

HEALTH

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF HIV, STD, AND TB SERVICES

SEXUALLY TRANSMITTED DISEASE PROGRAM

Expedited Partner Therapy

Proposed New Rules: N.J.A.C. 8:67

Authorized By: Judith Persichilli, RN, BSN, MA, Commissioner, Department of Health.

Authority: N.J.S.A. 26:4-48.2 through 26:4-48.4.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2022-064.

Submit written comments by July 15, 2022, electronically to <http://www.nj.gov/health/legal/ecomments.shtml> or by regular mail postmarked on or before July 15, 2022, to:

Joy L. Lindo, Director
Office of Legal and Regulatory Compliance
Office of the Commissioner
New Jersey Department of Health
PO Box 360
Trenton, NJ 08625-0360

The agency proposal follows:

Summary

On January 13, 2020, Governor Murphy approved P.L. 2019, c. 336, an act concerning treatment of sexually transmitted diseases and supplementing Title 26 of the Revised Statutes (effective May 1, 2020), codified at N.J.S.A. 26:4-48.2 through 48.4 (Act). The Act authorizes health care professionals to provide, “expedited partner therapy” (EPT). N.J.S.A. 26:4-48.2. EPT is a harm reduction practice by which a health care professional, who diagnoses a patient as having a sexually transmitted infection (STI), provides treatment for the patient’s recent sexual partners without first conducting an examination of the partners. N.J.S.A. 26:4-48.2.

A health care professional provides EPT by issuing a prescription for appropriate antibiotic drugs in each of the patient’s partners’ names, if known, or, if the patient does not know or declines to provide partners’ names, then in the name of “expedited partner therapy.” N.J.S.A. 26:4-48.2. In the alternative, the health care professional can dispense medication to the patient to give to the patient’s partners for their use. N.J.S.A. 26:4-48.2. The health care professional then gives the prescriptions or the medications, and certain written informational and guidance materials, to the patient and requests that the patient give these materials to the patient’s sexual partners and advise the sexual partners of the importance of seeking clinical treatment for the STI from a health care professional. N.J.S.A. 26:4-48.2. The patient, in turn, delivers the information and the prescriptions or medications to the partners. This enables the partners to immediately begin treatment by having the prescriptions filled and taking the dispensed medications, without having to await the scheduling of appointments with the

partners' own healthcare professionals for diagnosis and treatment of their likely infection with the STI.

To implement this practice in New Jersey, the Act requires the Department of Health ("Department" or "DOH") to develop, and make available to health care professionals in the State, informational materials and guidance concerning the safe and effective provision of EPT. N.J.S.A. 26:4-48.3. A health care professional who elects to provide EPT would give these materials to a patient whom the professional diagnoses as having an STI for subsequent delivery by the patient to all of the patient's sexual partners who are eligible for EPT, which would include persons with whom the patient had sexual contact with within the 60 days preceding the diagnosis. N.J.S.A. 26:4-48.2 and 48.3.

The Act further requires the Department to establish standards for implementation of the Act, to identify the STIs for which EPT is appropriate, based on guidance from the Centers for Disease Control and Prevention (CDC) of the United States Department of Health and Human Services, and to develop informational materials directed toward health care professionals. N.J.S.A. 26:4-48.3. The Act also authorizes the Department to provide educational programming for health care professionals and pharmacists. N.J.S.A. 26:4-48.3.

To encourage health care professionals and pharmacists to implement EPT, the Act immunizes them from civil and criminal liability and professional disciplinary action when they, in good faith, and absent gross negligence or willful misconduct, provide EPT or, with respect to pharmacists, fill an EPT prescription. N.J.S.A. 26:4-48.4.

Proposed new N.J.A.C. 8:67, Expedited Partner Therapy, would implement the rulemaking obligations that the Act assigns to the Department. Proposed new Subchapter 1, General Provisions, would establish the purpose and scope of the chapter and definitions the chapter uses. Proposed new N.J.A.C. 8:67-1.1, Purpose and scope, would establish the purpose and scope of the chapter. Proposed new N.J.A.C. 8:67-1.2, Definitions, would establish definitions of words and terms that the chapter uses. Proposed new N.J.A.C. 8:67-1.2(a) would incorporate by reference the definitions the Act establishes for the following terms: “Commissioner,” “Department,” “expedited partner therapy,” and “health care professional.” Proposed new N.J.A.C. 8:67-1.2(b) would define the following additional words and terms that the chapter uses: “CDC,” “EPT,” “STD Program,” and “STI.”

