Wyoming Communicable Disease Unit
340B and Retail Medication Guidance
For Participants

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

The Wyoming Communicable Disease Unit 340B STI, TB, and Other Pharmaceutical offerings as well as the CDU EPT (retail) offering are subject to availability of grant funding and medication availability.

CDU 340B Introduction

The Wyoming Department of Health Communicable Disease Unit (CDU) participates in the Health Resources and Services Administration (HRSA) 340B Drug Pricing Program. The 340B Drug Pricing Program enables sub-recipients and covered entities to purchase certain medications at a significantly reduced rate. Eligible health care organizations are 340B sub-recipients and must comply with certain regulations to participate in the 340B Program. With the exception of Penicillin G benzathine (bicillin) for treatment of syphilis, health care organizations with their own 340B designation are not eligible for CDU 340B medications.

The CDU supplies antibiotics for sexually transmitted infections (STIs) and tuberculin skin test (TST) supplies at no cost to eligible, compliant CDU 340B sub-recipients in the state of Wyoming through this program. 340B medications cannot be used for EPT (retail).

Sub-recipients under CDU's 340B STD designation may also purchase other pharmaceuticals. "Other Pharmaceuticals" is defined as CDU approved pharmaceuticals used for contraception and to treat non-reportable STIs and infections that may result in pelvic inflammatory disease, ectopic pregnancy, or infertility. Please see the CDU 340B "Other Pharmaceuticals" section of this document for details regarding that offering.

CDU staff will review unit guidance regarding 340B procedures routinely and make changes as necessary to maintain compliance with OPAIS.

CDU 340B Enrollment and Recertification

All entities wishing to become sub-recipients of the CDU 340B Program must meet eligibility requirements, request enrollment from the Prevention Program Manager, and if approved comply with all CDU 340B Program requirements.

Sub-recipients must notify the CDU 340B Coordinator if the 340B contact for their site changes and update their OPAIS 340B account when 340B contact or address (street, billing, shipping) changes occur.

The sub-recipient must meet the following criteria to be recertified each year for 340B STD and TB Office of Pharmacy Affairs Information System (OPAIS) accounts:

- OPAIS account information must be complete, accurate, and correct.
- The sub-recipient meets all CDU 340B eligibility requirements.
- The sub-recipient will comply with all requirements and any accompanying regulations including, but not limited to, the prohibition against duplicate discounts and diversion more information available at https://www.hrsa.gov/opa/340b-opais.
- The sub-recipients maintains auditable records (reporting) pertaining to compliance with the requirements.
- The sub-recipient acknowledges its responsibility to contact CDU as soon as possible if there is any change in 340B eligibility and/or breach by the sub-recipient.

All staff handing 340B medications from CDU or purchased under CDU's 340B STD or TB designations must read the current CDU 340B & Retail Medication Guidance and write their name, signature, and date on the location's CDU 340B & Retail Medication Compliance Log before handling 340B or retail medications from CDU or purchased under CDU's 340B STD or TB designations.

CDU 340B Eligible Use

340B medications can only be used for patients receiving healthcare services from the sub-recipient.

An individual is a patient of a 340B covered entity only if:

- the covered entity has established a relationship with the individual, such that the covered entity 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 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; ***and***
- 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 or federally-qualified health center look-alike status has been provided to the entity.

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

Individuals enrolled in Medicaid may not receive any medications purchased through 340B. Individuals with private insurance may receive medications purchased through 340B, however, priority should be given to individuals without insurance.

CDU 340B Medication Information

The CDU provides medications for treatment of STIs (chlamydia, gonorrhea, and syphilis) and testing supplies for TSTs. The medications and supplies that are available from CDU include, but are not limited to:

- Azithromycin
- Penicillin G benzathine (bicillin)
- Ceftriaxone
- Doxycycline
- Xylocaine
- Aplisol Purified Protein Derivative (PPD) Serum
- TB Syringes

CDU 340B Sub-Recipient Requirements

All sites utilizing the CDU's 340B designations will be required to follow the CDU's established guidance to ensure the same combined purchasing and distribution process is referred to.

