DEPARTMENT OF HEALTH

Expedited Partner Treatment (EPT) Toolkit for Minnesota Pharmacies

GUIDANCE FROM THE MINNESOTA DEPARTMENT OF HEALTH

Expedited Partner Therapy (EPT) Toolkit for Minnesota Pharmacies

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Purpose Statement and Legal Disclaimer

The purpose of this document is to provide Minnesota pharmacies, pharmacists, pharmacy technicians, and other pharmacy staff comprehensive and clear guidance regarding the practice, clinical appropriateness, and dispensing requirements of expedited partner therapy (EPT) in the state of Minnesota. **Legal advice is not provided within this document. Consultation with your and/or your organization's legal counsel is recommended if there are questions about the law, rules, statutes, and practices presented herein.**

Introduction to Expedited Partner Therapy (EPT)

Background and Rationale

Expedited partner therapy (also known as EPT, expedited partner treatment, or partner-delivered partner treatment) is a harm reduction strategy and is defined as:

> ***The practice of treating sexual partners of patients diagnosed with certain qualifying sexually transmitted infections by providing antimicrobial treatment and education for their partner(s) without a formal medical examination by a healthcare provider.***

The potential public health benefits of EPT include:

- To reduce the number of reinfections and persistent infections, especially amongst index patients
- To reduce complications associated with untreated sexually transmitted infections (STIs)
- To decrease the probability of acquisition of other STIs, including HIV
- To decrease overall antimicrobial exposure and thus, slow the development of antimicrobial resistance (AMR)

To address the increasing incidence of preventable sexually transmitted infections and their complications, the use of EPT in Minnesota is endorsed by the following agencies and professional organizations that are a part of the multidisciplinary medical community:

- Centers for Disease Control and Prevention
- American Osteopathic Association
- American Medical Association
- American Academy of Family Physicians
- American College of Obstetrics and Gynecology
- The Society for Adolescent Medicine
- American Academy of Pediatrics
- Minnesota Department of Health
- Minnesota Medical Association
- Minnesota Public Health Association
- Minnesota Pharmacists Association
- Minnesota Society of Health-System Pharmacists
- Minnesota Academy of PAs
- Minnesota Nurse Practitioners

- University of Minnesota College of Pharmacy
- University of Minnesota Medical School

While the ideal approach would all partners being promptly notified of their exposure(s) and being evaluated, tested, and treated with preferred treatment regimens, this may not always be feasible. **The CDC and/or MDH recommend that when partners of patients diagnosed with the following qualifying STIs are unable or unlikely to seek timely evaluation and treatment, EPT is recommended**:

- Chlamydia
- Gonorrhea
- Trichomoniasis*

* The 2021 CDC STI guidelines note "EPT might have a role in partner management for trichomoniasis, however no partner management intervention has been demonstrated to be superior in reducing reinfection rates." Some, but not all states offer EPT for infections due to *T. vaginalis.* Due to the potential consequences of untreated *T. vaginalis* infections, MDH allows licensed providers to prescribe EPT for trichomoniasis in Minnesota.

Impact on Antimicrobial Resistance

It is important to remember that recipients of EPT have a reasonable indication for antimicrobial therapy and that untreated STIs can have devastating consequences, many of which require more aggressive antimicrobial therapy such as pelvic inflammatory disease (PID). Concerns of EPT's potential impacts on bacterial ecology and antimicrobial resistance have been raised, however recall above that one of the goals of EPT is to reduce the number of reinfections and persistent infections, both of which would require additional antimicrobial therapy. Additionally, considering the number of incident cases of STIs amenable to EPT each year and the already staggering number of antimicrobials prescribed for a variety of other indications, the potential impact of EPT on antimicrobial resistance would not be expected to be significant. As treatment recommendations for index patients continue to evolve, we anticipate that the regimens recommended for EPT will evolve as well. Optimizing the pharmacokinetics and pharmacodynamics (PK/PD) of antimicrobials can play a significant role in deterring the future development of resistance. Further research to elucidate the optimal dose, frequency, and durations of the antimicrobials that are used in the treatment of both index patients and partners via EPT will be important to ensure any contribution to AMR by using EPT is minimized. It should be noted that drug resistant *Neisseria gonorrhoeae* has been identified as an urgent threat in the 2019 CDC Antimicrobial Resistance (AR) Threat Report[1]. EPT is one mechanism that might decrease the number of *N. gonorrhoeae* infections and thus the pathogen's exposure to antimicrobials resulting in slowing the further development of resistance.

Limitations of Evidence Supporting EPT

Published studies of EPT effectiveness primarily included heterosexual individuals. There is less certainty of the effectiveness of EPT due to limited evidence and complexity in certain aspects of care in the following populations:

- Men who have sex with men (MSM)

- Adolescents*
- Pregnant women

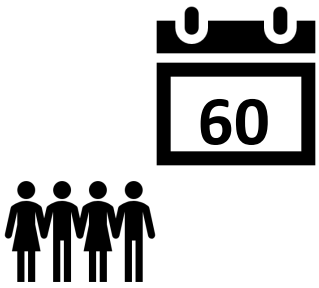
*Minnesota Statutes, Section 144.343 says, "[a]ny minor may give effective consent for medical, mental and other health services to determine the presence of or to treat pregnancy and conditions associated therewith, venereal disease, alcohol and other drug abuse, and the consent of no other person is required), see the section entitled "Providing EPT to Minors (under age 18) in Minnesota" below.

EPT is permissible in the above populations, however healthcare clinicians should make a good faith effort to educate the index patient and their partner(s) about the importance of timely medical evaluation, testing, and treatment using preferred treatment regimens, and use their best judgment to determine whether EPT is appropriate.

