

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** HB 1013 CS (PCS FOR HB 1013)

Lyme Disease

**SPONSOR(S):** Homan

**TIED BILLS:**

**IDEN./SIM. BILLS:** SB 2022

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REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Insurance Committee	15 Y, 0 N, w/CS	Tinney	Cooper
2) Health Care General Committee		Ciccone	Brown-Barrios
3) Fiscal Council			
4) Commerce Council			
5) _____			

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### SUMMARY ANALYSIS

Lyme disease (*Lyme borreliosis*) is a bacterial infection spread to humans through tick bites. When ticks are infected with this type of bacterium, they can transmit it by biting animals and humans. Lyme disease is the most common tickborne illness in the United States, although it is also found in Canada, Europe, and Asia. Current law does not require health insurers to provide specified coverage or treatment for Lyme disease.

The bill creates the Panel on Lyme Disease to be headed by the Secretary of the Department of Health, or his or her designee. Three other agency heads also serve on the panel: the Commissioner of Insurance Regulation, the Secretary of Health Care Administration (AHCA), and the Insurance Consumer Advocate, or their respective designees.

The panel is directed by the bill to study issues relating to the diagnosis and treatment of Lyme disease and to consider the following information:

1. Appropriate medical treatments and interventions;
2. Costs associated with the treatment and interventions;
3. Implications of requiring individual and group health insurance policies, as well as managed care organizations, to cover appropriate treatments of Lyme disease; and
4. Other related information identified by panel members.

The panel is directed to seek input and information from persons diagnosed as having the disease, health care providers who treat Lyme disease, health insurers, public health officials, and other parties the panel determines have pertinent information about Lyme disease. The bill requires the panel to submit a report of its findings, including recommendations and suggested legislation, if appropriate, by February 15, 2007. The panel will deliver copies of the report to the Governor, the Senate President, the Speaker of the House of Representatives, the majority and minority leaders of both the Senate and the House, and to the substantive legislative committees having oversight of health insurance. The panel is authorized to include recommendations in its report for complying with s. 624.215, F.S., if appropriate. The bill repeals provisions creating the Panel on Lyme Disease June 30, 2007.

There is minimal fiscal impact to the agencies participating in the panel for implementing the bill. The bill takes effect upon becoming law.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

**STORAGE NAME:** h1013a.HCG.doc

**DATE:** 4/9/2006

## FULL ANALYSIS

### I. SUBSTANTIVE ANALYSIS

#### A. HOUSE PRINCIPLES ANALYSIS:

**Provide Limited Government and Empower Families**—The bill creates a panel to study Lyme disease, including its diagnosis and treatment. The panel is required to submit a report of its findings, including possible legislation, to legislative leaders and the Governor by February 15, 2007. It is possible the panel will recommend the Legislature consider requiring individual and group health insurers to offer specified benefits to persons diagnosed with Lyme disease.

#### B. EFFECT OF PROPOSED CHANGES:

##### Lyme Disease: General Information

Lyme disease (*Lyme borreliosis*) is a bacterial infection spread to humans through tick bites. When ticks are infected with this type of bacterium, they can transmit it by biting animals and humans. Lyme disease is the most common tickborne illness in the United States, although it is also found in Canada, Europe, and Asia.<sup>1</sup> It was first described in the 1970s as an outbreak of arthritis in Lyme, Connecticut, and it was formally described in the medical literature in 1976.<sup>2</sup>

In the U.S., the two types of ticks that transmit Lyme disease bacteria are the deer tick (*Ixodes scapularis*), found most often in the northeastern and upper midwestern part of the country. Western black-legged ticks (*Ixodes pacificus*) are the second source of Lyme disease; they are seen most frequently along the Pacific coast, mostly in northern California and Oregon.<sup>3</sup>

The Centers for Disease Control and Prevention (CDC), an agency of the U.S. Department of Health and Human Services, is the federal agency tasked with tracking the identification, diagnosis, and treatment of Lyme disease, as well as many other infectious diseases. According to the CDC, in 2001, the first year the agency began tracking the incidence of Lyme disease, a total of 17,029 cases were reported. By 2002, the number of reported cases had risen by 40 percent, to 23,763 reported cases. In the 2002 report, only Hawaii, Montana, and Oklahoma did not report any cases of Lyme disease to the CDC.<sup>4</sup>

