2024 Wyoming Communicable Disease Unit 340B, Retail, and EPT Guidance

Additional information may be obtained from:

Prevention Program Manager Public Health Division Communicable Disease Unit 122 West 25th Street, 3rd Floor West Cheyenne, WY 82002

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Notice

All Wyoming Department of Health, Communicable Disease Unit (CDU) offerings are subject to availability of funding as well as medication and supply availability. This guidance is reviewed routinely and updated as necessary to maintain compliance with Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs and Services Administration (OPAIS), Centers for Disease Control and Prevention (CDC), and Wyoming Department of Health (WDH) regulations.

Communicable Disease Unit Prevention Website

The CDU Prevention website can be found at: https://health.wyo.gov/publichealth/communicable-disease-unit/hiv-prevention-program/

Communicable Disease Unit Staff Directory

The current Wyoming Department of Health Communicable Disease Unit (CDU) Staff Directory can be found on the CDU website at: https://health.wyo.gov/publichealth/communicable-disease-unit/staff/.

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CDU 340B Introduction

The Wyoming Department of Health, Communicable Disease Unit (CDU) participates in the Health Resources and Services Administration (HRSA) Office of Pharmacy Affairs (OPAIS) 340B Drug Pricing Program. The 340B Drug Pricing Program enables eligible entities to purchase certain medications and supplies at a significantly reduced cost. Eligible health care organizations must comply with certain regulations to participate in the HRSA 340B Drug Pricing Program. The CDU provides certain medications and supplies at no cost to eligible entities under CDU's 340B designations through this program.

The CDU staff will review this guidance routinely and make changes as necessary to maintain compliance with regulations.

CDU 340B Entity Eligibility Requirements

All entities wishing to obtain medications and supplies under CDU's 340B designation(s) must meet the following requirements:

- 1. Qualify under OPAIS eligibility requirements
- 2. Request enrollment under CDU's 340B designation from the <u>Prevention Program Manager</u>
- 3. Complete the required OPAIS and CDU trainings
- 4. Maintain compliance with all OPAIS and CDU 340B policies

Once these requirements have been met, the <u>340B Coordinator</u> will add the entity under CDU's 340B designation(s) for the next OPAIS enrollment period and notify the entity when enrollment is completed.

Federally Qualified Health Centers (FQHC) and Title X Funded Clinics

FQHCs and Title X funded clinics are independently eligible for 340B pricing and are therefore not eligible to enroll under CDU's 340B designation(s). If CDU funding is available, FQHCs and Title X funded clinics in Wyoming can invoice the CDU for reimbursement of approved 340B STD and TB medications and supplies purchased by the FQHC or Title X funded clinic from their 340B vendor. For questions regarding FQHC or Title X funded clinic 340B STD and TB medication and supply reimbursement please contact the <u>CDU Prevention Program Manager</u>. Approved invoices and purchase records may be sent to:

Wyoming Communicable Disease Unit **Prevention Program** 122 West 25th Street, 3rd Floor West Cheyenne, WY 82002

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Penicillin G Benzathine (Bicillin L-A®) for Treatment of Syphilis

There is a 340B provision which allows the CDU to provide penicillin G benzathine (Bicillin L- $A^{(R)}$) for treatment of syphilis to entities which are not under the CDU's 340B designation. Entities in need of penicillin G benzathine (Bicillin L- $A^{(R)}$) for treatment of syphilis should utilize all available resources to obtain penicillin G benzathine (Bicillin L- $A^{(R)}$) and contact their <u>CDU Area</u> <u>DIS</u> if they are unable to obtain penicillin G benzathine (Bicillin L- $A^{(R)}$) in a timely manner.

CDU 340B Entity Enrollment Requirements

Prior to enrolling in the 340B Drug Pricing Program under the CDU's 340B designation(s), all entity staff involved in the ordering, storage, and administration of medications and supplies obtained under the CDU's 340B designation(s) will be required to complete the following trainings and maintain documentation before handling medications or supplies under the CDU's 340B designation(s). After initial enrollment, any new staff that becomes involved in the entity's CDU 340B process will also need to complete the following training and maintain documentation before handling medications or supplies under the CDU's 340B designation (s).