MDH Antimicrobial Treatment Recommendations for EPT

Limits on Providing EPT in Minnesota

The following partner quantity and time limits are imposed on EPT in Minnesota:



ALL sexual partners **within the last 60 days** may be offered EPT

If no sexual partners in last 60 days:

The **single most recent** sexual partner may be offered EPT

The Minnesota legislation regarding EPT (Minnesota Statutes, Section 151.37 Subd. 2(g)) was written to meet people where they are and accommodate various life situations, including scenarios in which the index patient may have a significant number of sexual partners (e.g., sex work). EPT may be offered to **all** the sexual partners of the index patient within the 60 days preceding the diagnosis. There is no limit on the number of EPT prescriptions can be issued within this 60-day period. If the index patient reports not having any sexual partners within the last 60 days, EPT may be offered to the single most recent sexual partner.

Antimicrobial Treatment Regimens for Partners of Patients Diagnosed with Qualifying Sexually Transmitted Infections

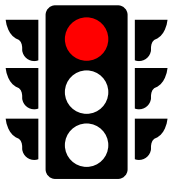
Infection	Preferred Regimen		Alternative Regimens	Safe in Pregnancy*
Chlamydia	Doxycycline 100 mg orally twice daily for 7 days		Azithromycin 1 gram orally for one dose	Azithromycin 1 gram orally for one dose†
Gonorrhea	Cefixime 800 mg orally for one dose		Cefpodoxime 400 mg orally for one dose	Either the preferred or alternative regimen
Trichomoniasis	Female	Metronidazole 500 mg orally twice daily for 7 days	Tinidazole 2 grams orally for one dose‡	Metronidazole 500 mg orally twice daily for 7 days
	Male	Metronidazole 2 grams orally for one dose		

***ALL pregnant partners of index cases should be linked to prenatal care in addition to receiving the recommended antimicrobial treatment regimen(s) listed above**

†For pregnant persons who have contraindications for azithromycin being used for chlamydia EPT, amoxicillin 500 mg orally three times daily for 7 days is an acceptable alternative for EPT

‡For females in whom a 7 day course of metronidazole is not feasible for Trichomoniasis, 2 grams of metronidazole orally for one dose is an acceptable alternative for EPT

All patients should be educated to abstain from ANY sexual activity for 7 days after FINISHING their treatment regimen(s) even if their symptoms improve



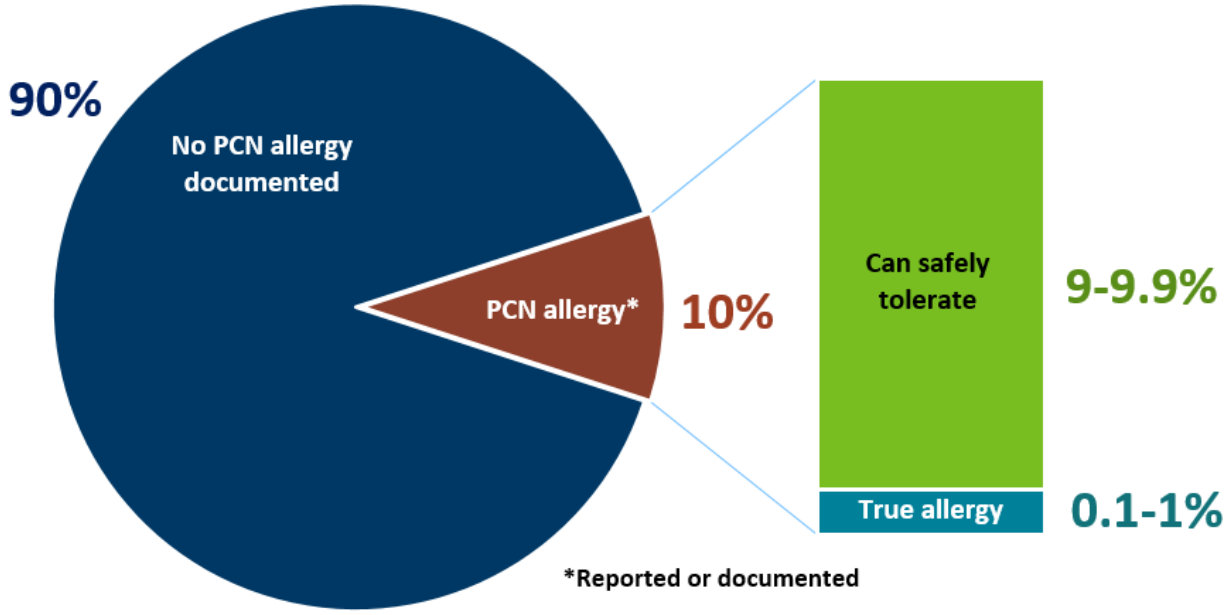
For a printable version of the above table, refer to EPT Regimen Quick Reference.

For recommendations on the management of index cases, please refer to the MDH STD Information for Health Professionals page and/or the 2021 CDC Sexually Transmitted Infection Treatment Guidelines.

Penicillin and Other β-lactam Allergies

At least 10% of patients in the United States have a penicillin allergy listed on their medical record, however when evaluated fewer than 1% of the population are truly allergic to penicillin[2]. Additionally, about 80% of patients with a true penicillin allergy confirmed by skin testing lose their sensitivity to the same penicillin after a period of 10 years[2]. Part of the discrepancy between reported allergy and actual allergy may be due to labeling expected side effects or intolerances as allergies and/or reporting of vague childhood reactions where details are unavailable. These seemingly small details can result in patients not being prescribed optimal antimicrobial treatment when they need it. The presence of a penicillin allergy on a

patient's medical record has been associated with poor health outcomes including increased overall antibiotic exposure and use of healthcare resources, increased prevalence of methicillin-resistant *Staphylococcus aureus* (MRSA) and *Clostridioides difficile* ("C. diff") infections, increased prevalence of vancomycin-resistant Enterococci (VRE), and even an increased cost to both inpatient and outpatient care[3]. Alternatives to penicillins and other β-lactam antibiotics typically have a broader spectrum of activity than is needed, are less effective, have more side effects, and selects for organisms with resistance to many antibiotics[2].



