Registry Public Search is a free directory of all active NPI records. Healthcare providers acquire their unique 10-digit NPIs to identify themselves in a standard way throughout their industry.
- **Office of Pharmacy Affairs (OPA):** OPA is the arm of the Health Resources and Services Administration (HRSA) that administers the 340B drug discount program.
- **OPAIS:** The Office of Pharmacy Affairs/Information System—HRSA's system for managing 340B registrations and compliance.
- **Prime Vendor Program (PVP):** Managed by Apexus, this program secures sub-ceiling prices and offers compliance tools.
- **Wholesaler:** A distributor of medications from manufacturers to entities, without relabeling or repackaging.

340B Program Overview

The CDU participates in the HRSA 340B Program, offering discounted medications for STDs, TB testing, and related services. CDU has been conferred the 340B designation by OPAIS under the following grants:

- CDC-RFA-PS19-190, Assistance Listing Number (ALN) 93.977.
- CDC-RFA-PS-25-0003, ALN 93.116.

CDU has completed registration in the 340B OPAIS database with 340B ID STD82002 and TB820021.

Additionally, covered entities approved by CDU receive 340B designations under CDU's Grantee ID(s). Current covered entities under the CDU's Grantee ID include Wyoming Public Health Nursing offices. Key responsibilities of covered entities include:

- Following OPAIS requirements.
- Maintaining patient, provider, and site eligibility documentation.
- Ensuring proper medication storage and reporting.
- Completing annual training and recertification.

The CDU's strategic use of the 340B Drug Pricing Program generates substantial cost savings for the WDH and its public health partners. These savings allow the program to:

- Increase access to critical medications and services for underserved populations.
- Support medication distribution, repackaging, and partner therapy programs at no cost to eligible sites.
- Fund reinvestments in program infrastructure, quality assurance, training, and staffing.

These cost savings are continuously monitored to ensure compliance with federal reinvestment guidance and maximize public health benefits across Wyoming.

CDU acknowledges its responsibility to contact OPA immediately in case of 340B ineligibility or material breach of HRSA 340B policies. If there is a breach of 340B requirements, CDU may be liable to the manufacturer of the covered outpatient drug that is the subject of the violation and, depending on the circumstances, may be subject to the payment of interest and/or removal from the list of eligible 340B entities.

340B Program and Medicaid

The CDU is a carve-out entity for Medicaid-insured clients and does not use 340B drugs for Medicaid patients to avoid duplicate discounts.

CDU directs covered entities not to bill Medicaid or other insurances for medications distributed by CDU under its 340B medication program. Any covered entity that may use 340B purchased medications on Medicaid-eligible patients is expected to inform CDU of this and provide documentation to reflect that activities were consistent with guidance information on the OPA website/Medicaid Exclusion File. CDU informs OPA immediately of any changes to its information on the OPA website/Medicaid Exclusion File.

CDU and all covered entities must ensure their information is current in the Medicaid Exclusion File. The Medicaid Exclusion File serves the following purposes:

- It prevents drug manufacturers from providing a 340B discount and a Medicaid rebate for the same drug.
- Is referenced by state Medicaid agencies to exclude claims from rebate requests to drug manufacturers.
- Requires entities to maintain current and accurate billing designations and promptly notify HRSA of any changes.

- Ensures contract partner entities that bill Medicaid for 340B medications reflect their billing practices in the Exclusion File.
- Helps manufacturers validate Medicaid rebate denial claims.

In the limited scope of operations currently used by CDU for its 340B STD and TB grantee combined purchasing and distribution of allowable medications, these items do not affect a Medicaid Exclusion file, as CDU purchases the drugs and does not bill for them. CDU will immediately notify HRSA of any changes in Medicaid billing status or participation. Covered entities are required to coordinate with the CDU to maintain their designation in this file, where applicable.

340B Program Eligibility Criteria

Site Eligibility

Sites must meet the following requirements to participate in the OPAIS 340B Program under CDU's STD and/or TB designations:

- Must be a public or nonprofit facility receiving support from CDU under a federally funded program (e.g., CDC STD or TB grant).
- The site must provide outpatient services consistent with 340B requirements.
- The site must be listed on the 340B OPAIS database under CDU's designation(s).
- Must complete CDU enrollment and recertification requirements, comply with storage, inventory, and record protocols, and undergo periodic audits as stated in this guidance.

