

340B Drug Pricing, Expedited Partner Therapy (EPT), and Contraceptive Programs

External 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 25th Street, 3rd Floor West
Cheyenne, WY 82002

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Notice

The Wyoming Communicable Disease Unit 340B STD medication, TB serum, TB syringe, and contraceptive programs as well as the EPT program are subject to availability of grant funding.

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 diseases (STDs) and tuberculin skin test (TST) supplies at no cost to eligible, compliant 340B sub-recipients in the state of Wyoming through this program.

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 OPAIS accounts:

- 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 hrsa.gov/opa/340b-opais/index.html)
- 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.

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.

340B Medication Information

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

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

340B Sub-Recipient Requirements

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

Introduction

Eligibility Overview

Compliance Cornerstones

340B Hot Topics

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

340B Sub-Recipient Medication Ordering

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

CDU 340B STD Medication Order Form: <https://forms.gle/C3xAXxLKYYV5BBpNd8>

CDU 340B TB Program Order Form: <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 cooler boxes 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.

Sub-recipients may also choose to order STD medications, TB serum, TB syringes, and contraceptives from their preferred 340B vendor under their CDU 340B designation. Note: This is limited to STD medications, TB serum, TB syringes, and contraceptives.

340B Medication Administration Reporting

Sub-recipients are required to report the administration of all 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 STD medications from the CDU:

- Must report 340B STD medication administration on the Google form.
340B STD Medication Administration Reporting Form
<https://forms.gle/dN1Mcf354yYtRzZB7>

Clinics receiving 340B TB serum and syringes from the CDU or under the CDU's 340B designation:

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

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

- Must maintain records of medications purchased under CDU's 340B 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 (STD only)
- 8) Medication
- 9) Medication Lot #
- 10) Medication Expiration date

Clinics that purchase approved CDU STD medications under CDU's 340B 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

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 below three months before the expiration date for any CDU supplied 340B STD 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>

Approve 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

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 below 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>

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

340B ‘None Given’ Reporting

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

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

340B Medication Storage

340B and Expedited Partner Therapy (EPT) medications must be labeled and stored separately from each other. 340B medications cannot be used for EPT.

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 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 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 STD Medications from CDU. If CDU funding is available, FQHCs and Title X funded clinics in Wyoming can invoice CDU for reimbursement of approved 340B STD medications purchased by the FQHC or Title X funded clinic from their 340B STD medication vendor. For questions regarding FQHC or Title X funded clinic STD medication reimbursement please contact the Prevention Program Manager.

Approved invoices and purchase records may be sent to:

Wyoming Communicable Disease Unit
Prevention Program
122 West 25th Street, 3rd Floor West
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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.

340B Contraceptive Introduction

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

340B Contraceptive Eligible Use

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

340B Contraception 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 hrsa.gov/opa/340b-opais/index.html)
- 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.

340B Contraceptive Availability

Complete CDU 340B Checklist.

340B Contraceptive 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.

340B Contraceptive Ordering

Sub-recipients may order contraceptives from their preferred 340B vendor under their CDU 340B designation. Note: This is limited to STD medications, TB serum, TB syringes, and contraceptives.

340B Contraceptive Program Reporting

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

- Clinic must maintain records of contraceptives purchased under CDU's 340B 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 Contraceptive 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 (STD only)
- 8) Medication
- 9) Medication Lot #
- 10) Medication Expiration date.

340B Contraceptive Storage

340B and retail contraceptives 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 Contraceptive 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 Contraceptive 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.

Expedited Partner Therapy (EPT) Program Introduction

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. 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 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 STD testing services, to the uninsured partner(s) of patients with a positive chlamydia or gonorrhea result.

EPT Program Enrollment

All entities wishing to become CDU EPT Sites must meet eligibility requirements, request enrollment from the Prevention Program Manager, complete the CDU EPT Program Enrollment Form, and if approved comply with all CDU EPT Program requirements.

EPT Program Eligible Use

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

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

- the EPT Eligible Site has established a relationship with the individual, such that the site 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 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.

An individual 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 medications from the CDU STD Medication Program 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.

EPT Program Medication Information

The CDU provides EPT STD medications for treatment of STDs. The medications that are available include, but may not be limited to:

- Azithromycin
- Doxycycline
- Cefixime

EPT Program Facility Requirements

EPT medication ordering and reporting as per program guidelines (below).

EPT Program Medication Ordering

Eligible sites may order EPT medications from CDU by completing the Google Form below.

CDU EPT STD Medication Ordering Form: <https://forms.gle/qKRal5nubwDBDRqU9>

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

EPT Program Medication Dispensed Reporting

Eligible sites are required to report all dispensed CDU EPT 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 STD Medication Dispensed Reporting Form: <https://forms.gle/YwEthd6aeyUKFh5d8>

EPT Program Short Dated Medication Reporting

In an effort to decrease wastage, sub-recipients receiving EPT STD medications from CDU must complete the Short Date Reporting Google Form below three months before the expiration date for any CDU supplied EPT medications which will not use prior to the expiration date. The CDU may ask sites to return short dated EPT 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 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

EPT Program Expired Medication Reporting

Clinics receiving EPT medications from CDU must report the expired EPT 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>

EPT Program 'None Given' Reporting

Clinics receiving EPT medications from CDU must report when they do not administer EPT STD 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>

EPT Program Medication Storage

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 in some circumstances. If a situation arises where the clinic would like to use EPT in place of 340B please contact the CDU 340B Coordinator.

EPT Program 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.

EPT Program Corrective Action Plan

In the event that an EPT Eligible Site is found to be non-compliant with the CDU EPT policy (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

ADAMS, Kim

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Communicable Disease Prevention Program Manager

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Vacant

Communicable Disease Epidemiologist Communicable Disease 340B Coordinator Communicable Disease TB Controller

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Vacant

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Michael Ceballos
Director

Mark Gordon
Governor

DATE

Ref: PHSS-20xx-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 the 340B Coordinator at 307-777-6563.

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



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•www.health.wyo.gov



Michael Ceballos
Director

Mark Gordon
Governor

DATE

Ref: PHSS-20xx-xxx

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 the 340B Coordinator at 307-777-6563.

Sincerely,

340B Coordinator
Communicable Disease Unit
Public Health Division

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