All sub-recipient facility staff involved in the administration, ordering, or dispensing of CDU 340B medications must attest to having completed the below training from 340B University by Apexus, as well as attestation to having read the most current CDU 340B guidance (see form at the end of this document).

1. *Introduction to the 340B Drug Pricing Program (14 minutes): Provides a foundational overview of the 340B Program and serves as a primer for the rest of the modules in the curriculum.*
2. *Eligibility Overview (24 minutes) Updated June 2021: Outlines the types of 340B-eligible organizations and compliance best practices for covered entities.*
3. *Compliance Cornerstones (14 minutes) Updated Nov 2020: Provides an overview of the compliance cornerstones of the 340B Program, including prevention of diversion and duplicate discounts, GPO Prohibition, and the Orphan Drug Exclusion.*

The online training is located at https://www.340bpvp.com/340b-university/online-learning.

Attestation to review of CDU 340B guidance and modules will need to be repeated as updates occur.

Sites will also be required to report administration, expiration, and ordering of any 340B medications under the CDU's 340B designations. See appropriate reporting section for more details.

CDU 340B Sub-Recipient Medication Ordering

Sub-recipients may order medications and supplies directly from CDU by completing the current CDU ordering form linked on the CDU Prevention website under the Supplies heading https://health.wyo.gov/publichealth/communicable-disease-unit/hiv-prevention-program/.

The ordering form will require the following:

- Email
- County Location
- Medication requested
- Contact Name
- Mailing Address
- Attestation that medications will not be given to Medicaid patient
- Attestation that medications cannot be ordered by clinics with their own independent 340B designation

- Attestation of inventory management and reporting requirements

To protect shipments and maintain the quality of temperature controlled shipments, CDU orders are mailed on Mondays through Wednesdays only.

Sub-recipients may also choose to independently purchase approved CDU 340B items from their preferred vendor using their 340B STD or TB designation under CDU.

TB coolers, ice packs, and cooler boxes from CDU are to be returned to the CDU within two weeks.

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

Sub-recipients may submit invoices and purchase records to CDU, at the above address, for reimbursement of postage costs related to returning TB coolers, ice packs, and cooler boxes to CDU.

CDU 340B Medication Administration Reporting

Sub-recipients are required to report the administration of all CDU 340B medications by the 7th of the month following the month the medication was provided. If medications are not reported by a sub-recipient, new orders from that sub-recipient will be held until reporting has been updated.

Reporting requirements by type of sub-recipient:

Clinics receiving 340B STI medications directly from the CDU:

- Must report CDU 340B STI medication administration on the Google form, 340B STI Medication Administration Reporting Form at https://forms.gle/dN1Mcf354yYtRzZB7
- This form will include:
  - Email
  - County Location
  - Medication administered
  - Medication Lot number
  - Expiration Date
  - NDC number
  - Diagnosis
  - Patient Insurance
  - Name of Patient
  - Patient's Date of Birth
  - Contact Name
  - Phone Number

Clinics receiving 340B TST supplies directly from the CDU or under the CDU's 340B TB designation:

- Must report TST administration and result in the Wyoming Immunization Registry (WyIR).

Clinics that independently purchase approved CDU STI medications under CDU's 340B STD designation:

- Must maintain records of medications purchased under CDU's 340B STD designation. Purchase records must be available upon request and for audits.
- Must log medications
  - Log must meet CDU requirements (below).
  - Log must be available upon request and for audits.