According to the CDC, in both 2001 and 2002, 12 states reported incidences of Lyme disease higher than the national average of 6 cases per 100,000 people in 2001 and 8.2 cases per 100,000 in 2002. The 12 states include Connecticut, Delaware, Maine, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Pennsylvania, Rhode Island, and Wisconsin. The CDC reports that an estimated 95 percent of the cases of Lyme disease identified in 2001 and 2002 were located in these 12 states.<sup>5</sup> The CDC conjectures that the increase in reported cases of the disease may be due to growing populations of deer, increased residential development of wooded areas, tick dispersal to new areas, improved disease recognition in areas where Lyme disease is prevalent, and enhanced reporting.<sup>6</sup>

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<sup>1</sup> Yahoo! Health; *Topic Overview: What is Lyme Disease*; available at [http://health.yahoo.com/ency/healthwise/hw77226/\\_hw77226-credits;\\_ylt=AhgXjiwnU66R2HTmCJlIIM3ogrME](http://health.yahoo.com/ency/healthwise/hw77226/_hw77226-credits;_ylt=AhgXjiwnU66R2HTmCJlIIM3ogrME); viewed April 3, 2006.

<sup>2</sup> Richard G. Bachur, MD, et al.; "Lyme Disease"; eMedicine: Instant Access to the Minds of Medicine; available at: <http://www.emedicine.com/ped/topic1331.htm>; viewed April 4, 2006.

<sup>3</sup> *Id.*; see also: Dr. Gary P. Wormser, et al.; "Guidelines from the Infectious Diseases Society of America: Practice Guidelines for the Treatment of Lyme Disease"; *Clinical Infectious Diseases*; 2000; 31 (Suppl 1): S1-14; available at: <http://www.cdc.gov/ncidod/dvbid/lyme/IDSA2000.pdf>; viewed April 3, 2006.

<sup>4</sup> "Lyme Disease: United States, 2001-2002;" *Morbidity and Mortality Weekly*; May 7, 2004; 53(17); 365-369; available at: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5317a4.htm>; viewed April 3, 2006.

<sup>5</sup> *Id.*

<sup>6</sup> *Id.*

## Lyme Disease: Diagnosis and Treatment

The bacterium that causes Lyme disease (*Lyme borreliosis*) is transmitted to humans through the bite of ticks infected with the bacterium. Once infected, a person generally develops symptoms of the disease within a few days or weeks. Early symptoms of the disease frequently include an expanding, circular red rash, similar in appearance to a bull's eye, referred to as *erythema migrans*, and flu-like symptoms, including body aches, fatigue, swollen lymph glands, and mild fever.<sup>7</sup> In the U.S., about 80 percent of those infected develop a circular rash at the site of the bite, however, some people do not develop any symptoms during the early stages of the disease.<sup>8</sup>

The incubation period for Lyme disease ranges from 7-14 days, although symptoms may occur as early as within 3 days or as late as 31 days after the tick bite.<sup>9</sup> If the early stage of symptoms is unnoticed, later symptoms may include swelling and pain in the joints (similar to arthritis); numbness and tingling in the hands, feet, or back; persistent fatigue; poor memory and reduced ability to concentrate; and weakness or paralysis in the muscles of the face, i.e., palsy.<sup>10</sup>

Lyme disease is most often treated with antibiotics such as doxycycline or amoxicillin. Antibiotic treatment for the early stages of Lyme disease is effective, and symptoms are generally resolved within 3 weeks of treatment. It is more effective to initiate antibiotic treatment as soon as possible after infection.<sup>11</sup> Research indicates administration of a single dose of doxycycline within 72 hours after being bitten by an infected tick, eliminates the chances of developing Lyme disease by 87 percent.<sup>12</sup> If Lyme disease is not diagnosed and treated shortly after exposure, it may take longer to treat the disease successfully.

### Delayed Diagnosis and Treatment

Lyme disease may progress in stages from mild symptoms to serious, long-term disabilities if left untreated. Health care providers have identified three stages of the disease: 1) early localized; 2) early disseminated; and 3) late persistent.