It was previously thought that the shared β-lactam ring was the only explanation for cross-reactivity between the various β-lactam antibiotics. However, more recent research suggests that the R1 and R2 side chains contribute the most to immunological recognition and are most frequently responsible for cross-reactivity[4,5]. This information supports the idea that β-lactam allergies should not be considered a class effect[6] and that early estimates of the rates of cross-reactivity between penicillins and cephalosporins are significantly overestimated. The table below describes the β-lactams used in EPT (cefixime and cefpodoxime) and the other β-lactams that should be used with caution or avoided based on similarities in their R1 and/or R2 side chains. **Note in the following table that neither cefixime nor cefpodoxime share any side chains with any of the penicillins and only have side chain similarities to a select few cephalosporins.**

β-lactam Antibiotic Used in EPT	USE WITH CAUTION if documented severe allergy to any of the following β-lactams (similar side chains):	AVOID USE if documented allergy to any of the following β-lactams (identical side chains):
Cefixime	Ceftaroline	Cefdinir
Cefpodoxime	Cefuroxime, ceftazidime	Cefditoren, cefotaxime, ceftriaxone, cefepime

Allergies to Other Antimicrobials Used for EPT

Macrolides

Despite the decades long history of macrolide use for a variety of infections due to their spectrum activity that includes gram positive, gram negative, and atypical bacteria, documented allergic reactions to any of the macrolides in the literature are very rare[7]. Azithromycin has largely replaced clarithromycin and erythromycin as the macrolide of choice owing to better pharmacokinetics and tolerability[7]. Since 1958, only 31 reports exist (including a total of only about 220 patients) detailing potential azithromycin allergic reactions ranging from mild itching to severe IgE-mediated or delayed hypersensitivity reactions[8]. In the context of countless courses of macrolides taken on an annual basis around the world, it is clear the risk for an allergic reaction to macrolides is incredibly low. There is limited information regarding the potential cross-reactivity between the individual macrolides[8]. Consider using alternatives (if possible) or using azithromycin with caution in patients with well-documented severe reaction(s) to any of the macrolides, including fidaxomicin.

Tetracyclines

Despite widespread use of tetracyclines since the 1940s, documented allergies to these antimicrobials have only very rarely been reported in the literature. Experience with these allergic reactions is limited to case reports and post-marketing surveillance and demonstrate an exceedingly rare incidence of immediate-type IgE-mediated hypersensitivity reactions to the tetracyclines[9]. Tetracycline is no longer widely available in the United States. Doxycycline is considered to be the best tolerated, least immunogenic, and most widely available tetracycline antibiotic. In contrast, minocycline appears to have more reports of non IgE-mediated dermatologic, pulmonary, and/or autoimmune adverse effects possibly owing to the metabolism of the parent compound into iminoquinone metabolites[9]. Most reports of adverse reactions to doxycycline and tetracycline, which do not get metabolized into iminoquinone derivatives, involve mostly mild non IgE-mediated dermatologic effects consisting of fixed erythematous drug eruptions[9]. Based on available information, it is clear the risk for an allergic reaction to tetracyclines, especially doxycycline, is incredibly low. Limited, conflicting evidence exists regarding potential cross-reactivity between the individual agents in the tetracycline class. Of note, an early concern regarding potential cross-reactivity between penicillins and tetracyclines has been disproven[10]. Consider using alternatives or using doxycycline with caution in patients with well-documented serious reaction(s) to other tetracyclines, glyclglycines (e.g., tigecycline), and/or aminomethylcyclines (e.g., omadacycline, eravacycline).

Nitroimidazoles

Nitroimidazoles are a versatile class of anti-infectives that have activity against a variety of pathogens, including obligate and facultative anaerobic bacteria and various protozoa including *T. vaginalis*. Documented hypersensitivity reactions to nitroimidazoles are exceedingly rare and limited to a small number of case reports in the literature[11]. Single digit numbers of IgE-mediated reactions have been reported for both metronidazole and tinidazole. Other possible delayed hypersensitivity reactions are also limited to single digit case reports each and include contact dermatitis, erythematous drug eruptions, serum sickness-like reaction, Stevens-Johnson Syndrome, acute generalized exanthematous pustulosis, and a possible case of drug rash with eosinophilia and systemic symptoms (DRESS) syndrome[11]. Due to the limited therapeutic options and evidence of potential cross-reactivity between metronidazole and tinidazole via patch testing[12], a patient or partner with well-documented severe reaction(s) to any nitroimidazole should be referred to a physician for testing and evaluation of potential need for desensitization to metronidazole and would not be an appropriate patient for EPT. It should also be noted that more recent evidence had shed significant doubt on the concept that mixing alcohol with nitroimidazoles yields a disulfiram-like reaction and must be avoided[13].

Minnesota State Law Regarding Dispensing EPT

Statutory Authority

Statutory authority expressly AUTHORIZES EPT in the State of Minnesota under Minnesota Statutes, Section 151.37, Subd. 2(g): Legend Drugs; Who May Prescribe, Possess. Nothing in this chapter prohibits a licensed practitioner from issuing a prescription or dispensing a legend drug in accordance with the Expedited Partner Therapy in the Management of Sexually Transmitted Diseases guidance document issued by the United States Centers for Disease Control, which references the most CDC's most recent STI prevention and treatment guidelines (found here).