CDU 340B Log Requirements

1) Facility Name
2) Date Medication Provided
3) Patient First Name
4) Patient Last Name
5) Patient DOB
6) Patient Insurance: Uninsured, Private Insurance, Medicaid
7) Diagnosis (STI only)
8) Medication
9) Medication Lot #
10) Medication Expiration date
11) NDC number

Clinics that independently purchase approved CDU STI medications under CDU's 340B STD designation can submit an invoice, with purchase records, to CDU for reimbursement. Reimbursement is dependent upon available funding. Please contact the Prevention Program Manager 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

In an effort to decrease wastage, sub-recipients receiving 340B medications or supplies from CDU directly must complete the Short Date Reporting Google Form three months before the expiration date for any CDU supplied 340B STI medications, unopened TB serum, or TB syringes the sub-recipient will not use prior to the expiration date. The CDU may ask sub-recipients to return short

dated items so they may be redistributed elsewhere for use before the expiration date. The sub-recipient may invoice CDU for reimbursement of postage costs related to returning medications or supplies to CDU.

Short Date Reporting Form: https://forms.gle/1qzBN3XzKqP9fBnM7

- This form will include:
  - Email
  - County Location
  - Medication
  - Medication Lot number
  - Expiration Date
  - NDC number
  - Quantity
  - Contact Name
  - Phone Number

Approved invoices and receipts for postage costs associated with returning short date medications and TB 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

With the exception of TB serum, sub-recipients receiving medications or supplies from CDU directly must report the expired medications or supplies via the Google Form no later than the 7th of the month following the expiration date. Expired medications and supplies do not need to be returned to the CDU. Please dispose of them as per your organization's policy.

Expired Reporting Form: https://forms.gle/1mZvmzbYVoEn4GzS7

- This form will include:
  - Email
  - County Location
  - Medication
  - Medication Lot number
  - Expiration Date
  - NDC number
  - Quantity
  - Contact Name
  - Phone Number

Expired CDU 340B TB serum is reported as waste in WyIR.

CDU 340B 'None Given' Reporting

Sub-recipients receiving medications or supplies directly from CDU must report when they do not administer 340B STI medications or TB serum over the course of the calendar month. 'None Given' reporting must completed on the Google Form by the 7th of the month following the month with 'None Given'.

None Given Reporting Form: https://forms.gle/wu9hxFj1jVAyB54T6

- This form will include:
  - Email
  - County Location
  - Select "340B STI None Given" and/or "340B TB None Given"
  - Contact Name
  - Phone Number

CDU 340B Medication Storage

340B and Expedited Partner Therapy (EPT retail) medications must be labeled and stored separately from each other.

Duty to Report 340B Designation

Sub-recipients must inform the CDU 340B Coordinator if they begin to receive Title X or other 340B qualifying funding.

CDU 340B Sub-Recipient Audit Procedures

The CDU will perform initial in-person audits at all sub-recipient facilities which participate in the 340B program. Future audits may be virtual. Audits are intended to assure that medications are being stored and used properly by each sub-recipient. Sub-recipients are subject to be audited once every three to four years. Sub-recipients will receive notification of an upcoming audit at least thirty (30) days prior to the date of the audit. Sub-recipients will need to provide required training and reporting documentation at least one (1) week prior to an audit. The CDU will provide an audit report to sub-recipients not more than thirty (30) days after the audit. If findings during the audit require attention, sub-recipients will be expected to respond within thirty (30) days of notice. Please see *Audit Notification* and *Audit Findings* forms in the appendix.

CDU 340B Corrective Action Plan

In the event that a sub-recipient is found to be non-compliant with any 340B regulation (i.e. medications used on a Medicaid patient, medication use not reported properly, failure to report

administration, short dates, or expiration), CDU will be made aware of the infraction immediately. If appropriate, the CDU will create a corrective action plan with the sub-recipient. A corrective action plan will be designed to resolve incorrect practices so that errors do not occur again.

Sub-recipients will have sixty (60) days after the implementation of a corrective action plan to correct all identified errors and complete corrective actions. If a corrective action plan does not successfully fix the identified problems, a new corrective action plan may be required.

Sub-recipients that are not in compliance with regulations may be responsible for payment of the difference in cost of medications between 340B and retail prices and may be denied further orders if not able to comply with regulations.

