CONFIDENTIAL

LEGISLATIVE BILL REVIEW FORM: 2013

Bill Number:_S.112/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 ; DE and HC 2/18/14___

Date of Bill Review: March 1, 2013_____ Status of Bill: (check one):

__X__Upon Introduction _____ As passed by 1st body _____As passed by both bodies _____ Fiscal

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Recommended Position:

_____Support __X__Oppose _____Remain Neutral _____Support with modifications identified in #8 below

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Analysis of Bill

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1. Summary of bill and issue it addresses. *Describe what the bill is intended to accomplish and why.*
The bill is an effort to legislate the standard of care at the request of advocates who believe that people are being denied care for Lyme disease. The recognized treatment for Lyme is a short course of antibiotic therapy. Some patients continue to experience symptoms of fatigue, pain, or joint and muscle aches for a period of months after completing treatment. Some refer to those lingering symptoms as "chronic Lyme disease." Medical professionals refer to this as "Post-treatment Lyme Disease Syndrome," or "PTLDS." Some individuals who believe that they suffer from so-called chronic Lyme want to receive long-term antibiotic therapy to treat their symptoms. They believe that the Board of Medical Practice is preventing them from obtaining their desired treatment.

2. Is there a need for this bill? *Please explain why or why not.*
Absolutely not. See rationale, below.

3. What are likely to be the fiscal and programmatic implications of this bill for this Department?
There will be a programmatic effect to the Board of Medical Practice in that it could impede the Board from executing its duty to 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. There is also a potential public health issue, in that inappropriate and unnecessary prescribing of antibiotics may add to the problems associated with drug-resistant organisms.

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?
a. Office of Professional Regulation. The bill is not well drafted, so, as written, it only applies to MDs who are licensed by the BMP, but it is likely that someone would recognize that and extend it to the prescribers licensed by OPR -- DOs, Nurse Practitioners, and perhaps others. OPR would be affected in the same way as the Board.
b. The mandate to pay for this unnecessary and sometimes harmful care, and the need to treat in response to harm caused by unnecessary antibiotic treatments, would cost the State through its funding of the State Employees' Medical Benefit Plan. One might reasonably expect that the Department of Human Resources

would be against a mandate to pay for treatment that is not beneficial and that can cause harm and side effects that might also result in more care. The Green Mountain Care Board would probably be against it for the same reasons. DVHA is likely to oppose it as well. Even though the mandate to pay for the unnecessary treatment probably would not be effective against DVHA, and would not force coverage of the medically unsupported care, Medicaid probably would bear the cost of treating the harm caused by the unnecessary treatment. The scientific literature on the use of long-term antibiotics has documented cases of serious health effects resulting from administration of long-term antibiotics.

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

a. Any entity that pays for health care and that is not exempt from state-mandated coverage provisions pursuant to ERISA – e.g., the Vermont League of Cities and Towns and insurance companies -- can be expected to be against this mandate to pay for unnecessary care, and perhaps additional care necessitated by side effects or other harms caused by the treatment.

b. The Vermont Medical Society is likely to be against it, in that the VMS generally is against the idea of treatment decisions that go against science and legislate a standard of 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? Anyone who believes in evidence-based medicine and that treatment decisions should be based on science. Anyone concerned about the development of drug-resistant organisms. Anyone concerned about contributing to the growth of health care costs from ineffective and unnecessary care.

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

a. The treatment is considered by some 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"). Very recent research (November 2012) published in the NEJM adds to the body of science against long-term treatment by offering strong evidence that once treated, Lyme does not relapse, but instead is the result of a new exposure (as demonstrated by the DNA of the bacteria causing the earlier and later infections). 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 the use of catheters for administration of the long-term antibiotics. Pursuit of ineffective treatment of what is perceived as Lyme symptoms may also cause patients to not pursue other, possibly more effective treatments.

b. The standard of care should not be legislated. The Board does not set the standard of care, but with the assistance of experts determines what the standard is in the medical community. What constitutes the standard of care for a particular condition may be continually changing, and those changes sometimes occur very quickly. 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. Given the controversy that is surrounding the

issue, there is no specific prohibition from the use of long term antibiotics for the treatment of PTLDS. This decision rests as it should between patient and physician.

c. As written, the bill has significant flaws. Even if one were to accept that health care professionals should be given a statutory green light to provide unnecessary and potentially harmful care, the bill would still be objectionable. In proposed § 1793, it provides immunity to physicians who prescribe long-term antibiotic therapy. The protection is against action by the Board "solely" for prescribing, administering, or dispensing long-term antibiotic therapy. Arguably, that is complete immunity for the acts covered. What if the physician in question was subject to an order preventing him or her from prescribing at all? What if the physician in question negligently prescribed an antibiotic to which the patient is severely allergic and harm resulted? At a minimum, the Board would face disputes over the extent of the immunity provided by the statute. The bill also redefines what constitutes a diagnosis of Lyme disease, contrary to the vast weight of published medical research.

d. The bill would add to the cost of health care. As discussed above, payment for ineffective treatments would cost something. There would be additional costs incurred for the treatment of harm caused by or in the delivery of the unnecessary antibiotics. There may be additional costs for delayed treatment of health problems that are treated as "chronic Lyme," when in fact the patient suffers from a treatable condition.

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: _____