Stage 1, an early, localized infection with Lyme disease generally manifests itself within 1 to 4 weeks of a tick bite. As noted previously, an estimated 80 percent of the people infected with Lyme disease develop an expanding circular red skin rash, *erythema migrans*, within 4 weeks after being bitten by an infected tick.<sup>13</sup> In up to half of the people diagnosed with Lyme disease, the expanding circular rash is accompanied by flu-like symptoms, including fatigue or lack of energy; headache and stiff neck; fever and chills; pain in the joints and muscles; and swollen lymph nodes. As many as 25 percent of infected persons have only flu-like symptoms, with no rash or no symptoms at all.<sup>14</sup>

Stage 2 occurs within 1 to 4 months after being infected and is referred to as early disseminated infection. If an infected person is not diagnosed and treated during stage 1, the infection may spread to the skin, joints, nervous system, and heart within weeks to several months after the initial infection.<sup>15</sup> Symptoms at this stage may include persistent fatigue; additional skin rashes throughout the body; pain, weakness, or numbness in the arms or legs; inability to control facial muscles, i.e., paralysis of facial

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<sup>7</sup> Yahoo! Health; *Topic Overview: What is Lyme Disease*; available at [http://health.yahoo.com/ency/healthwise/hw77226/hw77226-credits\\_ylt=AhqXjiwnU66R2HTmCJlIiM3ogrMF](http://health.yahoo.com/ency/healthwise/hw77226/hw77226-credits_ylt=AhqXjiwnU66R2HTmCJlIiM3ogrMF); viewed April 3, 2006.

<sup>8</sup> Centers for Disease Control and Prevention: Lyme Disease; Disease Information; Division of Vector-Borne Infectious Diseases; available at: <http://www2.ncid.cdc.gov/travel/yb/utl/ybGet.asp?section=dis&obj=lyme.htm>; viewed April 3, 2006.

<sup>9</sup> American Academy of Pediatrics; 2003; Lyme Disease (*Borrelia burgdorferi* infection); *Red Book: 2003 Report of the Committee on Infectious Diseases*; L. K. Pickering, editor; 26<sup>th</sup> ed.; pp. 407-411; Elk Grove, IL.

<sup>10</sup> See *supra*, Note 7.

<sup>11</sup> Hwang M.I.; 2000; "Dangers of Lyme Disease;" *Journal of the American Medical Association*; 283(5): 698.

<sup>12</sup> Nadelman, R.B.; 2001; "Prophylaxis with Single-dose Doxycycline for the Prevention of Lyme Disease after an *Ixodes scapularis* Tick Bite"; *New England Journal of Medicine*; 245(2).

<sup>13</sup> See *supra*, Note 7.

<sup>14</sup> *Id.*

<sup>15</sup> *Id.*

nerves; recurring headaches or fainting; poor memory or a reduced ability to concentrate; conjunctivitis (“pink eye”); occasional rapid heartbeats; or, in rare cases, more serious heart problems.<sup>16</sup>

If Lyme disease is not promptly or effectively treated, damage may occur to the joints, nerves, and brain. The third stage of Lyme disease, late persistent infections, causes symptoms including swelling and pain in the joints, especially the knees; severe fatigue; numbness and tingling in the hands, feet, or back; partial facial nerve paralysis; neurologic changes, including problems with mood, memory, sleep, and sometimes with speaking; chronic Lyme arthritis, including recurrent episodes of swelling, redness, and fluid buildup in one or more joints.<sup>17</sup> Heart, nervous system, and joint symptoms may be the first signs of Lyme disease in persons who do not develop an early rash or other symptoms of early infection.<sup>18</sup>

The prognosis for Lyme disease generally is excellent when patients are treated early with appropriate antibiotic regimens. For patients with chronic symptoms post infection, randomized controlled trials of extended antibiotic regimens have not proven to be effective.<sup>19</sup> Patients in the third stage of Lyme disease face the most difficulty in diagnosing and treating the disease. It is generally these patients, many of whom may have suffered from the disease for years, who advocate new or experimental treatments, many of which may not be covered by health insurers or managed care organizations.

### **Current Florida Law Governing Health Insurance**

Current Florida law specifying the coverage and benefits health insurers must include in health policies do not specify treatment or require a benefit specific to Lyme disease. This means individual and group health insurers, as well as managed care organizations, determine their respective benefits and coverage for Lyme disease through the insurance contract/policy. As a result, different health insurers may cover Lyme disease treatments at different levels, or not at all.