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

FQHC and Title X funded clinics are independently eligible for 340B pricing and are therefore not eligible to order 340B STI Medications from CDU. If CDU funding is available, FQHCs and Title X funded clinics in Wyoming can invoice CDU for reimbursement of approved 340B STI medications purchased by the FQHC or Title X funded clinic from their 340B STI medication vendor. For questions regarding FQHC or Title X funded clinic STI medication reimbursement please contact the Prevention Program Manager.

Approved invoices and purchase records may be sent to:

Wyoming Communicable Disease Unit
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Penicillin G benzathine (bicillin) for Treatment of Syphilis

There is a 340B provision which allows CDU to provide Penicillin G benzathine (bicillin) to non-340B sub-recipients for treatment of syphilis. Non-340B entities in need of Penicillin G benzathine (bicillin) for treatment of syphilis may contact the CDU Surveillance Program Manager with their request.

CDU 340B "Other Pharmaceuticals" Introduction

"Other Pharmaceuticals" is defined as CDU approved pharmaceuticals used for contraception and to treat non-reportable STIs and infections that may result in pelvic inflammatory disease, ectopic pregnancy, or infertility.

Eligible CDU 340B sub-recipients may order other pharmaceuticals from their preferred vendor under CDU's 340B STD designation.

340B medications cannot be used for EPT (retail).

CDU 340B Other Pharmaceutical Eligible Use

Wyoming Public Health Nursing (PHN) 340B sub-recipients that do not have an independent 340B designation such as a Title X or FQHC.

CDU 340B Other Pharmaceutical Enrollment and Recertification

All entities wishing to become sub-recipients of the CDU 340B Program must meet eligibility requirements, request enrollment from the Prevention Program Manager, and if approved comply with all CDU 340B Program requirements.

Sub-recipients must notify the CDU 340B Coordinator if the 340B contact for their site changes and update their OPAIS 340B account when 340B contact or address (street, billing, shipping) changes occur.

The sub-recipient must meet the following criteria to be recertified each year:

- OPAIS account information must be complete, accurate, and correct.
- The sub-recipient meets all 340B Program eligibility requirements.
- The sub-recipient will comply with all requirements and any accompanying regulations including, but not limited to, the prohibition against duplicate discounts and diversion, more information available at https://www.hrsa.gov/opa/340b-opais.
- The sub-recipients maintains auditable records (reporting) pertaining to compliance with the requirements.
- The sub-recipient acknowledges its responsibility to contact CDU as soon as possible if there is any change in 340B eligibility and/or breach by the sub-recipient.

All staff handing 340B medications from CDU or purchased under CDU's 340B STD or TB designations must read the current CDU 340B & Retail Medication Guidance and write their name, signature, and date on the location's CDU 340B & Retail Medication Compliance Log before handling 340B or retail medications from CDU or purchased under CDU's 340B STD or TB designations.

CDU 340B Other Pharmaceutical Requirements

- Wyoming PHN office has established a 340B account with a pharmaceutical supplier.
- Your 340B ID Number (to set up that account) can be found at https://340bopais.hrsa.gov/.
- Provide a list of the clinic's funding source(s) for contraceptive purchase.
- PHN office agrees to log all distribution of contraceptives.

CDU 340B Other Pharmaceutical Ordering

Sub-recipients may order other pharmaceuticals from their preferred 340B vendor under their CDU 340B STD designation. Note: This is limited to CDU approved pharmaceuticals used for contraception and to treat non-reportable STIs and infections that may result in pelvic inflammatory disease, ectopic pregnancy, or infertility.

CDU 340B Other Pharmaceutical Reporting

Sub-recipients are required to maintain purchase records and log the administration of other pharmaceuticals purchased under CDU's 340B STD designation.

- Clinic must maintain records of other pharmaceuticals purchased under CDU's 340B STD designation. Purchase records must be available upon request and for audits.
- Must log medications
  - Log must meet CDU requirements (below).
  - Log must be available upon request and for audits.
  - Log must be up to date by the 7th of the month following the month the contraception was dispensed.

