

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Budget Committee

BILL: SB 1474

INTRODUCER: Senator Gibson

SUBJECT: Public Health

DATE: February 24, 2012

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Davlanter</u>	<u>Stovall</u>	<u>HR</u>	Favorable
2.	<u>Bradford</u>	<u>Rhodes</u>	<u>BC</u>	Pre-meeting
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

I. Summary:

The bill requires the Department of Health (department) to create a pilot project in Duval and Gadsden Counties to use expedited partner therapy (EPT) to treat sexually-transmitted diseases (STDs).

The cost of the pilot project will be covered by identifying resources within the existing budget of the pilot project area or by developing partnerships. The department anticipates that the costs of the pilot could be about \$127,500.

This bill creates one undesignated section of law.

The effective date of the legislation is July 1, 2012.

II. Present Situation:

Sexually-Transmitted Diseases

STDs are infections which spread from person to person during sexual activity. Such infections include gonorrhea, Chlamydia, herpes, HIV, trichomoniasis, human papillomavirus (HPV), and syphilis. STDs infect both men and women, but they are more likely to cause symptoms in women. STDs in women who are pregnant can lead to birth defects, high-risk pregnancies, congenital infections, and other serious health risks for the unborn child.¹

¹ Medline Plus, *Sexually Transmitted Diseases*, available at: <http://www.nlm.nih.gov/medlineplus/sexuallytransmitteddiseases.html> (last visited on February 2, 2012).

Chlamydia, gonorrhea, and trichomoniasis can be treated with single doses of certain oral antibiotics. Syphilis can be treated with a single intramuscular dose of penicillin. HIV and HPV are unable to be cured once they are contracted.²

In Florida in 2011, Leon and Gadsden Counties had the highest rates of STDs as reported to the department. These two counties consistently have the highest rates of STDs in the state. The next-highest ranking counties for 2011 were Union, Hamilton, Alachua, and Duval. In 2010 department data showed similar trends.³

Expedited Partner Therapy

People who get STDs once are likely to get them again, often from the same sexual partner. Since STDs are often asymptomatic in men, they may be unaware that they have a disease. Upon treating a patient with a STD, it is common medical practice to advise that the patient's partner be tested and treated as well; however, partner management based on patient referral or provider referral has had only moderate success in assuring partner treatment.

EPT is the practice of treating the sex partners of persons with STDs without an intervening medical evaluation or professional prevention counseling. The usual implementation of EPT is through patient-delivered partner therapy (PDPT), meaning that health care providers give patients antibiotics to deliver to their partners, although other methods may be employed. Clinical studies comparing rates of recurrent STDs after patient referral and after EPT has shown a slight decrease in STD rates among patients treated with EPT, although further studies are needed to confirm any trends.

However, the practice of treating partners without a preliminary medical examination can have serious health ramifications. Partners treated with EPT may have more serious forms of the STD which require stronger treatment or even hospitalization, be allergic to the antibiotics they are given, or have co-existing STDs which the original patient was not tested for and are therefore not treated with EPT. All of these conditions will go unnoticed unless the person being treated has had his or her own medical evaluation. The patient treated with EPT will also lose the benefit of prevention counseling, an important part of an STD medical evaluation. Furthermore, it is unclear where the liability lies when a health care professional treats a patient he or she did not see and adverse outcomes occur.

The Centers for Disease Control and Prevention (CDC) recommends that EPT be considered by clinicians as an option for partner management, but not replace classic strategies such as patient referral or provider-assisted referral, and that EPT should be accompanied by information that advises recipients to seek personal health care.⁴

² Epocrates, *Epocrates Essentials*. A copy is on file with the Senate Health Regulation Committee.

³ Telephone conversation with staff from the Department of Health, Bureau of STD Prevention and Control.

⁴ Centers for Disease Control and Prevention, *Expedited partner therapy in the management of sexually transmitted diseases*, available at: <http://www.cdc.gov/std/treatment/EPTFinalReport2006.pdf> (last visited on February 2, 2012).

Expedited Partner Therapy in Other States

In 2009, the Texas Medical Board amended the Texas Administrative Code to permit EPT for the management of STDs. A professional relationship with a patient is not required for a physician to prescribe medications for sexually-transmitted diseases for partners of the physician's established patient, if the physician determines that the patient may have been infected with a sexually-transmitted disease.⁵ Similar rules also apply to advanced registered nurse practitioners.⁶ The Texas Department of State Health Services website provides many resources for EPT, including fact sheets for patients in English and Spanish and practice guidelines for health practitioners.⁷

Staff from the Texas Department of State Health Services report that STD rates have not changed since EPT became legal in the state. This is mainly due to the reluctance of health practitioners to prescribe EPT. Despite endorsements from leaders from state government, medical organizations, and nursing organizations, it is estimated that less than 40 percent of physicians who treat STD patients in Texas utilize EPT.⁸

EPT is currently prohibited in seven states, including Florida. It is potentially allowable in 13 states, meaning that no statutes or rules specifically permit or prohibit the practice, and is legally permissible in 30 states.⁹

III. Effect of Proposed Changes:

Section 1 requires the department to develop and implement an EPT pilot program in Duval and Gadsden Counties. The pilot project will exempt providers in those counties from the requirements of ss. 384.27 and 465.023(1)(h), F.S., and Rule 64B8-9.014, F.A.C.¹⁰ Under the proposed pilot project, a physician is authorized to provide a single dose of medication provided by the county health department (CHD) to infected patients for use by their partners. EPT is not mandated under the pilot project; rather, it is offered as a treatment option. The pilot project will also provide provider and patient education material concerning EPT developed by the CDC and by the state of Texas.