Proposed new N.J.A.C. 8:67-1.3, Publications incorporated by reference, would incorporate by reference, as amended and supplemented, the *CDC’s Sexually Transmitted Infections Treatment Guidelines, 2021 (STI Treatment Guidelines)* and provide recommendations and guidance for the effective provision of treatment for STIs and identify the STIs for which EPT is appropriate and the medications that are appropriate to treat each of these STIs, including dosages, protocols for different populations, contraindications, and alternative regimens.

The Act, at N.J.S.A. 26:4-48.39.a, directs the Department to develop and distribute informational material that health care professionals are to give to patients with instructions to deliver these materials to the patients’ partners for whom the health care professional issues EPT. Proposed new N.J.A.C. 8:67-1.4, Informational material,

would establish the means by which the Department will make available and distribute this material.

The Act, at N.J.S.A. 26:4-48.39.b, directs the Department to develop and distribute guidance directed at health care professionals about EPT. Proposed new N.J.A.C. 8:67-1.5, Expedited partner therapy guidance material for health care professionals pursuant to N.J.S.A. 26:4-48.3, would establish the means by which the Department will make available and distribute this material.

Proposed new Subchapter 2, Provision of Expedited Partner Therapy, would establish standards by which health care professionals are to provide EPT. The Act, at N.J.S.A. 26:4-48, requires the Department to identify the STIs for which EPT is indicated. Proposed new N.J.A.C. 8:67-2.1, STIs for which provision of EPT is indicated, at subsection (a), would identify EPT to be indicated for STIs for which the *STI Treatment Guidelines* say it is indicated and, at subsection (b), would require health care professionals who elect to provide EPT, in doing so, to adhere to the CDC's *STI Treatment Guidelines*, particularly with respect to the STIs for which EPT is indicated and the corresponding treatments. The *STI Treatment Guidelines* presently recommend EPT as appropriate for chlamydia and gonorrhea and identify the corresponding treatments. Therefore, by proposing new N.J.A.C. 8:67-2.1, the Department would fulfill its obligation pursuant to N.J.S.A. 26:4-48 by identifying the STIs for which EPT is indicated to be chlamydia, gonorrhea, and any other STIs for which the *STI Treatment Guidelines* identify EPT to be indicated, Proposed new N.J.A.C. 8:67-2.1 would require health care providers, in prescribing EPT, to adhere to the *STI Treatment Guidelines* that are in effect when a patient presents to a health care

provider with an STI, that is, as the *STI Treatment Guidelines* may be amended and supplemented. See proposed new N.J.A.C. 8:67-1.3 (incorporating by reference the *STI Treatment Guidelines*, “as amended and supplemented”). This would ensure that the EPT a health care provider issues is consistent with the most recently issued and scientifically accepted best practice recommended by the CDC, and would avoid delay attendant to the conclusion of Department rulemaking to identify additional STIs for which the CDC might come to recommend EPT as being indicated and/or changes to EPT modalities that the CDC might recommend as appropriate for STIs for which EPT is presently or newly identified as indicated.

Proposed new N.J.A.C. 8:67-2.2, Distribution of DOH informational material, would direct health care professionals to give the DOH informational material to patients when they prescribe EPT, with instructions to the patient to deliver the materials to their partners for whom the health care professional has issued EPT.

As the DOH has provided a 60-day comment period on this notice of proposal, this notice is excepted from the rulemaking calendar requirement, pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

Absent the express immunization from liability that the Act grants for providing EPT and filling EPT prescriptions, health care professionals and pharmacists might be unwilling to provide EPT, not having examined a patient’s sexual partners and/or screened them for contraindications. The proposed new rules would implement the Act by identifying the sources from which health care professionals can obtain the guidance

materials they need, both for their own informational purposes in providing EPT, and for their patients to give to their partners, accompanied by appropriate EPT prescriptions.