EPT is considered standard of care and broadly endorsed by the interprofessional medical community in Minnesota, therefore prescriptions for EPT should be dispensed from Minnesota pharmacies when prescriptions are issued. Pharmacies are strongly encouraged to process, dispense, and educate patients on EPT medications as outlined in MDH's EPT guidance document (Minnesota Board of Pharmacy News, October 2018). Former Executive Director stated "EPT prescriptions should be considered an order that may reasonably be dispensed by a Minnesota pharmacy, **ideally with a name provided, but also without a partner name provided**." Under MN Rule 6800.2250 Subp. 1(c), "[r]efusing to compound or dispense prescription drug orders that may reasonably be expected to be compounded or dispensed in pharmacies by pharmacists," (including EPT prescriptions) except as provided for in Minnesota Statutes, sections 145.414 and 145.42 is unprofessional conduct and could result in disciplinary action by employers and/or the Board of Pharmacy.

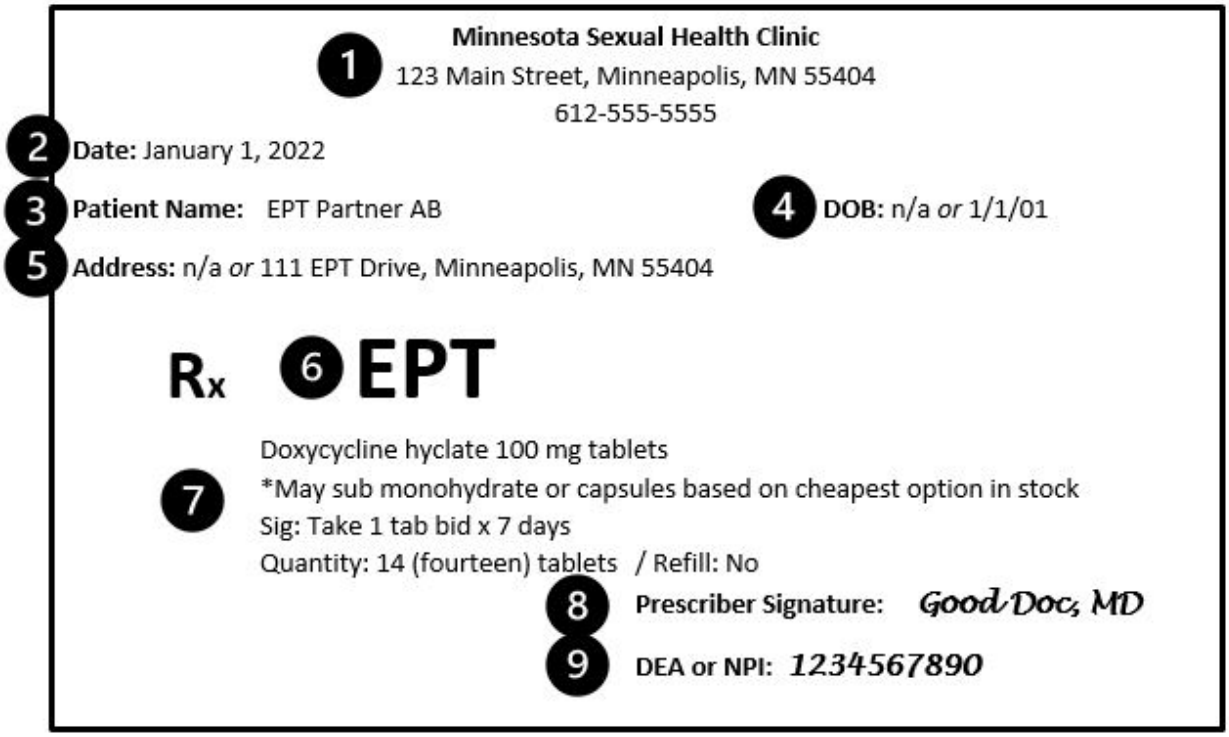
Additionally, pharmacists were involved in developing the EPT legislation language that is found within MN Rule 4605.7700 Subp. B: Sexually Transmitted Disease; Special Reports. "Notwithstanding any previous report, a health care practitioner who treats persons infected

with chlamydial infection, syphilis, gonorrhea, or chancroid shall ensure that contacts are treated or provide the names and addresses of contacts who may also be infected to the commissioner. If known, persons named as contacts to a person with human immunodeficiency virus (HIV) infection, including acquired immunodeficiency syndrome (AIDS), shall be reported to the commissioner."

Pharmacist Refusal

There is no exception for EPT under MN Rule 6800.2250 Subp. 1(c). Subsequently, Minnesota licensed pharmacists that refuse to dispense EPT prescription drug orders could be subject to disciplinary action for unprofessional conduct, however legal counsel should be consulted with questions about this possibility. Additionally, since EPT is considered the standard of care, pharmacist refusal could make the pharmacist vulnerable to liability for choosing not to provide the established standard of care to their patients. This is further discussed below in the section entitled "Pharmacist Liability When Dispensing EPT."

EPT Prescription Requirements



Prescribers are required to follow the requirements for a valid prescription as specified in Minnesota Statutes, Section 151.01 Subd. 16(a) with few allowable exceptions for EPT as shown in the example above and explained **in bold** below:

1. The name of the location with address and phone number at which the EPT prescriber can be reached
2. The date the EPT prescription is issued