Site Enrollment, Recertification, and Responsibilities

<u>Adding New Service Areas or Facilities</u>

Entities wishing to expand their 340B participation by adding new service areas or physical facilities must undergo a formal review and approval process with CDU. This includes:

- Submitting a written request to CDU outlining the new site's purpose, services offered, population served, and justification for inclusion under the 340B umbrella.
- Verifying that the proposed location meets HRSA's definition of an eligible outpatient facility and operates within the scope of the covered grant (e.g., STD-related services).
- Providing updated provider rosters, facility profiles, and a plan for staff training, medication storage, and compliance monitoring at the new location.
- Confirming whether the new site will appear in the HRSA OPAIS database and whether it will have its own Medicaid billing status.
- Participating in a CDU-led readiness review, including site-specific TA if applicable.

CDU reserves the right to deny or delay approval of expansion requests if the proposed site does not meet eligibility criteria. Additionally, requests may be denied if the requesting entity has

unresolved compliance issues or if CDU lacks the capacity or funding to manage additional 340B designations. All approved additions must be reflected in updated facility documentation and are subject to audit, like existing locations.

If a new site meets these criteria, the CDU 340B Coordinator completes the online registration process during the applicable registration window as follows:

- January 1-January 15 for an effective start date of April 1.
- April 1-April 15 for an effective start date of July 1.
- July 1- July 15 for an effective start date of October 1.
- October 1-October 15 for an effective start date of January 1.

Enrolled Sites

Covered entities must adhere to the following OPAIS and CDU requirements to participate in the OPAIS 340B Program under CDU's STD and/or TB designations:

- All staff involved in 340B processes at the clinic must complete the following trainings:
  - HRSA 340B University self-paced core curriculum. (https://340bpvp.com/education)
  - CDU orientation training for new program partners.
  - Annual refresher webinars hosted by CDU outlining current protocols, audit trends, and updated compliance guidance.
  - Site-specific training modules (e.g., EPT dispensing, inventory reconciliation) as assigned by CDU based on site designation.
- Designate a Primary Contact who is responsible for communication, documentation, and compliance coordination with CDU, including 340B OPAIS recertification.
- Maintain accurate OPAIS records and notify CDU within 30 days of any staffing, site, or procedural changes.

Recertification

Covered entities must recertify annually via OPAIS with CDU oversight to confirm continued eligibility and program participation using the following workflow:

- **Notification:** CDU notifies participating entities of the annual HRSA recertification. Notifications are emailed to the primary contact listed in OPAIS and include detailed instructions, HRSA deadlines, and support resources. If recertification has not been confirmed, reminders may also be sent at 15-day and 7-day intervals.
- **Review OPAIS Data:** The designated Primary Contact must log into the HRSA OPAIS portal to verify and update all information regarding:
  - Site address and contact information.
  - Covered entity details.
  - Provider listings and NPI numbers.

- **Certify in OPAIS:** Finalize the recertification by submitting the attestation in OPAIS within the HRSA-defined recertification period.
- **CDU Attestation of recertification in OPAIS:** CDU's 340B coordinator will serve as the authorizing official within the 340B OPAIS system for covered entities. Upon review of the initial certification submitted, the 340B coordinator will approve or deny recertification for the following year.
    - Reason for denial may include:
        - Failure to provide required documents.
        - Failure to correct findings discovered in an audit of a covered entity during the previous period of eligibility.
        - The covered entity asks not to be recertified.

Failure to adhere to these requirements or recertify by the annual HRSA deadline may result in removal from the 340B program. If this occurs, entities will be ineligible to receive or dispense 340B medications until recertification. CDU will identify and notify sites of the recertification deadline and provide support, but it is the entity's responsibility to ensure timely compliance.

Site Responsibilities

It is the responsibility of the covered entity to:

- Verify that the patient receiving 340B medication is eligible.
- Verify that the prescribing or dispensing provider is eligible and maintain readily available documentation that shows said provider to be eligible.
- Properly document medical care or services, and dispensing or administration of allowable drugs to ensure accurate and auditable records.
- If there is any question regarding the patient's eligibility, the covered medication will not be dispensed until patient eligibility has been clarified with the covered entity, clinic supervision, or appropriate CDU program staff.
- Complete the annual recertification process in the OPAIS database.