The Department anticipates that the proposed new rules would have a positive social impact on the State by facilitating and encouraging the provision of EPT in New Jersey, thereby reducing the impact of these infections on the health of individuals and communities. Failure to implement and encourage the provision of EPT in New Jersey would enable treatable STIs to develop into more serious conditions and spread among the population, thereby undermining the health of the people of the State, and increasing the demand for health care services and other resources.

The purposes and benefits of EPT include prevention of patient reinfection after treatment resulting from continued contact with infected partners; identification of asymptotically infected persons; treatment of STIs and alleviation of the associated symptoms in partners; interruption of the chain of STI transmission; implementation of a cost-efficient mechanism by which to implement partner notification that ordinarily would be performed by public health officials; and forestallment of the negative long-term effects of untreated STIs, particularly among partners who might be unwilling, or unable, to pursue treatment on their own. The complications of untreated STIs can include pelvic inflammatory disease, infertility, premature birth delivery, and transmittal of the infection to other parts of the body like the skin or joints. In addition, some STIs can be passed on to newborns during vaginal delivery and can cause newborns to have conditions such as eye infections, blindness, and pneumonia.

EPT is indicated when a partner is likely to be unable, or unwilling, to obtain needed healthcare services in a timely manner, such as when partners might be

concerned about privacy or have schedules that make setting routine medical appointments difficult.

The following entities have issued position statements supportive of the provision of EPT. Some of these entities' position statements include clinical guidance for implementation of EPT among specific populations.

American Academy of Family Physicians (AAFP), *Policy: Expedited Partner Therapy* (2012, 2017), available at <https://www.aafp.org/about/policies/all/expedited-partner-therapy.html>.

American College of Obstetricians and Gynecologists (ACOG), Committee on Gynecologic Practice and Committee on Adolescent Health Care, *Committee Opinion No. 737: Expedited Partner Therapy* (Interim Update, June 2018; reaffirmed 2019), *Obstetrics & Gynecology*, 131(6):1180-1181 available at <https://www.acog.org/clinical/clinical-guidance/committee-opinion/articles/2018/06/expedited-partner-therapy> and at <https://www.acog.org/-/media/project/acog/acogorg/clinical/files/committee-opinion/articles/2018/06/expedited-partner-therapy.pdf> (replacing *Committee Opinion* 632 of June 2015).

American Osteopathic Association (AOA), *Policy H626-A/18: Expedited Partner Therapy* (2018), *AOA Policy Compendium* (2019) at 49, available at <https://osteopathic.org/wp-content/uploads/2019-Policy-Compendium.pdf>.

Society for Adolescent Medicine (SAM), *Expedited Partner Therapy for Adolescents Diagnosed with Chlamydia or Gonorrhea: A Position Paper of the Society for Adolescent Medicine* (Policy statement approved by the Society for Adolescent Medicine Board of Directors, May 27, 2008, and supported by the American Academy of

Pediatrics, March 4, 2009), J Adolescent Health 45:303–309 (2009), available at [https://www.jahonline.org/article/S1054-139X\(09\)00205-5/fulltext](https://www.jahonline.org/article/S1054-139X(09)00205-5/fulltext) and at [https://www.jahonline.org/article/S1054-139X\(09\)00205-5/pdf](https://www.jahonline.org/article/S1054-139X(09)00205-5/pdf).

The American Bar Association, *Recommendation No. 116A*, adopted by the House of Delegates (August 11–12, 2008), Chicago (IL): ABA; 2008, available at: http://www.americanbar.org/content/dam/aba/directories/policy/2008_am_116a.authcheckdam.pdf.

Economic Impact

The proposed new rules would not impose direct costs on the State, other than the possibility of increasing the quantity of STI medications paid for by the Department for clinic sites that meet eligibility requirements for the Federal Health Resources and Services Administration drug pricing program pursuant to Section 340B of the Public Health Service Act (42 U.S.C. § 256b). The Department would subsume these costs within existing budgets for STI medication purchase. Therefore, the taxpaying public would realize negligible direct economic impact resulting from the proposed new rules.