- 1. Read the current CDU 340B, Retail, and EPT Guidance and write their name, signature, and date on the entity's CDU 340B, Retail, and EPT Compliance Log.
- 2. Complete the following 340B University trainings:
 - 1. Introduction to the 340B Drug Pricing Program
 - 2. Eligibility Overview
 - 3. Compliance Cornerstones

The 340B University training sessions can be found at: <u>https://www.340bpvp.com/340b-university/online-learning</u>.

Entities will need to appoint a staff person as the Primary Contact for its CDU 340B designation(s) in the OPAIS 340B database. The <u>CDU 340B Coordinator</u> will be listed as the Authorizing Official for your entity. Entities must notify the <u>CDU 340B Coordinator</u> if the Primary Contact for their facility changes and update their OPAIS 340B account when contact information or the entity's physical address changes.

Duty to Report 340B Designation

Entities under the CDU's 340B designation(s) must inform the <u>CDU 340B Coordinator</u> within 24 hours if they begin to receive FQHC, Title X, or other 340B qualifying funding.

CDU 340B Entity Recertification Requirements

Entities under CDU's 340B designation(s) must notify the <u>CDU 340B Coordinator</u> if the 340B contact for their site changes as well as update their OPAIS 340B account annually and when the 340B contact or address (street, billing, shipping) changes occur.

Entities under CDU's 340B designation(s) must also be recertified by <u>CDU 340B Coordinator</u> on an annual basis by meeting the following criteria:

- 1. OPAIS account information must be complete, accurate, and correct.
 - a. Once every calendar year, the Primary Contact for enrolled entities will receive notification from OPAIS that they need to complete this recertification. The Primary Contact will need to login into their OPAIS account to confirm or modify any information requested and submit it for the Authorizing Official to attest that the information provided from the Primary Contact is valid and true. The <u>CDU</u> <u>340B Coordinator</u> will be listed as the Authorizing Official and complete this attestation.
- 2. Acknowledge the entity's responsibility to meet all CDU and OPAIS eligibility requirements (<u>https://www.hrsa.gov/opa/340b-opais</u>), including contacting CDU immediately if there is any change in 340B eligibility and/or breach in compliance by maintaining a signature log stating that staff has attested to reading the most recent 340B, Retail, and EPT guidance.
- 3. Comply with all requirements and any accompanying regulations including, but not limited to, the prohibition against duplicate discounts and diversion.
- 4. Maintain auditable records pertaining to compliance with the requirements.

CDU 340B Patient Definition

CDU 340B medications can only be used for patients receiving healthcare services from the participating entity. An individual is a patient of a 340B entity only if:

- The entity has established a relationship with the individual, such that the entity maintains records of the individual's health care; *and*
- The individual receives healthcare services from a healthcare professional who is either employed by the 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 entity; *and*
- The individual receives a health care service or range of services from the entity which is consistent with the service or range of services for which grant funding or federallyqualified health center look-alike status has been provided to the entity

An individual will not be considered a patient of the entity if the only health care service received by the individual from the covered entity is the dispensing of a medication.

Medicaid enrolled individuals may not receive any medications or supplies purchased under CDU's 340B designations. Entities should contact the <u>CDU 340B Coordinator</u> immediately when there is a concern of 340B medication administration to a Medicaid insured individual.

Individuals with private insurance may receive medications and supplies purchased under CDU's 340B designations, however, priority should be given to individuals without insurance.

CDU 340B Approved Medications and Supplies

Under CDU's 340B STD designation entities may obtain the following medications:

- CDC approved treatment for chlamydia, gonorrhea, or syphilis
- Contraception
- CDC approved treatment for other STDs and infections that may result in pelvic inflammatory disease, ectopic pregnancy, or infertility
- Pre-Exposure Prophylaxis (PrEP) for HIV prevention
- Post-Exposure prophylaxis (PEP) for HIV prevention
- DoxyPEP for prevention of STIs

Under CDU's 340B TB designation

- Purified Protein Derivative (PPD) for Tuberculin Skin Tests (TSTs)
- TB syringes for administration of PPD for TSTs

CDU 340B Medication Ordering

Eligible entities under CDU's 340B designation(s) may order CDU 340B medications and supplies directly from CDU using the current CDU 340B, Retail, and EPT management platform linked on the <u>CDU Prevention Program webpage</u>. Protocols for this platform can be found <u>here</u>.