Provider Eligibility

Sites must adhere to the following OPAIS and CDU requirements to provide 340B medications under CDU's STD and/or TB designations:

- Providers must have a valid Wyoming health care license and appropriate privileges.
- Providers must be either employees of or contracted by the 340B covered entity.
- Providers prescribing or dispensing 340B medications must be documented in the entity's facility profile and submitted to CDU.
- Entities must verify and maintain documentation of all eligible providers via CDU 340B signature logs.

Patient Eligibility

- The individual must receive care from the covered entity and have health records maintained by the entity.
- The individual must be seen by a health care provider employed by or contracted with the covered entity.
- The services provided must align with those covered under the federal grant or designation that confers 340B eligibility (e.g., STD or TB grant).
- Patients are ineligible if the only service received is dispensing medication, with no clinical encounter.
- Medicaid-enrolled individuals cannot receive 340B medications.
- No billing is allowed for 340B medications provided by CDU.
- The current CDU medications instructions that correspond to the medication must be provided to the patient.

EPT Program Overview

Retail medications are provided for the partners of patients diagnosed with STDs. These are not 340B-funded medications but are supplied by CDU to approved sites. Key responsibilities of approved sites include:

- Following CDU requirements.
- Completing enrollment and training.
- Maintain patient and site eligibility documentation.
- Ensuring proper medication storage and reporting.

EPT Program Eligibility Criteria

Site Eligibility

- Sites must be local public health agencies, community health centers, or nonprofit safety-net providers that offer sexual health services.
- Sites must serve uninsured or underinsured individuals at risk of or diagnosed with STDs.
- Sites must have protocols for EPT implementation, storage, and documentation.
- Sites must agree not to bill patients or insurers for EPT medications.
- Sites must be able to document medication dispensing in alignment with CDU protocols and to return shipping materials for CDU-supplied medications.
- Sites must comply with the CDU-approved EPT medication usage and reporting responsibilities.

Site Enrollment and Recertification

- Entities must request EPT site designation from CDU.
- Entities must provide documentation that they offer STD testing or treatment services.
- All staff responsible for ordering, storing, dispensing, or documenting medications must complete CDU EPT-specific training.
- Staff must sign and submit the CDU Retail and EPT Compliance Log to CDU.

Provider Eligibility

- Providers must be licensed healthcare professionals authorized to prescribe or dispense medications under Wyoming law (e.g., MD, DO, NP, PA).
- Providers must complete CDU-approved EPT training.
- Providers must agree to follow Wyoming's standing orders or clinical protocols for EPT.
- EPT providers must retain documentation of the index patient's diagnosis and consent for partner notification/medication provision.
- Providers must comply with reporting requirements and support the site's adherence to CDU documentation standards.

Patient Eligibility

- The index patient (the diagnosed individual) must have a documented clinical visit at the EPT-eligible site and be under the care of a qualified provider.
- The provider must assess that the partner is unlikely or unable to seek timely medical evaluation and would benefit from presumptive treatment.
- For CDU Retail and EPT, insured individuals may receive medications, but priority is given to the uninsured.
- No billing is allowed for CDU provided Retail and EPT medications.
- The current CDU medications instructions that correspond to the medication must be provided to the patient.

340B and EPT Program Medication Access, Utilization, and Reporting

CDU Provided 340B and EPT Medications and Use

The following 340B and EPT medications are supplied through a central distribution model at no cost to covered entities. CDU 340B medication is distributed through an HRSA-approved distribution model.

- 340B STD: Bicillin*, Doxycycline, Ceftriaxone, Xylocaine, Azithromycin.
- Retail & EPT: Azithromycin, Doxycycline.

- Ceftriaxone, Xylocaine with prior approval.

Refer to the appendix to review medication quantity limits.

*Bicillin L-A (Penicillin G Benzathine) is a critical component of the CDU Prevention Program for the treatment of syphilis. It may also be provided, in limited cases, to non-340B patients for the treatment of syphilis when Bicillin access is otherwise unavailable. Clinics should exhaust all alternative procurement options and contact their CDU Area DIS or the CDU 340B Coordinator to request Bicillin in these instances.