CDU 340B Other Pharmaceutical Log Requirements

1) Facility Name
2) Date Medication Provided
3) Patient First Name
4) Patient Last Name
5) Patient DOB
6) Patient Insurance: Uninsured, Private Insurance, Medicaid
7) Diagnosis (STI only)
8) Medication
9) Medication Lot number
10) NDC number
11) Medication Expiration date.

CDU 340B Storage

340B and retail purchases must be labeled and stored separately from each other.

Duty to Report 340B Designation

Sub-recipients must inform the CDU 340B Coordinator if they begin to receive Title X or other 340B qualifying funding.

340B Other Pharmaceutical Audit Procedures

The CDU will perform initial in-person audits at all sub-recipient facilities which participate in the 340B program. Future audits may be virtual. Audits are intended to assure that 340B purchases are being stored and used properly by each sub-recipient. Sub-recipients will likely be audited once every three to four years. Sub-recipients will receive notification of an upcoming audit at least thirty (30) days prior to the date of the audit. Sub-recipients will need to provide required training and reporting documentation at least one (1) week prior to an audit. Requested documentation during audit may include patient charts, receipt of 340B medication purchases, and logs of administration, expiration, and short dating of 340B medications. The CDU will provide an audit report to sub-recipients not more than thirty (30) days after the audit. If findings during the audit require attention, sub-recipients will be expected to respond within thirty (30) days of notice. Please see *Audit Notification* and *Audit Findings* forms in the appendix.

340B Other Pharmaceutical Corrective Action Plan

In the event that a sub-recipient is found to be non-compliant with any 340B regulation (i.e. medications used on a Medicaid patient, medication use not reported properly, failure to report administration, short dates, or expiration), CDU will be made aware of the infraction immediately. If appropriate, the CDU will create a corrective action plan with the sub-recipient. A corrective action plan will be designed to resolve incorrect practices so that errors do not occur again.

Sub-recipients will have sixty (60) days after the implementation of a corrective action plan to correct all identified errors and complete corrective actions. If a corrective action plan does not successfully fix the identified problems, a new corrective action plan may be required.

Sub-recipients that are not in compliance with regulations may be responsible for payment of the difference in cost of medications between 340B and retail prices and may be denied further orders if not able to comply with regulations.

CDU Expedited Partner Therapy (EPT) (retail) Introduction

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. While it is preferred that all partners be tested prior to treatment, partners are not always able or willing to access testing. The CDU provides EPT (retail) medications at no cost to eligible locations; these medications are purchased at retail prices and are not purchased through the 340B program. This program is primarily designed for, but not limited to, locations offering safety-net STI testing services, to the uninsured partner(s) of patients with a positive chlamydia or gonorrhea result.

EPT (retail) may be used in place of 340B medications in some circumstances. If a situation arises where the clinic would like to use EPT (retail) in place of 340B contact the CDU 340B Coordinator.

CDU EPT (retail) Enrollment

All entities wishing to become CDU EPT Sites must meet eligibility requirements, request enrollment from the Prevention Program Manager and if approved comply with all CDU EPT (retail) requirements. All staff handing CDU EPT (retail) medications must read the current CDU EPT (retail) Medication Guidance and write their name, signature, and date on your location's CDU 340B & Retail Medication Compliance Log before handling EPT (retail) medications from CDU.

CDU EPT (retail) Eligible Use

CDU EPT (retail) medications can be provided to EPT Eligible Site clinic patients who test positive for chlamydia or gonorrhea. The clinic patient will then provide the CDU EPT medication packet to their sexual partner(s) at risk for chlamydia or gonorrhea.

An individual is a clinic patient of the EPT Eligible Site if:

- the EPT Eligible Site has established a relationship with the clinic patient, such that the site maintains records of the individual's health care; ***and***
- the clinic patient receives health care services from a health care professional who is either employed by the site or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the EPT Eligible Site.

A clinic patient will not be considered a patient of the site if the only health care service received by the individual from the site is the dispensing of a medication.

Individuals with insurance may receive EPT (retail) medications from the CDU however, priority should be given to individuals without insurance.

CDU EPT Eligible Sites cannot charge for EPT medication(s) provided by CDU or charge the patient a fee for providing CDU EPT medications.