3. The name of the patient – **for EPT: if the partner's information is available, this should be included otherwise as shown above, it is NOT required in order to fill and dispense an EPT prescription according to former Board of Pharmacy executive director Dr. Cody Wiberg. Generic dummy names acceptable. The format of generic dummy names is flexible and will vary based on software capability. However, in order to make matching EPT prescriptions to the correct patient as easy as possible, best practice would be to include initials of the index patient (e.g., EPT Partner AB) in the dummy name. Prior to EPT legislation passed in 2008, the patient's name was required.**
4. The date of birth of the patient – **for EPT: if the partner's DOB is available, this should be included otherwise as shown above, it is NOT required in order to fill and dispense an EPT prescription. Blank, "n/a", or generic dummy birthdays (e.g., 1/1/01) are acceptable.**
5. The address of the patient – **for EPT: if the partner's address is available, it should be included otherwise as shown above, it is NOT required in order to fill and dispense an EPT prescription. Blank, "n/a", or generic dummy addresses (e.g., 111 EPT Drive, Minneapolis, MN 55404) are acceptable.**
6. **For EPT: while not required, best practice is to indicate somewhere on the prescription that the intent is the issued prescription will be used for EPT. This indication would explain potentially missing information that would otherwise be required under the statute.**
7. The usual details about the drug being prescribed including full name of the drug including the drug strength, the "sig" or directions which should be as specific as possible to ensure the patient uses the medication properly, the quantity to dispense ideally written both numerically and alphabetically, and the number of refills – **for EPT: refills are not allowed.**
8. Signature of the prescriber (either manual if it is a written prescription or electronic if it is an electronic prescription)
9. The DEA is not required as none of the medications ordered for the purposes of EPT are controlled substances, however including the NPI number of the prescriber is recommended as a best practice (but not required)

For a printable version of the above figure & information, refer to EPT Prescription Requirements Quick Reference.

Transferring EPT Prescriptions Between Pharmacies

A prescription order that meets the above criteria is considered a valid prescription that may be transferred between pharmacies under Minnesota Rule 6800.3120. Potential scenarios in which this may occur include: if the recommended antimicrobial indicated per the guidance herein is not stocked at the pharmacy receiving the EPT prescription, if the EPT recipient is restricted to a particular pharmacy (see the section on providing EPT to partners enrolled in the Minnesota Restricted Recipients Program), and/or based on the index patient or EPT recipient preference.

Can Obstetricians and Gynecologists Issue EPT Prescriptions for Male Partners?

Yes. A prescription order for EPT for a male patient issued by a board-certified obstetrician and gynecologist (OB/GYN) or another licensed medical professional practicing in the specialty is considered valid if the provider is appropriately licensed. This practice is encouraged by the American College of Obstetricians and Gynecologists (ACOG)[14]. Recall that one of the primary goals of EPT is to reduce recurrent and persistent infections (particularly amongst index patients), thus treating the male partner(s) of the index patient is an intervention to reduce the chance of recurrent and/or persistent infection in the index patient (e.g., the OB/GYN provider's patient).

Generic Substitution and Cost Minimization

Minnesota Statutes, Section 151.21, Subd. 4. states that a pharmacist shall not dispense a drug of a higher retail price than that of the drug prescribed and requires the pharmacist to dispense the least expensive available therapeutically equivalent and interchangeable drug product. This is especially important as it pertains to EPT as many partners may not wish to provide their personal information and will be paying out-of-pocket. Other strategies for minimizing cost of EPT prescriptions include:

- Asking the partner(s) for personal information so that it may be billed to their insurance (if applicable)
- Encouraging and accepting the use of prescription coupon cards
- Use of institutional or foundation grant funding for cases in which index patients and/or their partner(s) cannot afford to pay out-of-pocket for EPT

2022 Approximate Cost of Common EPT Regimens in Without Insurance

EPT Condition	EPT Regimen	Approximate Cost in 2022* (w/o insurance)	Comments
Chlamydia	Doxycycline 100 mg orally twice daily for 7 days	$12.00 (tablets) $19.75 (capsules)	Pharmacists legally obligate to dispense cheapest option in stock Cost of hyclate vs. monohydrate may fluctuate, be significantly different
Chlamydia	Azithromycin 1 gram orally for one dose	$12.00	Cost of 250 mg vs. 500 mg tablets may be significantly different
Gonorrhea	Cefixime 800 mg orally for one dose	$44.86	Less widely available and stocked by pharmacies Review section of this guidance re: β-lactam allergies
Gonorrhea	Cefpodoxime 400 mg orally for one dose	$20.48	Less widely available and stocked by pharmacies Review section of this guidance re: β-lactam allergies

EPT Condition	EPT Regimen	Approximate Cost in 2022* (w/o insurance)	Comments
Trichomoniasis	Metronidazole 500 mg orally twice daily for 7 days	$13.24	Affordable, widely available Review EPT regimen variations based on biological sex given at birth
Trichomoniasis	Metronidazole 2 grams orally for one dose	$12.00	Affordable, widely available Review EPT regimen variations based on biological sex given at birth
Trichomoniasis	Tinidazole 2 grams orally for one dose	$38.06	Less widely available and stocked by pharmacies More expensive than metronidazole

*Does not reflect potential savings due to the use of prescription discount coupons and/or differences between pharmacies that may be due to differences in dispensing fees or AWP

Index Patient and/or Partner Required Prescription Counseling

Under MN Rule 6800.0910, Minnesota pharmacists must consult with the patient or patient's agent or caregiver and inquire about the patient's understanding of the use of the drug, including the elements described in Subp. 2(a). Subp. 2(b) says that the pharmacist may vary or omit the patient information, if in the pharmacist's professional judgment, it serves the best interest of the patient. The law also requires that if there is any material variation from the minimal information required by this subpart in the information provided or, if consultation is not provided, that fact and the circumstances involved shall be noted on the prescription, in the patient's records, or in a specially developed log. Elements of the consultation procedure as defined by the rule include:

- Name and description of the drug
- Dosage form, dose, route of administration, and duration of therapy
- Intended use of the drug and expected action
- Special directions and precautions for preparation, administration, and use by the patient
- Common severe side effects, adverse effects,
- Techniques for self-monitoring of drug therapy
- Proper storage
- Prescription refill information (no refills are allowed on EPT prescriptions)
- Action to be taken in the event of a missed dose
- Pharmacist comments relevant to the patient's drug therapy

If the partner presents to the pharmacy, the consultation procedure described herein must occur. However, if the index patient presents to the pharmacy and will deliver the EPT

prescription to their partners, the index patient should be counseled on the partner's prescription. If the index patient or partner refuse the consultation procedure required by MN Rule 6800.0910 Subp. 2, the refusal must be documented as already required in MN Rule 6800.0910 Subp. 2(b). In this situation, best practice is to give the index patient or partner written education documents that can be referenced by the EPT recipient if there are questions. Additionally, a phone number in which the EPT recipient can contact a pharmacist should be emphasized. Patient friendly and translated materials are available on the Minnesota Department of Health EPT website and linked towards the bottom of this document.

