

CONFIDENTIAL
LEGISLATIVE BILL REVIEW FORM: 2013

Bill Number: H.123 Name of Bill: An act relating to Lyme disease and other tick-borne illnesses

Agency/ Dept: AHS/VDH Author of Bill Review: David Herlihy, Board of Medical Practice ; David Englander, Senior Policy and Legal Advisor Approved by Dr. Harry Chen

Date of Bill Review: May 10, 2014 Status of Bill: (check one):

☐ Upon Introduction ☐ As passed by 1st body ☒ As passed by both bodies ☐ Fiscal

Recommended Position:

☐ Support ☐ Oppose ☒ Remain Neutral ☐ Support with modifications identified in #8 below

Analysis of Bill

1. Summary of bill and issue it addresses. *Describe what the bill is intended to accomplish and why.*

Some individuals believe that there is a condition that they refer to as "chronic Lyme disease." "Chronic Lyme" cannot be identified through recognized biomedical tests, but instead is generally identified through the presence of subjective symptoms such as chronic fatigue, malaise, depression, and pain of unidentified etiology. A small but vocal number of physicians believe, contrary to the positions of recognized medical literature, the CDC, and the Infectious Diseases Society of America, that so-called chronic Lyme should be treated with long-term antibiotic therapy. Such treatment is described in guidelines issued by the International Lyme and Associated Diseases Society (ILADS). Recognized studies have shown that such treatment is less effective than placebos, presents risks of harm to the patients, and presents a risk to all of us through the contribution made to the development of medication resistant organisms through unnecessary overuse of antibiotics. There is also a risk that patients may not receive needed treatment for an recognized, treatable illness or condition if this course of treatment is. Advocates for such treatment sought legislation that would establish it in law as acceptable medical treatment that meets the standard of care. They believe that the reason why most physicians refuse to provide long-term antibiotic treatment for patients who believe they have chronic Lyme is that they fear discipline by the Board of Medical Practice because they would be engaging in unprofessional conduct by failing to practice in accordance with the standard of care. As originally introduced, the bill would have legislated the standard of care. As it was passed by both chambers, the bill instead requires the Board of Medical Practice, Osteopathic Board, Office of Professional Regulation, and Nursing Board to issue policy statements declaring that it is each Board's policy that licensees will not be disciplined based solely on the fact that they provide care in accordance with ILADS guidelines. The policy statements are also to provide that there must be documentation of the basis for the Lyme diagnosis, that the provider must provide information about Lyme testing and the meaning of test results, and that they must obtain a written informed consent before providing long-term treatment for Lyme disease. The bill also tasks the Health Department with reporting on Lyme trends and its educational efforts.

2. Is there a need for this bill? *Please explain why or why not.*

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No. See rationale, below.

3. What are likely to be the fiscal and programmatic implications of this bill for this Department?

There is potential that the Board of Medical Practice could feel inhibited exercising its authority investigate and respond to unprofessional conduct in cases that involve prescribing long-term antibiotics inappropriately or in a manner that causes harm to the patient.

4. What might be the fiscal and programmatic implications of this bill for other departments in state government, and what is likely to be their perspective on it?

The implications are similar for the Office of Professional Regulation and the Boards under OPR that would be affected. The fiscal implications would be seen by the state programs that pay for health care - the State Employees' Medical Benefit Plan and DVHA. Their funds might have to be spent to provide unnecessary and potentially harmful treatments, and to provide treatment for injuries or illnesses caused by the long-term antibiotic therapy.

5. What might be the fiscal and programmatic implications of this bill for others, and what is likely to be their perspective on it? (for example, public, municipalities, organizations, business, regulated entities, etc)

Any entity that pays for health care may see higher costs from unnecessary and potentially harmful care.

6. Other Stakeholders:

6.1 Who else is likely to support the proposal and why? The advocates who believe that this is helpful treatment.

6.2 Who else is likely to oppose the proposal and why? Those who beliefs are consistent with the CDC , IDSA, and the finding of peer-reviewed literature that does not support the use of long-term antibiotics. Those concerned about contributing to the growth of health care costs from unproven and potentially ineffective and unnecessary care and those concerned with increasing antibiotic resistance.

7. Rationale for recommendation: *Justify recommendation stated above.*

a. The treatment is considered by the medical community to be medically unsound. The CDC and NIH recommend against long-term antibiotic therapy. There is no demonstrated benefit from treatment with long-term antibiotic therapy and those therapies carry risks for both the patient (injury, adverse reactions & side effects) and the population at large (contribution to the creation of "super bugs"). The CDC and NIH studies that underlie their shared position on this issue include ample evidence of the kinds of harm that can result from the unnecessary treatment that is the goal of the proponents of the bill. It is not only a waste of money. For example, there are documented cases of death associated with complications arising from prolonged use of catheters for administration of the long-term antibiotics. Pursuit of ineffective treatment for what is perceived as chronic Lyme symptoms may also cause patients to not pursue other legitimate treatment.

b. The standard of care should not be legislated. By compelling the Boards and OPR to issue a policy, the Legislature is effectively legislating the standard of care. The standard of care is based on science and should not be set in law based upon work by advocates who reject the evidence provided by scientific study.

c. The bill would add to the cost of health care. As discussed above, payment for ineffective treatments would cost something.

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d. There are positive aspects to this bill. The direct legislation of the standard of care that was seen in the bill as it was introduced is more of concern than the final bill. Advocates have been pursuing a bill on this subject for years; passage of this slightly-less-objectionable bill may prevent further attempts to have the standard of care directly dictated by statute. Also, the compelled policy statements include positive elements. They require documentation of the basis for diagnosis and a written informed consent. It is also good that the Legislature included explicit language that makes it clear that a licensee can be disciplined for errors, omissions, or other unprofessional conduct when practicing within the ILADS guidelines. That is important because, for example, it would allow for discipline of a licensee who failed to diagnose an actual cause of a medical problem, and who instead directed long-term antibiotic treatment.

For the reasons listed above, the Board of Medical Practice opposes this bill.

The Department of Health is neutral on the bill. While it shares many of the concerns that raised by the Board, the practical effect of the bill itself, will be likely be minimal. The relevant boards still retain the jurisdiction and the authority to pursue investigations of medical professionals that do not meet the standard of care when treating patients.

8. Specific modifications that would be needed to recommend support of this bill: *Not meant to rewrite bill, but rather, an opportunity to identify simple modifications that would change recommended position.*

Secretary/Commissioner has reviewed this document: _____ **Date:** _____