Although the law does not specify the types of treatment and benefits a health insurer must offer, the law provides general guidelines regarding coverage. For example, in s. 627.411, F.S., which governs insurance contracts/policies, generally, the law authorizes OIR to disapprove an insurance form if it is ambiguous or if the form contains information that deceptively affects the risk covered by the policy. Similarly, the law requires a health policy to be clear in specifying the services or treatments that are not covered by the policy.

Similar provisions in current law govern the services offered by a health maintenance organization (HMO) or other managed care policy. For example, in s. 641.19(11), the law requires a health maintenance contract to provide “comprehensive health care services” to its members. The law defines the term “comprehensive health care services” to mean services, medical equipment and supplies, treatment of disease, or correction of defects for human beings.

It is generally left to a health insurer or managed care organization to indicate in its policy the specific services and treatment covered and excluded by the contract. However, OIR is authorized by law to prohibit the use of forms the office determines to be unfairly discriminatory or misleading. Competition among providers also helps determine the level of services and care each will provide to its policyholders.

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<sup>16</sup> Evans, J.; 2002; Lyme Disease; *Conn's Current Therapy*, pp. 127-132; R.E. Rakel, et al., editors; W.B. Saunders; Philadelphia.

<sup>17</sup> Steer, A.C.; 2000; “*Borrelia burgdorferi* (Lyme disease, Lyme borreliosis)”; *Principles and Practice of Infectious Diseases*, 5<sup>th</sup> edition; vol. 2, pp. 2504-2518; G. Mandell et al., eds.; Churchill Livingstone.

<sup>18</sup> See supra, Note 7.

<sup>19</sup> See supra, Note 17.

## Health Insurance Mandates/Required Benefits

Section 624.215, F.S., requires every person or organization seeking consideration of legislation to mandate a specific health coverage first to submit to the Agency for Health Care Administration (AHCA) and the Legislature a report assessing the social and financial impacts of the proposed benefit. The law requires the report to include the following information, if it is available:

- The extent to which the treatment or service is generally used by a significant portion of the population;
- The extent to which the insurance coverage is generally available;
- If the coverage is not generally available, to what extent does the lack of coverage result in unreasonable financial hardship;
- The level of public demand for the treatment or service;
- The level of public demand for insurance coverage of the treatment or service;
- The level of collective bargaining agents in negotiating for the inclusion of this benefit in group health contracts;
- The extent to which the coverage will increase or decrease the cost of the treatment or service;
- The extent to which the coverage will increase the appropriate uses of the treatment or service;
- The extent to which the coverage will be a substitute for a more expensive treatment or service;
- The extent to which the coverage will increase or decrease the administrative expenses of insurers and the premium and administrative expenses of policyholders; and
- The impact of providing this coverage on the total cost of health care.

To date, proponents of requiring insurance policies to cover treatment for Lyme disease have not prepared the report required by law.

### Changes Proposed by the Bill

The bill creates the Panel on Lyme Disease to be headed by the Secretary of the Department of Health, or his or her designee. Three other agency heads also serve on the panel: the Commissioner of Insurance Regulation, the Secretary of Health Care Administration (AHCA), and the Insurance Consumer Advocate, or their respective designees.

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### C. SECTION DIRECTORY:

**Section 1** creates the Lyme Disease Panel; assigns members and duties to the panel; requires a report of the panel; and provides for the future repeal of the law governing the panel.

**Section 2** specifies the bill takes effect upon becoming a law.

## II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

### A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill requires the Department of Health, OIR, AHCA, and the Department of Financial Services to provide staff support to the panel in carrying out its duties. Although the affected agencies may incur some minor costs in support of the panel, such costs should be paid from existing appropriations to the respective agencies.

### B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

### C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

### D. FISCAL COMMENTS:

None.

## III. COMMENTS

### A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

None.

2. Other:

None.

### B. RULE-MAKING AUTHORITY:

None.

### C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

#### **IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES**

On April 5, 2006, the Insurance Committee adopted a proposed committee substitute for HB 1013. The original bill required health insurance policies and health maintenance organization contracts to provide coverage for the diagnosis and treatment of Lyme disease, including long-term antibiotic therapy or other newly developed evidence-based therapy as deemed to be medically necessary by a physician. The bill as amended now only requires the creation of a panel on Lyme disease to study related issues as well as the submission of a report of the panel's findings and recommendations.

This staff analysis has been updated to reflect the bill as amended in the Insurance Committee.