The proposed new rules would have a negligible economic impact on patients for whom medical insurance would cover the cost of prescription medications or for whom a health care professional dispenses medications without charge. The Department anticipates the possibility of minimal financial impact on uninsured and under-insured patients who would pay out-of-pocket fees for medications. The Department anticipates that public clinics (such as local health department clinics, Federally Qualified Health Centers, family planning clinics, and the like) would absorb much of the cost for

medications for patients who are uninsured or underinsured. The economic impact on such clinics would be negligible as costs would be subsumed by existing programs, such as 340B, that provide medications to these clinics for distribution to uninsured and underinsured patients.

Failure to implement EPT through the proposed new rules would enable untreated STIs among a diagnosed patient's sexual partners to continue to reinfect the patient and to infect others, and to develop into more serious conditions in the partner, the partner's partners, and among newborns born to untreated infected persons, which would impose greater and more expensive demands on healthcare and other resources than would EPT implementation.

The proposed new rules would require health care professionals who elect to provide EPT to distribute the informational and guidance materials that the Department promulgates pursuant to the Act to the patients whom they diagnose as having STIs, for delivery to their partners. Health care professionals can print the material from the Department's website, and thereby would incur costs for printing supplies. The STD Program will also maintain a supply of printed material for distribution to providers upon telephone request to the STD Program. The proposed new rules would require health care professionals who choose to provide EPT, in doing so, to adhere to the CDC STI Treatment Guidelines for providing EPT, as amended and supplemented. The CDC makes available additional resources, such as wall charts, a mobile telephone application, and a "pocket guide" to the *STI Treatment Guidelines*, and informational handouts for patients, which health care professionals might elect to request from the CDC or download from its website.

Federal Standards Statement

The Department proposes N.J.A.C. 8:67 to fulfill its rulemaking obligations pursuant to the Act, specifically at N.J.S.A. 26:4-48.3, and not to implement, comply with, or participate in, any program established under Federal law or State law that incorporates or refers to any Federal law, standard, or requirement. The Department proposes to incorporate by reference into the chapter otherwise non-mandatory Federal (CDC) guidelines and recommendations for treatment of STIs and provision of EPT as a minimum standard to which health care professionals are to adhere in providing EPT. Therefore, a Federal standards analysis is not required.

Jobs Impact

The Department does not expect that the proposed new rules would result in the generation or loss of jobs in the State.

Agriculture Industry Impact

The proposed new rules would have no impact on the agriculture industry of the State.

Regulatory Flexibility Analysis

The proposed new rules would establish no reporting or recordkeeping requirements, but would establish compliance requirements, which would apply to health care professionals in the State who choose to provide EPT upon diagnosing

patients as having certain STIs. Some of these health care professionals' practices might be small businesses within the meaning of the Regulatory Flexibility Act, N.J.S.A. 52:14B-16, et seq. The Department is able to estimate neither the number of health care professionals in the State who routinely or sporadically might engage in the diagnosis, care, and treatment of STIs among their patients, nor the number among these professionals who might elect to provide EPT.

The Economic Impact describes the costs that health care professionals would incur to comply with the proposed new rules. Health care professionals would not need to retain the services of professionals to comply with the proposed new rules.

The Department proposes no standards for health care professionals whose practices are small businesses that are less than or differ from those that uniformly would apply to all health care professionals, which the Summary above describes. The Department has determined that the proposed new rules would establish the minimum standards necessary to fulfill its rulemaking obligations under the Act while maintaining a consistent minimum standard of care among health care professionals that choose to provide EPT.

Housing Affordability Impact Analysis

The proposed new rules would have no impact on the affordability of housing in New Jersey and would not evoke a change in the average costs associated with housing, because the proposed new rules would establish a health care practice standard for the elective provision of EPT and would have no bearing on housing costs. Accordingly, no further analysis is required.

Smart Growth Development Impact Analysis

The proposed new rules would not evoke a change in the housing production within Planning Areas 1 or 2, or within designated centers, under the State Development and Redevelopment Plan, because the proposed new rules would establish a health care practice standard for the elective provision of EPT and would have no bearing on housing production or planning.

Racial and Ethnic Community Criminal Justice and Public Safety Impact

The Department has determined that the proposed new rules would not have an impact on pretrial detention, sentencing, probation, or parole policies concerning adults or juveniles in the State. Accordingly, no further analysis is required.