Providing EPT to Minors (under the age of 18) in Minnesota

Minnesota Statutes, Sections 144.341-347 allow minors to consent to certain types of health care services without parent or guardian permission. A provision exists specifically for the purposes of determining the presence of or treatment of sexually transmitted diseases (Minnesota Statutes, Section 144.343 Subd. 1), which says, "[a]ny minor may give effective consent for medical, mental and other health services to determine the presence of or to treat pregnancy and conditions associated therewith, venereal disease, alcohol and other drug abuse, and the consent of no other person is required. According to Minnesota Statutes, Section 144.335 Subd. 1(a) and the Minnesota Health Records Act (Minnesota Statutes, Section 144.291 Subd. 2(g)), pharmacists are not allowed to provide a minor's health records to a parent or guardian in the event they are requested). However, Minnesota law (Minnesota Statutes, Section 144.346) allows a medical professional to inform the parent or legal guardian where, in their judgment, failure to inform the parent or guardian would seriously jeopardize the health of the minor. In these cases, best practices encourage a discussion with the minor about why confidentiality is being broken. Consult with your and/or your organization's legal counsel with questions about these provisions.

Filling EPT Prescriptions for Partners Enrolled in the Minnesota Restricted Recipients Program (MRRP)

The Minnesota Restricted Recipient Program (MRRP) is authorized by federal regulations and was developed to improve safety and the quality of care, as well as reduce costs for Minnesota Health Care Program (MHCP) recipients who have misused or abused services. MRRP recipients are required to receive health services only from their designated providers and/or facilities and pharmacies. As of 2021, there were approximately 2,000 Minnesotans enrolled in the program.

MRRP recipients may either be managed by the Minnesota Department of Human Services (DHS) or by managed care organization (e.g., Blue Cross Blue Shield, HealthPartners, UCare). Specific policies relating to the level of restriction and exceptions (e.g., in the event of the need for emergency care or if the recipient's designated provider is not available) vary by the entity that the recipient is managed through. **In general, MRRP recipients must get their EPT prescriptions filled at their restricted pharmacy.** Some entities may require the primary restricted provider to write the prescription while others may issue exceptions and allow other providers (e.g., an emergency department provider) to issue to the prescription.

The MN-ITS system shows the current restriction status of recipients and lists their designated provider, pharmacy, and facility(ies). Only eligible providers (which can include pharmacists or

pharmacies) who are enrolled with MHCP and registered with the MN-ITS system maintain access. If an eligible and registered user is not readily available and you have questions relating to the care of an MRRP recipient at your pharmacy or institution, call DHS at 651-431-2648 or the patient's managed care organization.

Pharmacist Liability When Dispensing EPT

Civil Liability and Standard of Care

As mentioned in previous sections, EPT has been legal in Minnesota since 2008 under Minnesota Statutes, Section 151.37, Subd. 2(g) and has since become the standard of care with nothing prohibiting Minnesota pharmacies from filling EPT prescriptions when issued, according to the Board of Pharmacy. As further evidenced by the guidance herein, including the broad endorsement of the practice of EPT by numerous organizations representing the multidisciplinary medical community in Minnesota, EPT is considered the standard of care in Minnesota. Additionally, pharmacists who refuse to provide their patients services that are consistent with the established standard of care may be responsible for potential harms that result from that standard not being provided. Pharmacists should consult with their personal and/or organization's legal counsel for legal advice and/or questions regarding this issue.

Duty to Warn and the Learned Intermediary Doctrine

A specific area in which pharmacists might minimize any potential liability is through ensuring that any theoretical duty to warn requirement is met, even though an STI may not automatically trigger a legal requirement for duty to warn[15]. In the case of the practice of EPT where the prescriber issues a specific prescription for the partner (even in the absence of identifying information, an established relationship, and/or medical evaluation), the transfer of liability to the drug manufacturer under the learned intermediary doctrine may not apply, and the prescriber or pharmacist *may* have a duty to warn[16]. According to the CDC Legal/Policy Toolkit for Implementation of Expedited Partner Therapy, this duty to warn may be accomplished through either in-person counseling or providing written educational documents[16]. For further clarification or questions on this issue, consult with your and/or your organization's legal counsel. This requirement is discussed in further detail above in the "Index Patient and/or Partner Required Prescription Counseling" section.

Liability Resulting from Adverse Reactions to Antimicrobials Used in EPT

This document gives pharmacists the tools they need to critically evaluate drug allergies as they pertain to antimicrobials used in EPT. Additionally, the risk of adverse reactions to the antimicrobials used in EPT is minimal and can be managed with reasonable care and precautions (which are included in MDH's partner education documents). This results in a low threat of malpractice claims, especially in the setting of practicing the standard of care. It should be noted that a lack of reported judicial decisions does not mean that liability claims have not been filed or that they have not been settled outside of court. One systematic review of professional liability when prescribing β-lactams for a patient with a known penicillin allergy suggests that clinicians are unlikely to be found liable when prescribing a penicillin or carbapenem for a patient with a known penicillin allergy but avoiding cephalosporins with

similar side chains to the agent that caused the allergy is likely legally prudent[17]. However, you should consult with your organization or legal counsel for legal advice.