To protect shipments and maintain the quality of temperature-controlled shipments, CDU orders are mailed on Mondays, Tuesdays, and Wednesdays only, on normal business days.

Coolers, ice packs, and cooler boxes received from CDU are to be returned to the CDU within two (2) weeks to the address below:

Wyoming Communicable Disease Unit **Prevention Program** 122 West 25th Street, 3rd Floor West Chevenne, WY 82002

For reimbursement of postage costs related to returning CDU coolers, ice packs, and cooler boxes to CDU, entities may submit an invoice and purchase records to CDU, at the above address.

Page 7 of 19 Communicable Disease Unit 340B, Retail, and EPT Guidance Updated 03/11/2024 Entities under CDU's 340B designation(s) may also choose to independently purchase approved CDU 340B medications and supplies from their preferred vendor using their 340B designation(s) under CDU. Entities that choose this option must maintain an accurate inventory at all times and be able to track recalled medications and supplies within 24 hours of recall notification.

CDU 340B Medication Administration Reporting

Entities under the CDU's 340B designations are required to report the administration of all CDU 340B medications by the 7th of the month following the month the medication was administered. If administered medications are not reported by the 7th of the month following the month the medication was administered, new orders may be held until reporting has been updated.
Example: Medication administered February 10th must be reported as administered before March 7th.

Reporting administered medication protocols for the current CDU 340B, Retail, and EPT management platform can be <u>here</u>.

Entities receiving CDU 340B medications and supplies directly from the CDU: Must report administration and usage on the current CDU 340B, Retail, and EPT management platform

Entities that independently purchase CDU approved 340B medications and supplies under CDU's 340B designation(s) must follow the requirements below:

- These medications should not be entered into the current CDU 340B, Retail, and EPT management platform
- Records may be maintained either physically on paper or digitally
 - Maintain an accurate inventory at all times and be able to track medications and/or supplies within 24 hours should a recall occur
 - Maintain records of medications purchased under CDU's 340B designation(s)
 - Purchase records must be available upon request and for audits.
 - Log medication administration
 - Log must meet CDU requirements (below) and log must be available upon request.
 - Facility Name
 - Date Medication Provided
 - Patient First Name
 - Patient Last Name
 - Patient DOB
 - Patient Insurance: Uninsured, Private Insurance, Medicaid
 - Diagnosis
 - Medication name
 - Dose of medication
 - Medication Lot #

- Medication Expiration date
- Quantity
- NDC number

Entities that independently purchase approved medications under CDU's 340B designation(s) can submit an invoice, with purchase records, to CDU for reimbursement if CDU funding is available. Please contact the <u>Prevention Program Manager</u> regarding requests for reimbursement. Approved invoices and purchase records may be sent to:

Wyoming Communicable Disease Unit **Prevention Program** 122 West 25th Street, 3rd Floor West Cheyenne, WY 82002

CDU 340B Short Dated Medication and Supplies

Entities that order 340B medications and supplies directly from CDU:

In an effort to decrease wastage, entities receiving 340B medications and supplies directly from CDU may be instructed to return or transfer short dated items to another CDU 340B site before the expiration date. Protocols for transferring shorted dated medication in the current CDU 340B, Retail, and EPT management platform can be found <u>here</u>.

Entities transferring medications at CDU's request may invoice CDU for reimbursement of postage costs related to returning or transferring medications or supplies. Approved invoices and receipts for postage costs associated with returning or transferring short dated CDU 340B medications and supplies to CDU may be sent to:

Wyoming Communicable Disease Unit **Prevention Program** 122 West 25th Street, 3rd Floor West Cheyenne, WY 82002

CDU 340B Expired Medication and Supply Reporting

Entities that order CDU 340B medications and supplies directly from CDU:

The current CDU 340B, Retail, and EPT management platform tracks expiration dates. Protocols for wasting expired medications to maintain a correct inventory count in the current CDU 340B, Retail, EPT management platform can be found <u>here</u>.