Full text of the proposed new rules follows:

CHAPTER 67

EXPEDITED PARTNER THERAPY

SUBCHAPTER 1. GENERAL PROVISIONS

8:67-1.1 Purpose and scope

(a) The purpose of this chapter is to implement expedited partner therapy in the State, in accordance with P.L. 2019, c. 336, an act concerning treatment of sexually transmitted diseases and supplementing Title 26 of the Revised Statutes (effective May 1, 2020) (Act), codified at N.J.S.A. 26:4-48.2 through 48.4.

(b) This chapter applies to health care professionals in the State who elect to provide expedited partner therapy.

8:67-1.2 Definitions

(a) The following words and terms, as used in this chapter, have the meanings that N.J.S.A. 26:4-48.2 establishes:

1. "Commissioner";
2. "Department";
3. "Expedited partner therapy"; and
4. "Health care professional."

(b) The following words and terms, as used in this chapter, have the following meanings, unless the context clearly indicates otherwise:

"CDC" means the Centers for Disease Control and Prevention of the Public Health Service of the United States Department of Health and Human Services.

"EPT" means expedited partner therapy.

"STD Program" means the Sexually Transmitted Disease Program within the Division of HIV, STD, and TB Services of the Department, for which the contact information is PO Box 363, Trenton, NJ 08625-0369, telephone (609) 826-4869, and website <https://www.nj.gov/health/hivstdtb>.

"STI" means sexually transmitted infection.

8:67-1.3 Publications incorporated by reference

(a) The following publication of the CDC is incorporated herein by reference, as amended and supplemented:

1. Workowski KA, Bochman LH, Chan PA, et al, and CDC, *Sexually Transmitted Infections Treatment Guidelines, 2021*. MMWR Recomm Rep 2021; 70 (No. RR-43): 1-187 (July 23, 2021), available at <https://www.cdc.gov/std/default.htm> (hereinafter referred to as “STI Treatment Guidelines”).

8:67-1.4 Informational material

(a) The STD Program shall post to its website the informational material it develops pursuant to N.J.S.A. 26:4-48.3, for distribution by health care professionals to each patient whom the health care professional diagnoses as having a sexually transmitted disease and for whom the professional elects to provide EPT for subsequent delivery by the patient to all of the patient’s sexual partners who are eligible for expedited partner therapy (DOH EPT informational material).

(b) The Department shall:

1. Distribute free copies of the DOH EPT informational material throughout the State at conferences, trainings, and other professional gatherings of health care professionals; and

2. Make available copies of the DOH EPT informational material to health care professionals upon telephone request to the STD Program.

(c) The Department shall update the DOH EPT informational material from time to time, as needed, to reflect changes in scientific knowledge and best practices associated with the provision of EPT and prevention of the spread of STIs.

8:67-1.5 Expedited partner therapy guidance material for health care professionals pursuant to N.J.S.A. 26:4-48.3

(a) The STD Program shall post to its website, the guidance material it develops pursuant to N.J.S.A. 26:4-48.3 to guide health care professionals in the provision of EPT (DOH EPT guidance for health care professionals).

(b) The Department shall:

1. Distribute free copies of the DOH EPT guidance for health care professionals throughout the State at conferences, trainings, and other professional gatherings of health care professionals; and

2. Make available copies of the DOH EPT informational material to health care professionals upon telephone request to the STD Program.

(c) The Department shall update the DOH EPT guidance for health care professionals from time to time, as needed, to reflect changes in scientific knowledge and best practices associated with the provision of EPT and prevention of the spread of STIs.

SUBCHAPTER 2. PROVISION OF EXPEDITED PARTNER THERAPY

8:67-2.1 STIs for which provision of EPT is indicated

(a) Pursuant to N.J.S.A. 26:4-48, the Department identifies EPT to be indicated for the STIs for which the STI Treatment Guidelines identify EPT to be indicated.

(b) In prescribing EPT, a health care professional shall adhere to the STI Treatment Guidelines, particularly with respect to the STIs for which the STI Treatment Guidelines state that EPT is indicated, and the corresponding treatments.

8:67-2.2 Distribution of DOH informational material

When a health care professional issues EPT, the health care professional shall give the patient a sufficient number of copies, depending on the number of partners a patient identifies, of the DOH EPT informational material, with instructions to the patient to give the DOH EPT informational material that is for partners to the patient's partners.