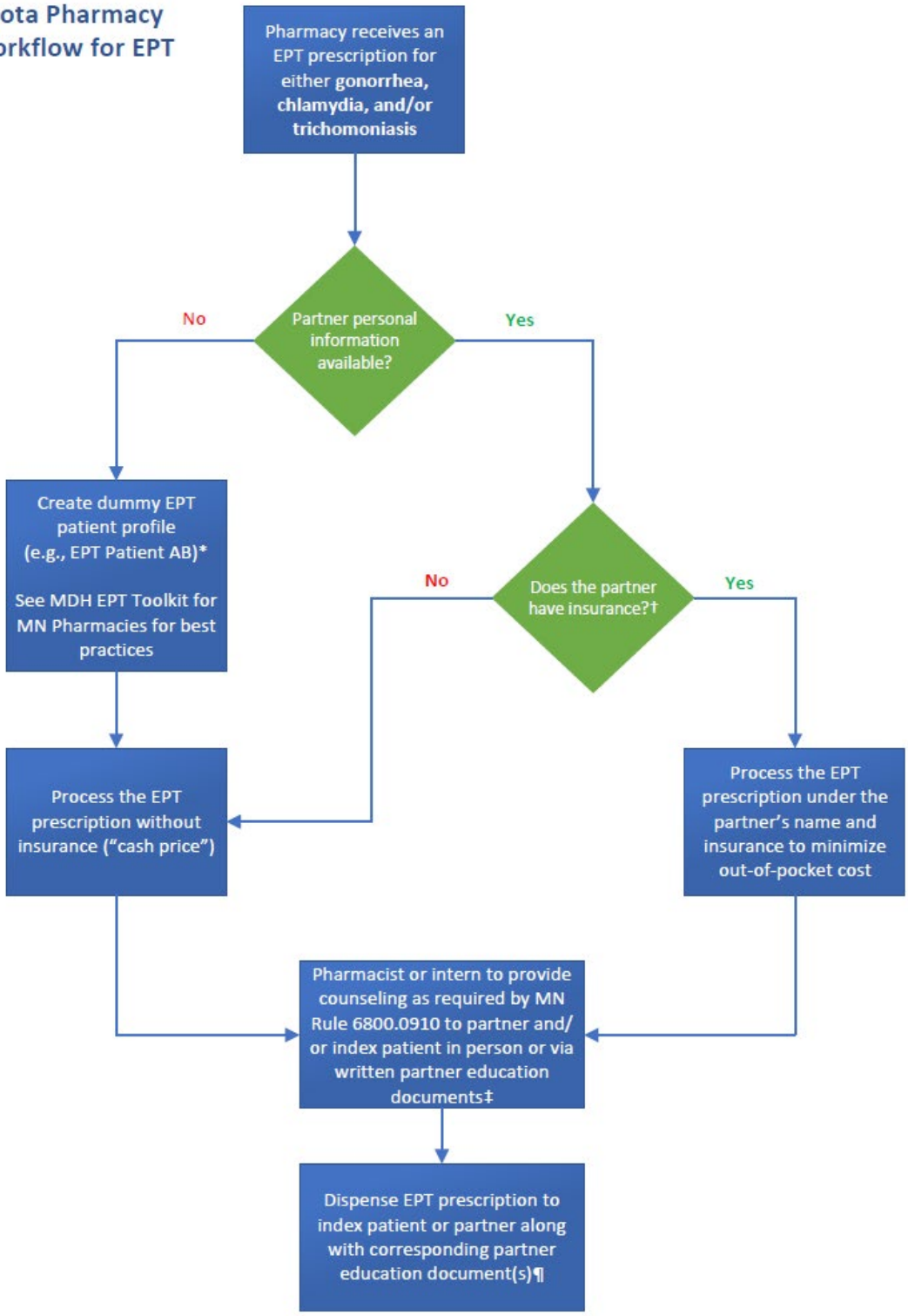
Development of EPT-specific Pharmacy Processes

Due to significant heterogeneity in workflows between pharmacies based on several factors, it is encouraged that each pharmacy develops their own EPT-specific pharmacy processes in order to efficiently and appropriately process and dispense EPT prescriptions. Standardized processes will help reduce confusion and ensure that pharmacies are prepared to participate in this important public health program.

Examples of EPT-specific pharmacy processes that may be developed include:

- Development of a standardized method of handling EPT prescriptions without partner personal information (e.g., dummy patient information, leaving DOB and address fields blank, using "n/a" for fields in which partner information is not available, etc.)
- Collection of EPT-specific educational materials to be given to patients at the point of dispensing
- Ensure typical antimicrobials used in the treatment of qualifying STIs are stocked in the pharmacy
- Develop a chart that provides transparency relating to out-of-pocket prices of the recommended EPT regimens listed above to that they can be relayed to patients on request

Example Minnesota Pharmacy Standardized Workflow for EPT



*Allowable per former BOP director Dr. Wiberg & Minn. Stat. § 151.37 Subp. 2(g). Exact format will vary based on pharmacy software.
†In order to be billed through insurance, the partner must be enrolled – refills for partner(s) on the index patient's Rx are not permitted
‡In person consultation with the index patient or partner is preferred, however MN Rule 9800.0910 Subp. 2(b) allows requirements for counseling to be met via distribution of written educational materials to the partner as long as contact information/availability of pharmacist for questions is included
¶Official partner education documents for chlamydia, gonorrhea, and trichomoniasis are available on MDH's website in English, Spanish, Somali, and Hmong languages

EPT Education for Pharmacy Employees

EPT-Specific Education

In a recently published survey-based study of 623 healthcare providers who reported providing STI treatment in the past year in Minnesota[18]:

- Only 76% of the providers had heard of EPT prior to taking the survey
- Only 70% of the providers thought EPT was legal
- Only 37% of healthcare providers currently provide EPT as a prescription or direct medication
- Of those who do not currently provide EPT, 78% said they would provide the service under certain circumstances

This underscores the importance of healthcare professional education, visibility, and awareness of EPT as a public health program. Pharmacies are encouraged to provide standardized processes as referenced above and expected to provide adequate education for their pharmacy employees surrounding the role and use of EPT in Minnesota. This will ensure unnecessary confusion and barriers to providing the standard of care are minimized. Examples of methods of education about EPT that could be used to educate pharmacists, pharmacy technicians, and other pharmacy staff include:

- Guidance from local and/or state departments of health (e.g., this document)
- EPT should be included in every healthcare professional program curriculum (e.g., nursing, medicine, physician assistant/associate, nurse practitioner, pharmacy, etc.)
- Outreach and partnerships with the Minnesota Department of Health STD/HIV/TB Section and/or local health departments
- Informational presentations about EPT at organizational conferences and meetings
- Partnerships with local academic institutions to create continuing education (e.g., CME, CEU, ACPE, etc.) opportunities via webinars or live lectures for healthcare professionals
- Consideration of required or elective electronic learning modules
- Inclusion of EPT as part of an on-boarding or orientation checklist for new employees
- Required attestation of commitment providing equitable healthcare via vision statements, mission statements, and/or official policy that includes a provision for EPT
- Expand responsibility for STI awareness and care by appointing an EPT champion at each practice location or institution
- Encourage healthcare professionals who provide EPT services and/or learners (e.g., students, residents, fellows) to share knowledge and experiences or educate others

Education Regarding Taking a Meaningful Sexual History

Minnesota pharmacists may have a scope of practice that includes patient assessment, including patients with concerns for STIs, which necessitates the ability to take a meaningful

sexual history. A sexual history should involve discussing specific risk factors, behaviors and practices, prevention measures, past history of STIs, and pregnancy intention however these conversations can be awkward or embarrassing for both patients and providers and thus ignored or skipped. Following a standardized framework can be helpful to ensure providers elicit meaningful information from their patients without getting too distracted by the emotions that may be produced by the discussion. One of the most common frameworks for taking a sexual history is the "5 P's" which include:

- Partners
- Practices
- Protection from STIs
- Past History of STIs, including HIV
- Pregnancy

Useful resources for clinicians looking to improve their ability to take a sexual history include:

- The CDC National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention provides an in-depth guide to taking a sexual history that is based on the "5 P's" which can be found here
- The California Prevention Training Center provides an example provider-patient interaction in which a physician uses the "5 P's" framework to take a comprehensive sexual history which can be found here
- The New York City Department of Health and Mental Hygiene adapted a quick reference for taking a sexual history using the "5 P's" framework which can be found here

EPT Treatment in Unit Dose Packages

Under MN Rule 6800.3200, if a pharmacy is prepacking medications, they must be dispensed by that pharmacy. Prepacking medications by a pharmacy for dispensing in a different setting (such as a clinic) is considered manufacturing and is not allowed.

Unit dose packs for EPT treatment courses would be allowed if the drugs were bought and packaged for dispensing by the clinic under the practitioner dispensing rules in MN Rules 6800.9950-9954. Clinics engaging in practitioner dispensing of EPT treatment must follow applicable drug storage (MN Rule 6800.9951), dispensing (MN Rule 6800.9952), and labeling (6800.9953) requirements. The clinics must also keep the following information on file and readily retrievable for a period of at least 2 years (MN Rule 6800.9954):

- A record or invoice of all drugs received for purposes of dispensing to patients
- A prescription record of the drugs dispensed, filed by prescription number or date, showing the patient's name and address (the aforementioned exceptions regarding this information for EPT applies), date of the prescription, name of the drug, strength of the drug, quantity dispensed, directions for use, signature of the provider
- Refills should not be provided for EPT prescriptions as to avoid potential insurance fraud and/or encourage follow-up, so MN Rule 6800.9954 Subp. C does not apply

- Patient profile requirements under MN Rule 6800.3110

Best Practices Regarding Payment and Insurance Claim Adjudication

Handling insurance and cost of medications is nothing new for Minnesota's pharmacies. However, due to the allowable exceptions to the EPT dispensing process afforded by Minnesota Statutes, Section. 151.37, Subd. 2(g), the availability of patient information may be limited or absent.

Currently, most pharmacy benefit managers (PBMs) do not provide coverage of EPT prescriptions for partners of their enrolled beneficiaries. Patients are encouraged to ask their PBMs if this is a benefit that they offer. Pharmacies are not allowed to accept prescriptions for treatment of index patients with refills to give to their partner(s).

Pharmacists and pharmacy technicians are encouraged to ask index patients and their partners for personal information for the purposes of filling the prescription, billing to their respective insurance plans, and/or to aid in the clinical review of the prescription, however for the purposes of EPT, this information is not required according to the Board of Pharmacy.

If personal information from the partner(s) is obtained:

- The EPT prescription may be run through the partner(s) personal insurance as long as the prescription is in their name
- The partner(s) may pay for the prescription out of pocket (e.g., without insurance)

If personal information from the partner(s) is not available and a dummy patient is used:

- The EPT prescription cannot be run through any type of insurance
- Encourage the use of prescription discount cards to reduce the out-of-pocket cost
- Consider use of institutional or foundational grant funding to provide EPT prescriptions at no cost

EPT Patient Education and Reference Documents for Minnesota Pharmacies

Link to printable version of recommended antimicrobial treatments quick reference

Link to printable version of EPT prescription requirements quick reference

Link to partner education documents

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