CDU EPT (retail) Medication Information

The CDU provides EPT (retail) STI medications for treatment of STIs. The medications that are available include, but may not be limited to:

- Azithromycin
- Doxycycline
- Cefixime

CDU EPT (retail) Medication Ordering

Eligible sites may order EPT (retail) medications directly from CDU by completing the current CDU ordering form linked on the CDU Prevention website at under the Supplies heading. https://health.wyo.gov/publichealth/communicable-disease-unit/hiv-prevention-program/

To protect shipments and maintain the quality of temperature controlled shipments, CDU medication and supply orders are mailed on Mondays through Wednesdays only.

Treatment of Pharyngeal Gonorrhea

The partner(s) of clinic patients with pharyngeal gonorrhea **MAY NOT** receive CDU EPT and must seek testing and treatment in the office.

> *The only recommended treatment for uncomplicated gonococcal infection of the pharynx is 500mg Ceftriaxone. No reliable alternative treatments are available for pharyngeal gonorrhea.*
> *2021 CDC STI Treatment Guidelines*

CDU EPT (retail) Medication Dispensed Reporting

Eligible sites are required to report all dispensed CDU EPT (retail) medications on the Google Form below and this must be reported by the 7th of the month following the month the medication was dispensed. If medications are not reported by an EPT eligible site, new orders from that EPT eligible site will be held until reporting has been updated.

CDU EPT STI Medication Dispensed Reporting Form: https://forms.gle/YwEthd6aeyUKFh5d8

CDU EPT (retail) Short Dated Medication Reporting

In an effort to decrease wastage, sub-recipients receiving EPT (retail) STI medications from CDU must complete the Short Date Reporting Google Form below three months before the expiration date for any CDU supplied EPT (retail) medications which will not use prior to the expiration date. The CDU may ask sites to return short dated EPT (retail) medications so they may be redistributed elsewhere for use before the expiration date. The eligible site may invoice CDU for reimbursement of postage costs related to returning CDU EPT (retail) medications to CDU.

Short Date Reporting Form: https://forms.gle/1qzBN3XzKqP9fBnM7

Invoices and receipts for postage costs associated with returning short date medications to CDU may be sent to:

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

CDU EPT (retail) Expired Medication Reporting

Clinics receiving EPT (retail) medications from CDU must report the expired EPT (retail) medications via the Google Form below no later than the 7th of the month following the expiration date. Expired medications do not need to be returned to the CDU. Please dispose of them as per your organization's policy.

Expired Reporting Form: https://forms.gle/1mZvmzbYVoEn4GzS7

CDU EPT (retail) 'None Given' Reporting

Clinics receiving EPT (retail) medications from CDU must report when they do not administer EPT (retail) STI medications over the course of the calendar month. 'None Given' reporting must be completed on the Google Form by the 7th of the month following the month with 'None Given'.

None Given Reporting Form: https://forms.gle/wu9hxFj1jVAyB54T6

CDU EPT (retail) Medication Storage

EPT (retail) and 340B medications must be labeled and stored separately from each other.

CDU EPT (retail) Eligible Site Audit Procedures

The CDU may perform initial in-person audits at all EPT Eligible Sites which participate in the CDU EPT program. Future audits may be virtual. Audits are intended to assure that medications are being stored and used properly by each EPT Eligible Site. Sites will likely be audited once every three to four years. Sites will receive notification of an upcoming audit at least thirty (30) days prior to the date of the audit. Sites will need to provide required reporting documentation at least one (1) week prior to an audit. The CDU will provide an audit report to Site not more than thirty (30) days after the audit. If findings during the audit require attention, Sites will be expected to respond within thirty (30) days of notice.

CDU EPT (retail) Corrective Action Plan

In the event that an EPT Eligible Site is found to be non-compliant with the CDU EPT (retail) guidance (i.e. medication use not reported properly, failure to report administration, short dates, or expiration), CDU will be made aware of the infraction immediately. If appropriate, the CDU will create a corrective action plan with the EPT Eligible Site. A corrective action plan will be designed to resolve incorrect practices so that errors do not occur again.

