

HEALTH

PUBLIC HEALTH SERVICES BRANCH

DIVISION OF HIV, STD, AND TB SERVICES

SEXUALLY TRANSMITTED DISEASE PROGRAM

Expedited Partner Therapy

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

Proposed: May 16, 2022, at 54 N.J.R. 855(a).

Adopted: December 16, 2022, by Judith M. Persichilli, RN, BSN, MA, Commissioner, Department of Health, in consultation with the Public Health Council.

Filed: December 16, 2022, as R. 2023 d.010, **without change**.

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

Effective Date: January 17, 2023.

Expiration Date: January 17, 2030.

Summary of Public Comments and Agency Responses:

The Department of Health (Department) received comments from the following:

1. Elise M. Barry, MS, CFRE, Chief Executive Officer, New Jersey Pharmacists Association, Princeton, NJ; and

2. Rachel Baum, President and CEO, New Jersey Family Planning League, Newark, NJ.

Quoted, summarized, and/or paraphrased below are the comments and the Department's responses. The numbers in parentheses following the comments below correspond to the commenter numbers above.

1. COMMENT: A commenter "support[s] the concept of expedited partner therapy." (1)

2. COMMENT: A commenter states: “STI rates have risen considerably in New Jersey and across the country over the past decade, and the COVID-19 pandemic intensified the demands on an already strained public health infrastructure. Multiple factors likely contributed to rising STI rates during the COVID-19 pandemic, including reduced frequency of annual in-person exams during which STI screening generally takes place, reassignment of public health staff from STI work to COVID-19 response, medical test and laboratory supply shortages, and lack of health insurance coverage due to unemployment. Expedited partner therapy is an important tool in helping to reverse the rise in STI rates, as well as improving access to healthcare.” The commenter “fully supports the Department ... as it expands and promotes availability of expedited partner therapy in New Jersey.” (2)

RESPONSE TO COMMENTS 1 AND 2: The Department acknowledges the commenters’ support of the proposed new rules.

3. COMMENT: A commenter states, “Dispensing a prescription without a partner name would be cited during a pharmacy audit because the record would not have the proper documentation about the partner. Using ‘EPT’ is not enough to satisfy current audit requirements. A pharmacist would not have critical information about the partner and dispensing a prescription could cause harm, yet the pharmacist has corresponding responsibility. Insurance coverage for patient would not necessarily extend to the partner, especially in the case of an unnamed partner.”

The commenter states, “To mitigate [the commenter’s] concerns and encourage participation,” the commenter “believes it would be both advantageous and appropriate

for the Department ... to consider the development of a standing order for pharmacists that explicitly: Waives professional responsibilities and outlines liability protections included in the Act[;] Notes that payment is required for duplicate therapy that can't be billed to insurance[;] Requires second EPT prescription from prescriber labeled 'EPT-patient name' to tie it to the patient for whom the prescriptions are filled[; and] Provides a dispensing checklist [as follows:]

 Create partner record labeled 'EPT-Patient Name'[;]

 State that 'history unavailable due to EPT' is acceptable for pharmacy audit purposes on partner record[; and]

 Record payment type for second prescription on partner record[.]” (1)

RESPONSE: As the Department states in the notice of proposal Summary, “the Act immunizes [healthcare professionals and pharmacists] 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.” 54 N.J.R. 855(a), 856. The Act, at N.J.S.A. 26:4-48.2, Expedited partner therapy, directs health care professionals to prescribe or dispense medication for the treatment of a sexually transmitted disease “in the sexual partner’s name or, if not known, in the name of ‘Expedited Partner Therapy.’”

Therefore, given the immunity provision at N.J.S.A. 26:4-48.4, a pharmacist who fills a prescription written to “Expedited Partner Therapy,” in good faith, and absent gross negligence or willful misconduct, is not subject to repercussion in the form of disciplinary action or other liability. As the Act provides this express immunity from liability, to restate the law by a change to the proposed new rules or the issuance of a

standing order would be unnecessary. Moreover, the requested changes for “pharmacy audit purposes” would appear to exceed the Department’s rulemaking obligations, pursuant to the Act. Inasmuch as the State Board of Pharmacy holds regulatory authority over the practice of pharmacy, the Department suggests that the commenter might elect to direct any further concerns to that Board.

With respect to insurance coverage, the Act states, at N.J.S.A. 26:4-48.4 at subsection b, that: “Nothing in this act shall be construed to require a patient’s health benefits plan or prescription benefits plan to pay for or provide reimbursement for anyone other than the patient who is provided expedited partner therapy pursuant to this act unless the person to whom expedited partner therapy is being provided is listed as a beneficiary under the patient’s health benefits plan or prescription benefits plan.” Therefore, the commenter is correct in noting that the insurance coverage of the person diagnosed with an STD would not extend necessarily to the partner who is to receive EPT.

However, as the Department states in the notice of proposal Economic Impact statement: “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 under-insured patients.” 54 N.J.R. at 856. The STD page on the Department’s website provides information identifying locations from which uninsured and underinsured persons can receive STD testing and treatment at low or no cost. See <https://www.nj.gov/health/hivstdtb/stds/>. The informational material that the Department will issue, pursuant to N.J.S.A. 26:4-48.3, will contain the website link and the telephone number of the STD program of the Department.

For the foregoing reasons, the Department will make no change on adoption in response to the comment.

4. COMMENT: Are any OBRA requirements triggered? (1)

RESPONSE: The Department assumes the commenter is referring to the “Omnibus Budget Reconciliation Act of 1987” (OBRA). The commenter provides no information as to how the proposed new rule could trigger “OBRA requirements” and the Department is not aware of how the proposed new rule could trigger “OBRA requirements.”

5. COMMENT: “In the future, DOH may want to consider developing and implementing reporting criteria ([for example,] the number of patients who were offered and accepted EPT for their partners) to evaluate EPT’s use, [and] identify disparities in access and areas for improvement.” (2)

RESPONSE: The Department will explore best practices and feasibility for EPT usage tracking in the future.

Federal Standards Statement

The Department adopts 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 is incorporating by reference into the chapter otherwise non-mandatory Federal (CDC) guidelines and recommendations for the treatment of STIs and the 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.

Full text of the adopted new rules follows:

TEXT