

**340B Drug Pricing and  
Expedited Partner  
Therapy Program  
Guidance for Program  
Participants**

**Communicable Disease Unit  
Prevention Program**

Additional information may be obtained from:

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

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## **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 bicillin for treatment of syphilis, health care organizations with their own 340B designation are not eligible for CDU 340B medications. See FQHC and Title X Funded Clinics on page nine for exceptions.

The CDU supplies STD antibiotics and TST supplies at no cost to eligible, compliant 340B sub-recipients in the state of Wyoming through this program.

## **Enrollment and Recertification**

All entities wishing to become sub-recipients of the CDU 340B Program must meet eligibility requirements, apply for the program, and if approved comply with all CDU 340B Program requirements.

Bicillin for treatment of syphilis may be available to non-340B sub-recipients, please see Bicillin For Treatment of Syphilis on page eight.

## **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 with 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.

## **Medication Information**

The CDU provides medications for treatment of sexually transmitted diseases (STDs) and testing supplies for tuberculosis (TB). The medications and supplies that are available include, but are not limited to:

- Azithromycin
- Bicillin
- Ceftriaxone
- Doxycycline
- Cefixime
- Xylocaine
- Aplisol
- TB Syringes

## **Sub-recipient Requirements**

All sub-recipient facility staff involved in the administration, ordering, or dispensing of 340B medications must read this 340B Guidance and complete the following modules of the 340B University online training:

*Introduction*

*Eligibility Overview*

*Compliance Cornerstones*

*340B Hot Topics*

That training is located at <https://www.340bpvp.com/education/340b-u-ondemand/> .

## **Sub-Recipient Ordering**

Sub-recipients may order medications and supplies from CDU by completing the appropriate Google Form.

CDU 340B STD medications ordering: <https://forms.gle/C3xAXxLKYYV5BBpNd8>

CDU Retail EPT STD Medication Ordering: <https://forms.gle/qKRra15nubwDBDRqU9>

CDU 340B TB Program Ordering: <https://forms.gle/5VP9jnvKiphqVDc49>

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

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

Wyoming Communicable Disease Unit  
Prevention Program  
122 West 25<sup>th</sup> Street, 3<sup>rd</sup> Floor West  
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Sub-recipients may invoice CDU, at the above address, for reimbursement of postage costs related to returning TB coolers, ice packs, and coolers boxes to CDU.

### **Medication Reporting**

Sub-recipients are required to report the administration of all 340B medications. STD medication use must be documented on the appropriate Google Form.

CDU TB testing: Must be reported in the Wyoming Immunization Registry (WyIR)

CDU 340B STD Medication Administration Reporting: <https://forms.gle/dN1Mcf354yYtRzZB7>

CDU EPT STD Medication Administration Reporting: <https://forms.gle/YwEthd6aeyUKFh5d8>

340B and EPT medication may be reported as part of the charting process when it is given to the patient or sub-recipient staff may use a log and enter the information into the appropriate Google Form on a monthly basis. If reported on a monthly basis they must be reported by the 7<sup>th</sup> 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.

### **Short Dated Medication and Supplies**

In an effort to decrease wastage, complete the Short Date Reporting Google Form three months before the expiration date for any CDU supplied medications or TB supplies the sub-recipient will not use prior to the expiration date. The CDU may ask sub-recipients to return short dated medications or supplies 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 CDU STD Medication and TB Testing Supply Reporting:  
<https://forms.gle/1qzBN3XzKqP9fBnM7>

Invoices 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 25<sup>th</sup> Street, 3<sup>rd</sup> Floor West  
Cheyenne, WY 82002

### **Expired Medication and Supplies**

In the event that a sub-recipient has expired medication(s) or supplies provided by CDU, the sub-recipient must complete the appropriate Google Form to report the expired medication(s) and supplies no later than the 7<sup>th</sup> 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 CDU STD Medication, TB Serum, and TB Syringe Reporting:

<https://forms.gle/1mZvmzbYVoEn4GzS7>

### **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.

### **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 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. 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 and Retail Expedited Partner Therapy (EPT)**

Retail Expedited Partner Therapy (EPT) is the practice of treating the sex partners of persons with sexually transmitted diseases (STDs) without a clinical assessment by a health care provider. The CDU provides Retail EPT medications at no cost to eligible locations; these medications are not purchased through the 340B program. EPT and 340B medications must be labeled and stored separately from each other. 340B medications cannot be used for EPT. EPT may be used in place of 340B medications under some circumstances. If a situation arises where the organization would like to use EPT in place of 340B please contact the CDU 340B Coordinator.