EPT Eligible Sites will have sixty (60) days after the implementation of a corrective action plan to correct all identified errors and complete corrective actions. If a corrective action plan does not successfully fix the identified problems, a new corrective action plan may be required.

EPT Eligible Sites that are not in compliance with regulations may be responsible for reimbursing the cost of the medications and may be denied further orders if not able to comply with regulations.

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/.

WDH Communicable Disease Unit 340B &

Retail Medication Guidance Compliance Log

By signing this sheet, I acknowledge that I have read the most current CDU 340B and Retail Guidance.

Facility Name: _____

NAME	SIGNATURE	DATE

Wyoming Department of Health

Public Health Nursing
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122 West 25th Street, 3rd Floor West
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Stefan Johansson
Director

Mark Gordon
Governor

Friday, July 22, 2022

Ref: PHSS-[xxxx]-[xxx]

Re: 340B Audit

Dear [Insert Name],

The Wyoming Department of Health Communicable Disease Unit (CDU) has selected your facility for a 340B audit. Your audit is scheduled to occur on [Insert Day, Date, Time]. 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, dispensing, and reporting of 340B medications for the clinic. The audit will be conducted in-person by CDU staff. Please ensure meeting space is available for the audit. During the audit, you will be asked to provide information pertaining to the administration of 340B medications in your facility.

Pre-audit information is 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]- 340B" by [Insert Day and Date].

Pre-Audit Information:

1. List of nurses in the clinic who order, dispense, or report medications.
2. Training documentation for all staff involved in the ordering, dispensing, or reporting of medications. Documentation should include names of staff and dates that training was completed. 340B Training modules are at https://www.340bpvp.com/education/340b-u-ondemand/. Staff should complete the following modules: *Introduction, Eligibility Overview, and Compliance Cornerstones.*
3. Documentation that staff involved in the ordering, dispensing, or reporting of medications has read the CDU 340B guidance. Guidance can be found at https://health.wyo.gov/wp-content/uploads/2021/06/FINAL-June-2021-CDU-340B-Contraceptives-EPT-Guidance.pdf

Audit Procedure:

The in person audit will include the following:

Physical inspection of medication storage
Review of work flow process (especially Medicaid/insurance determination for patients)
Review of 5-10 patient records
Review of Google Drive Logs and WyIR

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: Debi Anderson, Manager, Communicable Disease Unit, Public Health Division
Melanie Pearce, CDU Liaison, Public Health Nursing, Public Health Division

Wyoming Department of Health

Public Health Nursing
Public Health Division
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Stefan Johansson
Director

Mark Gordon
Governor

Friday, July 22, 2022

Ref: [Reference Letter #]

Re: 340B Audit

Dear [Insert name]:

The Wyoming Department of Health (WDH) Communicable Disease Unit (CDU) visited your facility for a 340B audit on [Insert Date and Time]. Below are the audit results:

Items checked below were found to be in compliance:

- ☐ Nursing staff has read 340B Guidance
- ☐ Nursing staff has completed appropriate 340B training
- ☐ 340B STD medications stored and labeled properly (exempt for Title X clinics)
- ☐ 340B TB testing supplies stored and labeled properly
- ☐ 340B contraceptive medications stored and labeled properly
- ☐ EPT Medications stored separately from all 340B medications
- ☐ Patient chart audits including insurance information, diagnosis, medications, primary nurse, risk assessment
- ☐ Record of medication ordering, administration, short date, and expirations appropriately logged

Items that are not checked were found to not be in compliance. Please respond to the items that were note in compliance by letter or email within 30 days. If these items are not responded to within 30 days, a corrective action plan will be established.

We appreciate your commitment to assuring compliance for the 340B program by letting us visit your facility for this audit. 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: Debi Anderson, Manager, Communicable Disease Unit, Public Health Division
Melanie Pearce, CDU Liaison, Public Health Nursing, Public Health Division