Entities that independently purchase allowable 340B medications under CDU's 340B designation(s) must follow the requirements below:

- These medications are not entered into the current CDU 340B and Retail management platform and entities must follow the reporting requirements below
- These records may be maintained either physically on paper or digitally
 - CDU 340B Expiration Log Requirements
 - o Medication name
 - \circ Dose of medication
 - Medication Lot #
 - Medication expiration date
 - o Quantity
 - NDC number

Expired medications and supplies are not to be returned to the CDU. Please dispose of them as per your organization's policy.

CDU 340B Medication Storage

Medications and supplies purchased under the CDU's 340B designation(s) must be labeled and stored separately.

CDU 340B Audit Procedures

CDU will perform audits of all entities under the CDU's 340B designation(s). Audits are intended to assure that medications and supplies purchased under the CDU's 340B designation(s) are being stored and used properly. Entities under the CDU's 340B designation(s) will receive notification of an upcoming audit at least thirty (30) days prior to the date of the audit. Entities will be required to provide training and reporting documentation at least one (1) week prior to an audit. CDU will provide an audit report to the entity not more than thirty (30) days after the audit. If findings during the audit require corrective action, the entity must provide a Corrective Action Plan (CAP) to the <u>CDU 340B Coordinator</u> within thirty (30) days of notice. Please see *Audit Notification* and *Audit Findings* forms in the appendix.

CDU 340B Corrective Action Plan (CAP)

In the event that an entity under the CDU's 340B designation(s) is found to be non-compliant with any CDU 340B requirements, the <u>CDU 340B Coordinator</u> will be made aware of the infraction immediately. If appropriate, CDU will create a CAP for the entity which will be designed to resolve compliance issues and prevent similar issues in the future

Entities under CDU's 340B designation(s) will have sixty (60) days after the implementation of the CAP to correct all identified compliance issues. If the CAP does not successfully remediate the identified issue(s), a new CAP may be required.

Entities under CDU's 340B designation(s) that are not in compliance with the current CDU 340B guidance may be responsible for payment of the difference in cost of medications between 340B and retail prices, restricted from placing future orders, and/or terminated from CDU's 340B designation(s) in OPAIS.

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CDU Retail and EPT Medication Introduction

CDU retail medication is primarily used for Expeditated Partner Therapy (EPT). EPT is the practice of treating the sex partners of persons with sexually transmitted infections (STIs) without a clinical assessment by a health care provider, this practice is permissible by Wyoming State law. While it is preferred that all partners be tested prior to treatment, sex partners are not always able or willing to access testing. The CDU provides EPT medications at no cost to eligible clinics; these medications are purchased at retail prices and are not purchased through the 340B drug pricing program. CDU EPT is primarily designed for, but not limited to, clinics offering safety-net STI testing services to the uninsured sex partner(s) of established clinic patients with a positive STI result.

The CDU staff will review this guidance routinely and make changes as necessary to maintain compliance with regulations.

CDU Retail and EPT Eligibility

CDU Retail and EPT medications are primarily for, but not limited to, entities offering safety-net STI testing services to uninsured sex partner(s) of established clinic patients with a positive STI result.

To enroll as a CDU Retail and EPT site, entities must request enrollment from the <u>Prevention</u> <u>Program Manager</u>, and comply with all CDU Retail and EPT enrollment training requirements discussed below.

CDU Retail and EPT Enrollment

Prior to enrolling as a CDU Retail and EPT site, all entity staff involved in the ordering, storage, and administration of medications obtained from the CDU's Retail and EPT inventory will be required to complete the training and documentation listed below before handling CDU Retail and EPT medication. After initial enrollment, any new staff that becomes involved in the entity's CDU Retail and EPT medications will also need to complete this training and documentation before handling CDU 340B Retail and EPT.