The cost of the pilot project may be covered by identifying resources within the existing budget of the pilot project area or by developing partnerships. The funds will be used to purchase medication, provide additional material for physicians and patients, and evaluate the progress of the project.

⁵ 22 Tex. Admin. Code s. 190.8(1)(L)(iii).

⁶ 22 Tex. Admin. Code s. 222.4(e).

⁷ Texas Department of State Health Services, *Expedited Partner Therapy (EPT)*, available at: <http://www.dshs.state.tx.us/hivstd/ept/default.shtm> (last visited on February 2, 2012).

⁸ Telephone conversation with staff from the Texas Department of State Health Services.

⁹ Centers for Disease Control and Prevention, *Legal Status of EPT*, available at: <http://www.cdc.gov/std/ept/legal/default.htm> (last visited on February 2, 2012).

¹⁰ Section 384.27, F.S., relates to physical examination and treatment of patients with STDs. Section 465.023(1)(h), F.S., prohibits a pharmacist from dispensing any drug when the pharmacist knows or has reason to believe that the prescription offered for that drug is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation. Rule 64B8-9.014, F.A.C., prohibits allopathic physicians and physician assistants from issuing prescriptions unless a documented patient evaluation has taken place and treatment options have been discussed with the patient.

Section 2 provides an effective date of July 1, 2012.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of the bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Partners of patients with STDs in Duval and Gadsden Counties will have easier access to antibiotic treatment. Transmission of STDs may be reduced, thereby reducing health care costs.

C. Government Sector Impact:

CHDs will experience a negative fiscal impact as they will be asked to provide additional dosages of antibiotics for patients participating in the EPT program. However, CHD leadership in both Gadsden and Duval Counties support implementation of an EPT pilot program.¹¹ State and local government may also experience increased costs related to other aspects of the pilot project, depending on the success of developing partnerships with private organizations.

The department estimates that it will experience \$127,535 of recurring costs related to hiring an epidemiologist to evaluate the project, purchasing antibiotics and laboratory tests for use in the pilot project, and printing of educational and instructional materials for providers and patients. Estimates are based on treatment of 4,000 patients and their partners each year for Chlamydia and gonorrhea, although it is possible that many more

¹¹ Telephone conversation with Department of Health staff.

individuals will participate in the pilot project and that other STDs might be identified and need treatment in such individuals.¹²

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill provides that the department develop and implement an EPT pilot project in Duval and Gadsden Counties. However, it does not specify in which institutions the pilot project will occur. CHDs must provide the extra doses of medication needed for the EPT pilot project, but it is unclear if the project is limited only to CHDs.

Further, the bill requires CHDs to provide a dose of medication to a physician, who then provides the dose to an infected patient. If such a physician is in private practice, providing a dose of medication would violate s. 499.003(54), F.S., the wholesale distribution law.

The bill exempts providers from the requirements of Rule 64B8-9.014, F.A.C., which prohibits an allopathic physician from issuing a prescription without performing a physical exam on a patient. However, the bill does not provide an exemption from Rule 64B15-14.008, F.A.C., a similar rule which governs osteopathic physicians.

Lines 43-46 allow physicians to provide a single dose of medication to infected patients for use by their partners. Not only does this language fail to specify the types of physicians permitted to provide such medications (assumedly the intention is physicians licensed or registered under chs. 458 or 459, F.S.), but there is no language in the bill to permit nurse practitioners and physician assistants to participate in the project. Nurse practitioners and physician assistants also have prescribing authority under state law and constitute a significant proportion of the primary care providers in Florida.

The bill does not specify the length of time for which the pilot project should be enacted. Pilot projects generally do not continue indefinitely.

Lines 56-59 state that funding for the pilot project may be appropriated for various uses, including evaluating the progress of the project. However, no provision is made to report such progress or findings to any government entity. Customarily, progress reports for projects, task forces, and other agencies are submitted by a certain date to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

It is unclear if physicians will be liable for any adverse reactions occurring to a partner as a result of EPT treatment.

The bill exempts pharmacy permit holders from professional discipline for dispensing to a person known not to have a prescriber-patient relationship with the prescriber, notwithstanding

¹² Department of Health, *2012 Bill Analysis, Economic Impact, and Fiscal Note for SB 1474*. A copy is on file with the Senate Health Regulation Committee.

s. 465.023(1)(h), F.S. Section 465.016(1)(s), F.S., addresses pharmacists and could cover dispensing practitioners under s. 465.0276, F.S. This protects dispensing pharmacy personnel in the Duval CHD Pharmacy. However, the Gadsden CHD has no pharmacy. In the Gadsden CHD, partner medication would be dispensed under the Nurse Issue program in s. 154.04(1)(c), F.S., or by order of a CHD physician. Neither the CHD physicians nor CHD nurses are pharmacy permittees under ch. 465, F.S., and therefore remain subject to professional discipline. Neither are such CHD physicians and nurses registered as dispensing practitioners under s. 465.0276, F.S., so compliance with the bill could expose them to the risk of professional discipline.

Similarly, all private sector physicians in both Duval and Gadsden Counties may be subject to professional discipline for the above-described dispensing activity and possibly could be at risk for related prescribing activity.

The bill does not provide specific authority sufficient to support adoption of rules to implement the pilot project.

VIII. Additional Information:

A. **Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. **Amendments:**

None.