### **Reporting ‘None Given’**

Clinics with CDU 340B and/or Retail EPT stock that do not administer stock over the course of the calendar month must report none given by the 7<sup>th</sup> of the follow month using the Google Form.

340B and/or Retail EPT None Given Reporting: <https://forms.gle/wu9hxFj1jVAyB54T6>

### **FQHCs 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 STD medications from CDU. However, if CDU funding is available, FQHCs and Title X funded clinics in Wyoming can invoice CDU for reimbursement of 340B STD medications the FQHC or Title X funded clinic has purchased from their 340B medication supplier. For questions regarding FQHC or Title X funded clinic STD medication reimbursement please contact the CDU Prevention Program Manager.

Approved invoices may be sent to:

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Cheyenne, WY 82002

### **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.

### **Bicillin for Treatment of Syphilis**

There is a 340B provision which allows CDU to provide bicillin to non-340B sub-recipients for treatment of syphilis. Non-340B entities in need of bicillin for treatment of syphilis may contact the CDU Prevention Program Manager.



## Communicable Disease Unit Staff Directory

### **ADAMS, Kim**

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#### **Manager**

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### **PETERSON, Matthew**

#### **Communicable Disease Epidemiologist**

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•www.health.wyo.gov



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Michael Ceballos  
Director

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Mark Gordon  
Governor

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Friday, July 10, 2020

Ref: PHSS-2020-XXX

Re: 340B Audit

Dear [name of PHN manager]:

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 date and 2 hour block of 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 PHN office name here]" by [insert date 1 week prior to audit].

**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, Compliance Cornerstones, and 340B Hot Topics.*

**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 Forms data and WyIR PPD records

If you have any questions or concerns please contact Matt Peterson at [matthew.peterson@wyo.gov](mailto:matthew.peterson@wyo.gov) or 307-777-6563.

cc: Debi Anderson, Manager, Communicable Disease Unit, Public Health Division  
Leslie Fowler, Prevention Program Manager, Communicable Disease Unit, Public Health Division  
Melanie Pearce, Communicable Disease Liaison, Public Health Nursing, Public Health Division



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Michael Ceballos  
Director

Mark Gordon  
Governor

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Monday, June 15, 2020

Ref: PHSS-2020-

Re: 340B Audit

Dear [name of PHN nurse manger],

[Name of person how conducted audit] visited your facility on behalf of the Wyoming Department of Health (WDH) Communicable Disease Unit (CDU) for a 340B audit on [date of audit]. Below are the audit results.

Items checked below were found to be in compliance:

- Training documentation for nursing staff
- Nursing staff has read 340B External Guidance
- STD Medication stored properly
- TB testing supplies stored properly
- EPT medications stored separately from 340B medications
- Patient chart audits including insurance information, diagnosis, medications, nurse, risks
- WyIR PPD Records
- CDU 340B Google Form Data

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

We appreciate your commitment to assuring compliance for the 340B program. If you have further questions, please contact Matt Peterson at [matthew.peterson@wyo.gov](mailto:matthew.peterson@wyo.gov) or 307-777-6563.

Sincerely,

Matthew Peterson  
340 Coordinator  
Communicable Disease Unit  
Public Health Division

cc: Debi Anderson, Manager, Communicable Disease Unit, Public Health Division  
Leslie Fowler, Prevention Program Manager, Communicable Disease Unit, Public Health Division  
Melanie Pearce, Communicable Disease Liaison, Public Health Nursing, Public Health Division