1. Read the current CDU Retail and EPT Guidance and write their name, signature, and date on the location's CDU Retail and EPT Compliance Log. Email log to <u>cdusupplies@wyo.gov</u>

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CDU EPT Patient Definition

An individual is an established clinic patient only if:

- The clinic has established a relationship with the individual, such that the clinic maintains records of the individual's health care; *and*
- The individual receives health care services from a health care professional who is either employed by the clinic or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the clinic; *and*
- The individual receives a health care service or range of services from the clinic which is consistent with the service or range of services for which grant funding or federallyqualified health center look-alike status has been provided to the clinic

CDU EPT medications are for the sex partner(s) of established clinic patients with a positive STI result. An individual will not be considered an established patient of the clinic if the only health care service received by the individual from the clinic is the dispensing of a medication.

Billing and CDU Retail and EPT Allowable Uses

Individuals with insurance may receive CDU Retail and EPT medications however, priority should be given to individuals without insurance.

CDU Retail and EPT entities cannot charge a fee for CDU Retail and EPT medications or charge a fee for dispensing CDU Retail and EPT medications.

CDU Retail and EPT medications may be used in place of CDU 340B medications in some circumstances. If a situation arises where the clinic would like to use CDU Retail or EPT medications in place of CDU 340B medications contact the <u>CDU 340B Coordinator</u>.

CDU Retail and EPT Medications and Supplies

CDU provides Retail and EPT medications for treatment of STIs at no cost to eligible and enrolled entities. The medications that are available include, but may not be limited to:

- Azithromycin (EPT Retail)
- Doxycycline (EPT Retail)
- Ceftriaxone and Xylocaine (Retail)

CDU EPT medications <u>must</u> be dispensed with the appropriate CDU Medication Instructions for the established patient to provide to their sex partner(s). CDU EPT medications are shipped from CDU in packets that include the appropriate CDU EPT Medication Instructions.

CDU Retail and EPT Medication Ordering

Eligible sites may order CDU Retail and EPT medications directly from CDU by using the current CDU 340B, Retail, and EPT management platform linked on the <u>CDU Prevention</u> <u>Program webpage</u>. Ordering protocols for this platform can be found <u>here</u>.

To protect shipments and maintain the quality of temperature-controlled shipments, CDU orders are mailed on Mondays, Tuesdays, and Wednesdays only, on normal business days.

Coolers, ice packs, and cooler boxes received from CDU are to be returned to the CDU within two (2) weeks.

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For reimbursement of postage costs related to returning CDU coolers, ice packs, and cooler boxes to CDU, entities may submit an invoice and purchase records to CDU, at the above address.

CDU Retail and EPT Medication Dispensed Reporting

Eligible CDU Retail and EPT entities are required to report the dispensing of all CDU provided Retail and EPT medications using the current CDU 340B, Retail, and EPT management platform. Reporting administered medication protocols for this platform can be found <u>here</u>.

CDU Retail and EPT Short Dated (Transferring) Medication Reporting

In an effort to decrease wastage, entities receiving CDU Retail and/or EPT medications may be instructed to return or transfer short dated items to another CDU Retail and EPT site before the expiration date. Protocols for transferring shorted dated medication in the current CDU 340B, Retail, and EPT management platform can be found <u>here</u>.

Entities transferring medications at CDU's request may invoice CDU for reimbursement of postage costs related to returning or transferring medications or supplies. Approved invoices and receipts for postage costs associated with returning or transferring short dated CDU Retail and EPT medications and supplies to CDU may be sent to:

Wyoming Communicable Disease Unit **Prevention Program** 122 West 25th Street, 3rd Floor West Cheyenne, WY 82002

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CDU Retail and EPT Expired Medication Reporting

The current CDU 340B, Retail, and EPT management platform tracks expiration dates for medications and supplies ordered directly from CDU. Protocols for wasting expired medications to maintain a correct inventory count in this platform can be found <u>here</u>.

Expired medications and supplies are not to be returned to the CDU. Please dispose of them as per your entity's policy.

CDU Retail and EPT Medication Storage

Medications and supplies ordered from CDU's Retail and EPT stock must be labeled and/or stored separately from all other medication stocks.