Medication Procurement & Shipping

CDU does not directly dispense medications to patients or use a contract pharmacy. Instead, covered entities may order CDU-provided and 340B-approved medicines at no cost through CDU's centralized drop-ship model as detailed below:

1. CDU leverages its account with an HRSA-approved 340B wholesaler to purchase eligible medications cited in the CDC treatment guidelines in bulk quantities (e.g., 5 or 10 dose boxes).
2. Medications are shipped to CDU, per the HRSA-approved central distribution model.
3. All medication packing slips are maintained per current state prescription record requirements. These shall be available for inspection by the Board of Pharmacy and state auditors.
4. The Wyoming Department of Health partners with the Department of Health Financing to engage a licensed Medicaid pharmacist to support the safe and compliant distribution of 340B and EPT medications. This pharmacist:
    a. Receives and reconciles shipments received with orders, keeps records of shipments received, and provides those to CDU to match with order records.
    b. Repackages bulk medications (e.g., doxycycline and azithromycin) procured by CDU via the 340B wholesaler.
    c. Prepares medication kits for contract partner sites, including discrete pre-labeled doses and partner therapy packs as applicable. Each kit is labeled with the appropriate NDC, lot number, and expiration date and includes CDU-provided patient and partner instructions.
    d. Supports quality assurance by ensuring that packaging, labeling, and tracking comply with HRSA standards and state regulations. The pharmacist also collaborates with CDU staff to ensure proper documentation, including medication logs, is maintained throughout the chain of custody. This includes preparing inventory summaries for audits and assisting with reconciling orders, shipments, and usage records.
5. Covered entities order medications through CDU's current 340B and EPT inventory platform, which ships repackaged medications to contract partner covered entities per the

HRSA-approved central distribution model. Contract partner entities reconcile shipments received with orders and notify CDU of discrepancies.

6. When the medication is shipped, a shipping receipt is sent through the CDU medication management platform. The receiving entity inspects the shipment upon arrival, assures cold-chain integrity during transit, and accepts the shipment in the CDU medication management platform.

Medication Inventory Management

At both CDU and covered entities:

- All inventory transfers are tracked using 11-digit NDCs at each stage—from wholesaler to CDU inventory, CDU to covered entity, and entity to patient—with documentation including packing slips, transfer logs, medication logs, and patient administration records.
- Medication is appropriately stored in a monitored area to ensure it is not stored outside the required temperatures. A log is kept at the facility to demonstrate continuous maintenance of proper storage conditions.
- Medications are labeled and segregated 340B, Retail, and EPT medications in secure storage in such a way as to ensure that CDU 340B medications are not administered or dispensed to ineligible patients.

Medication Administration, Expiration, Short-date, and Waste Reporting

- All administration, expiration, and waste of medications must be tracked and reconciled with inventory logs to:
    - Prevent duplicate Medicaid billing.
    - Avoid diversion and track usage accurately.
- Tracking will include full details of dispensed, expired, and wasted medications by the current CDU 340B and EPT inventory platform guidance.
    - Staff accurately log medication(s) when dispensed or administered by a provider in medication log(s) and document by the current CDU 340B and EPT inventory platform guidance.
- Transfer short-dated items as able.
    - CDU-supplied medication must be transferred by the current CDU 340B and EPT inventory platform guidance.
- Monitor medications for expiration date.
    - Any medication that expires before use or is determined to have quality issues due to improper storage should be disposed of according to the appropriate internal medication disposal procedure at the storage facility.
    - Any expiration, waste, or loss of 340B medication is documented by the current CDU 340B and EPT inventory platform guidance.

Non-CDU Provided 340B and EPT Medications Purchase and Use

CDU understands that covered entities may purchase medications and other items outside those provided by CDU with their 340B designation. Covered entities are responsible for ensuring that medications purchased independently under their 340B designation must be administered within the scope of the STD and/or TB grant and follow CDU's procurement, inventory, and reporting guidance.

The following 340B medications may be purchased independently by covered entities under CDU's 340B designations with their funding sources:

- 340B STD: Medications are within the scope of the current STD Prevention grant.
- 340B TB: Medications are within the scope of the current TB Prevention grant.