CDU Retail and EPT Audit Procedures

CDU will perform audits of all clinics receiving CDU Retail and EPT medications. Audits are intended to assure that CDU Retail and EPT medications are being stored and used properly. Clinics receiving CDU Retail and EPT medications will receive notification of an upcoming audit at least thirty (30) days prior to the date of the audit. Entities will be required to provide training and reporting documentation at least one (1) week prior to an audit. CDU will provide an audit report to CDU Retail and EPT clinics not more than thirty (30) days after the audit. If findings during the audit require corrective action, the entity must provide a Corrective Action Plan (CAP) to the CDU 340B Coordinator thirty (30) days of notice. Please see *Audit Notification* and *Audit Findings* forms in the appendix.

CDU Retail and EPT Corrective Action Plan (CAP)

In the event that a clinic receiving CDU's Retail and EPT medications is found to be non-compliant with any CDU Retail and EPT requirements the <u>CDU 340B Coordinator</u> will be made aware of the infraction immediately. If appropriate, CDU will create a CAP for the entity which will be designed to resolve compliance issues and prevent similar issues in the future

CDU Retail and EPT clinics will have sixty (60) days after the implementation of the CAP to correct all identified compliance issues. If the CAP does not successfully remediate the identified issue(s), a new CAP may be required.

CDU Retail and EPT clinics that are not in compliance with the current CDU Retail and EPT guidance may be responsible for the cost of medications provided by CDU, restricted from placing future orders, and/or terminated from CDU's EPT program.

CDU 340B, Retail, and EPT Quantity Limits

On CDU's new 340B, Retail, and EPT ordering and reporting platform, CDU is no longer able to include quantity limits. The limits below apply **only** to 340B, retail, and EPT ordered directly from CDU. These limits are designed to prevent short date transfers, preserve funding, and conserve supply during shortages. To request exceptions to any of the quantity limits below, email <u>cdusupplies@wyo.gov</u>. All prior quantity limit exceptions will carry forward, an additional request is not needed.

CDU 340B		
340B Aplisol PPD Serum 10 doses/vial, 1 vial = 10 doses	50 doses	
340B Aplisol PPD Serum 50 doses/vial, 1 vial = 50 doses	250 doses	
340B Azithromycin, 250mg, four tablets/bottle, 1 bottle = 1 course	1 course	
340B Bicillin-LA, 1.2U tube, 2 tubes = 1 dose	Katelyn's approval only	
340B Ceftriaxone, 500mg/vial, must be reconstituted with Xylocaine, 1 vial =1 dose	5 doses	
340B Doxycycline, 100mg, 14 tablets/bottle, 1 bottle = 1 course	10 courses	
340B VanishPoint TB syringes, 100 syringes/box, 1 syringe = 1 dose	200 doses	
340B Xylocaine 1%, 10mg/mL, 2mL vial, for reconstitution of Ceftriaxone, 1 vial =1 dose	5 doses	
CDU Retail Expediated Partner Therapy (EPT)		
Retail EPT Azithromycin, 250mg, four tablets/bottle, 1 bottle = 1 course	1 course	
Retail EPT Doxycycline, 100mg, 14 tablets/bottle, 1 bottle = 1 course	5 courses	
CDU Retail (not EPT): for Treatment of Gonorrhea Infection in Patients with Medicaid		
Retail Xylocaine 1%, 10mg/mL, 2mL vial, for reconstitution of Ceftriaxone, 1 vial =1 dose	Katelyn's approval only	
Retail Ceftriaxone, 500mg/vial, must be reconstituted with Xylocaine, 1 vial =1 dose	Katelyn's approval only	

WDH Communicable Disease Unit

340B, Retail, and EPT Medication and Supply Guidance Compliance Log

By signing this sheet, I acknowledge that I have read the most current (check all the apply):

□ CDU 340B Medication and Supply Guidance

CDU Retail and EPT Guidance

CDU 340B, Retail, and EPT Management Platform Protocols

Facility Name: _____

NAME	SIGNATURE	DATE



Public Health Division 122 West 25th Street, 3rd Floor West Cheyenne, WY 82002 (307) 777-7275 • 866-571-0944 Fax (307) 777-7278 • www.health.wyo.gov



Stefan Johansson Director Mark Gordon Governor

Monday, March 04, 2024

Ref: PHSS-[xxxx]-[xxx]

Re: CDU 340B, Retail, and/or EPT Audit

Dear Facility Name:

The Wyoming Department of Health (WDH) Communicable Disease Unit (CDU) visited your facility for a CDU 340B, Retail, and/or EPT audit on Date and Time. Below are the audit results:

Items checked below were found to be in compliance:

- All staff involved in CDU 340B, Retail, and/or EPT at the site have read the most recent Wyoming Communicable Disease Unit 340B, Retail, and EPT Guidance
- All staff involved in CDU 340B, Retail, and/or EPT at the site have completed the appropriate CDU 340B and/or Retail and EPT training as stated in the most recent Wyoming Communicable Disease Unit 340B, Retail, and EPT Guidance
- CDU 340B, Retail, and/or EPT are properly stored and labeled
- 340B medications and supplies purchased under CDU's 340B designation(s) are properly stored and labeled
- CDU Retail and/or EPT are properly stored and labeled separate from all 340B and private stock
- Audited patient charts included insurance information, completed risk assessment, diagnosis, medications administered/dispensed, and listed the primary nurse overseeing care
- Record of medication ordering, administration/dispense, short date, and expirations appropriately logged

Notes from site visit:

Items above that are not checked, were out of compliance. Please respond to these items by letter or email within 30 days. If these items are not been addressed within 30 days, a corrective action plan will be established.

We appreciate your commitment to assuring compliance for the CDU 340B, Retail, and EPT program. If you have any questions or concerns, please feel free to contact Sarah Hendricks (sarah.hendricks@wyo.gov, 307-777-6563) or Leslie Fowler (leslie.fowler@wyo.gov, 307-777-3562).

cc: Shawna Pena, Manager, Communicable Disease Unit, Public Health Division Melanie Pearce, CDU Liaison, Public Health Nursing, Public Health Division

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Stefan Johansson Director Mark Gordon Governor

Monday, March 04, 2024

Ref: PHSS-[xxxx]-[xxx]

Re: CDU 340B, Retail, and/or EPT Audit

Dear [Insert Name],

The Wyoming Department of Health Communicable Disease Unit (CDU) has selected your site for a CDU 340B, Retail, and/or EPT Audit. Your audit is scheduled to occur on [Insert Day, Date, and Time] and will address medications and supplies ordered from CDU and/or purchased under CDU's 340B designation(s) in the last three years. During the audit, you will be asked to provide information pertaining to the ordering, storage, administration, dispensing, short dating, and expiration of CDU 340B, Retail, and/or EPT at your site. Please ensure that the nurse manager and one staff member are available for the audit. The staff member should be someone who does the ordering, storage, administration, dispensing, and reporting of CDU 340B, Retail, and/or EPT for the site. The audit will be conducted by CDU staff. If the audit is being conducted in-person, please ensure meeting space is available for the audit.

Pre-audit information should be provided to the CDU one (1) week prior to your scheduled audit. Please upload all pre-audit information into the Google Drive folder titled "[Insert Site] - CDU 340B, Retail, and EPT" by [Insert Day and Date].

Pre-Audit information to be provided by the site:

- 1. A list of all staff involved in CDU 340B, Retail, and/or EPT at the site
- Signature log showing all staff involved in CDU 340B, Retail, and/or EPT at the site have read the most recent Wyoming Communicable Disease Unit 340B, and/or Retail and EPT Guidance
- Signature log showing all staff involved in CDU 340B, Retail, and/or EPT at the site have completed the appropriate training as stated in the most recent Wyoming Communicable Disease Unit 340B, Retail, and EPT Guidance

Audit procedure:

The audit will include the following:

- Inspection of physical medication storage
- Review of work flow process related to CDU 340B, Retail, and/or EPT
- Review of five-ten (5-10) CDU 340B, Retail, and/or EPT related patient records
- Review of medication ordering, storage, administration, dispensing, short date, and expiration records

If you have any questions or concerns, please feel free to contact Sarah Hendricks (sarah.hendricks@wyo.gov, 307-777-6563) or Leslie Fowler (leslie.fowler@wyo.gov, 307-777-3562).

cc: Shawna Pena, Manager, Communicable Disease Unit, Public Health Division Melanie Pearce, CDU Liaison, Public Health Nursing, Public Health Division

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