1. Covered entities that purchase other items at a 340B discount must have a policy and procedure in place to ensure proper purchasing, receipt, storage, and dispensing or administration of these items, including clear and/or separate inventory storage to avoid diversion of discounted items to ineligible patients.
2. Medications purchased independently by the clinic must be tracked internally and include full details of dispensed, expired, transferred, and wasted medication.
    a. The tracking mechanism must include: patient initials, DOB, medication name, dose, lot number, expiration date, and NDC.
3. Items purchased at the 340B discount may only be dispensed or administered for patients who meet the selected grant and 340B eligibility as listed above in this guidance.
4. If a covered entity bills Medicaid for these items, the covered entity is responsible for ensuring that billing is performed correctly to prevent duplicate discounts:
    a. Billing includes the correct institutional NPI number.
    b. Billing includes the correct NDC for the item.

340B and EPT Program Compliance and Auditing

Documentation

- CDU requires that covered entities using CDU 340B and/or EPT medications maintain records of all transactions for at least 3 years in a readily retrievable and auditable format.
- Audit and monitoring documentation will be stored for at least 5 years.

Auditing

CDU reviews 340B OPAIS to ensure the accuracy of the information for all site locations at a minimum annually at the time of recertification, at any time a covered entity submits an update to their medication facility profile, and quarterly, as capacity permits.

- CDU reviews the Medicaid Exclusion File (MEF) to ensure the accuracy of the information for contract partner covered entities at a minimum annually and at any time a contract partner covered entity submits an update to their medication facility profile.
- At the time of annual recertification, CDU requires that contract partner entities receiving and using CDU-provided 340B medications provide documentation that the medication inventory is being appropriately logged and tracked as a condition of continued participation in the program.

CDU will review the use of 340B and EPT medication via a covered entity site audit at least once every three years. This may be conducted jointly with other WDH programs.

- Selection of sites for audit may be random or tied to risk concerns related to past issues in proving continuing compliance with 340B medication program requirements.
- Sites will be notified of the audit 30 days before the site visit.
- In the audit process, CDU staff do the following with the covered entity:
    - Review the entity's OPAIS record for accuracy and note any errors for correction.
    - Request documentation from the entity of stored orders, records of medications received, and dispensing or administration records for the audit period.
    - Reconcile 340B purchasing, receiving, and dispensing records to ensure that covered outpatient drugs purchased through the 340B Program are dispensed or administered only to patients eligible to receive 340B drugs.
    - Document any variances, verify entity documentation, and determine if variances amount to diversion.
- CDU staff reconcile dispensing records to patients' health care records and/or surveillance system records to ensure that all medications dispensed were provided to patients eligible for 340B drugs. CDU will select up to 5 records.
- If applicable to the site, CDU staff will request records from contract partner covered entities to reconcile dispensing or administration records and Medicaid billing practices to demonstrate that no Medicaid billing occurred for CDU 340B medications administered or dispensed by the site.
    - The correct institutional NPI number will be verified in OPAIS before the audit.
    - A sample of dispensing records will be reviewed to verify that 340B discounted item(s) were dispensed to eligible patient(s) and documented clearly and correctly.

    - A sample of billing records will be reviewed to verify that 340B discounted items were billed with the correct institutional NPI number as reflected in OPAIS, and the correct NDC was documented in the billing.
- Results of audits will be reviewed by the CDU Prevention Program Manager and other staff as necessary to determine passage or failure of the audit before being provided to the covered entity.
- Regardless of passage or failure to pass the audit, reports of audit findings will be provided to the audited covered entity site staff within 30 days of monitoring.
    - If any material breach of regulations is identified, CDU will report this immediately to OPA.
    - The CDU Prevention Program staff determines the severity of the breach after review of the reported breach.
    - If an incident of diversion or duplicate discount is identified, CDU will work with the entity or internal resources and manufacturers to repay the costs of medications that were part of the diversion or duplicate discount.
    - If the contract partner site successfully passes the audit but has some findings, the site staff will be asked to provide a corrective action plan, which includes a timeframe by which corrective action will be completed, and to provide evidence that corrective action has been completed.
        - If the corrective action plan is not provided or shown to have been completed, the contract partner site will be suspended from participation in the CDU 340B and/or EPT medication program until findings are corrected.
    - If the contract partner site does not successfully pass the audit, the site and 340B Grantee ID will be suspended from participation in the CDU 340B and/or EPT medication program.
        - Partner site staff will be asked to provide a corrective action plan, which includes a timeframe by which corrective action will be completed, and to provide evidence that corrective action has been completed.
        - Once the corrective action has been performed, the covered entity site can register to be reinstated in the program within the appropriate registration period.
