



DEPARTMENT OF

**Professional &
Financial Regulation**

STATE OF MAINE

- OFFICE OF SECURITIES
- BUREAU OF INSURANCE
- CONSUMER CREDIT PROTECTION
- BUREAU OF FINANCIAL INSTITUTIONS
- OFFICE OF PROF. AND OCC. REGULATION

A Report to the Joint Standing Committee on Insurance and Financial Services of the 128th Maine Legislature

Review and Evaluation of LD 1417
*An Act to Require Insurance Coverage
for the Diagnosis and Treatment of Lyme Disease*

December 2017

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I. Executive Summary

The Joint Standing Committee on Insurance and Financial Services (Committee) of the 128th Maine Legislature directed the Bureau of Insurance (Bureau) to review LD 1417, An Act to Require Insurance Coverage for the Diagnosis and Treatment of Lyme Disease. The review was conducted as required by Title 24-A, Section 2752. This document and review is a collaborative effort of NovaRest, Inc. and the Bureau.

The amended LD 1417 states, “A carrier offering or renewing a health plan in this State shall provide coverage for the diagnosis and short-term and long-term antibiotic therapy of Lyme disease. An increase in enrollee cost sharing to achieve compliance with this section may not be implemented.”¹

The original language in the bill mandated diagnosis and short-term and long-term treatment of Lyme disease, as opposed to specifying antibiotic therapy. We believe this would have significantly increased the cost of the proposed mandate because it could have required carriers to cover alternative treatments above antibiotic therapy. According to the CDC, alternative treatments include: IV infusions of hydrogen peroxide, immunoglobulin therapy, hyperbaric oxygen therapy, electromagnetic frequency treatments, garlic supplements, colloidal silver, and stem cell transplants.²

The amended language in the bill, although more specific than the original language, is still quite vague and does not specify which forms of antibiotic therapy, the length of treatment, and if intravenous, where it would be administered.³ We were required to make several assumptions to develop our cost estimate, which will be described in the following sections. In addition, we are unclear how a change in enrollee cost sharing to achieve compliance with the bill would be determined given that cost sharing frequently changes from one year to the next to meet actuarial value (AV) requirements and/or to lessen rate increases. We assumed this would not impact our cost estimate.

In order to develop our cost estimate, we performed a survey of the largest carriers in Maine to determine the level of coverage already available and other critical information. Our survey revealed that all of the carriers included in the survey already cover diagnosis and short-term

¹ The amended LD 1417 was provided by the Insurance and Financial Services Committee.

² Marzec, Natalie S. MD, et al. “Serious Bacterial Infections Acquired During Treatment of Patients Given a Diagnosis of Chronic Lyme Disease — United States.” 2017. <https://www.cdc.gov/mmwr/volumes/66/wr/mm6623a3.htm> . Accessed October 19, 2017.

³ The amendment cites 32 MRSA Sec. 3282-B(1)(A), which defined long-term antibiotic therapy as “the administration of oral, intramuscular or intravenous antibiotics, singly or in combination, for a period of time in excess of 4 weeks.”

antibiotic therapy. The carriers define short-term antibiotic therapy as less than 28 days. The carriers, however, do not cover antibiotic therapy for longer than 28 days because they consider it experimental and investigational. Therefore, our cost estimate is the cost of extending antibiotic therapy for Lyme disease more than 28 days. Our analysis concluded that the cost of long-term antibiotic therapy ranges from \$0.14 per member per month (PMPM) to \$0.82 PMPM depending on the market and the additional months treated. Our assumptions are explained in the following sections.

II. Background

According to the Centers for Disease Control and Prevention (CDC), Lyme disease was the sixth most common Nationally Notifiable disease in 2015 and is the most commonly reported vector borne illness in the United States.⁴ They also noted that in 2015, 95% of confirmed Lyme disease cases were reported from 14 states, shown below:

Connecticut	New Jersey
Delaware	New York
Maine	Pennsylvania
Maryland	Rhode Island
Massachusetts	Vermont
Minnesota	Virginia
New Hampshire	Wisconsin

Confirmed cases must meet the following criteria:

- 1) A person with erythema migrans (circular or bull's-eye rash); or
- 2) A person with at least one disseminated manifestation and laboratory confirmation of one of the following:

- Positive culture for *B. burgdorferi*;
- IgG positive Western blot;
- Positive ELISA test and an IgM positive Western blot within 30 days of onset. This should be confirmed by IgG Western blot;
- CSF antibody positive by EIA or IFA, where the titer is higher than it was in serum.

Probable cases must meet one of the laboratory criteria mentioned above and be physician diagnosed.

⁴ Centers for Disease Control and Prevention. "Lyme Disease Data and Statistics." 2017. <https://www.cdc.gov/lyme/stats/index.html>. Accessed October 16, 2017.

Diagnosis for Lyme disease can be difficult in some cases. Typically, a bull's-eye pattern, known as erythema migrans, forms and expands slowly over days, which can make diagnosis easier as it is one of the hallmarks of Lyme disease.⁵ However, if this rash does not develop or develops in an area where it is not visible, it can be difficult to diagnose Lyme disease. Other symptoms include flu-like symptoms, joint pain, neurological problems, nausea and vomiting, heart problems, eye inflammation, liver inflammation, and severe fatigue.⁶ Because many of these symptoms are consistent with other conditions, patients can often be misdiagnosed.

In addition, many patients who have Lyme disease test negative, so several rounds of testing may be required. According to LymeDisease.org, negative Lyme disease test results can be due to several factors including; the time it takes for antibodies to develop, the immune system may be suppressed; or the person may be infected with a strain the test doesn't measure.⁷ They also note that 20-30% of patients have false negative antibody tests⁸ and according to one study 56% of patients with Lyme disease test negative using the two-tiered testing system recommended by the CDC.⁹ According to the International Lyme and Associated Diseases Society, for those 40% of Lyme patients ending up with long term health problems, the average patient sees five doctors over nearly two years before being diagnosed.¹⁰ The quality of life of patients with chronic Lyme disease is similar to patients with congestive heart failure.¹¹ Lingering symptoms include fatigue, arthritis and joint pain, head problems (headaches and memory issues), numbness, Bell's palsy, heart problems, depression, and stress.¹²

⁵ Mayo Clinic Staff. "Lyme Disease Symptoms." 2016. <https://www.mayoclinic.org/diseases-conditions/lyme-disease/basics/symptoms/con-20019701>. Accessed October 16, 2017.

⁶ Mayo Clinic Staff. "Lyme Disease Symptoms."

⁷ Lyme Disease.org. "Lyme Disease Diagnosis." <https://www.lymedisease.org/lyme-basics/lyme-disease/diagnosis/>. Accessed October 16, 2017.

⁸ Lyme Disease.org. "Lyme Disease Diagnosis."

⁹ Stricker, Raphael B, and Lorraine Johnson. "Let's Tackle the Testing." 2007. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2078675/>. Accessed October 17, 2017.

¹⁰ International Lyme and Associated Diseases Society. "ILADS About Lyme." <http://www.ilads.org/lyme/lyme-quickfacts.php>. Accessed October 17, 2017.

¹¹ Lyme Disease.org. "Lyme Disease Diagnosis." <https://www.lymedisease.org/lyme-basics/lyme-disease/treatment/>. Accessed October 16, 2017.

¹² WebMD. "Chronic Lyme Disease – Complications." 2016. <https://www.webmd.com/arthritis/chronic-lyme-disease-complications>. Accessed October 16, 2017.

The recommended treatment for Lyme disease is generally a 2-4 week course of antibiotics.¹³ Typically, patients treated with appropriate antibiotics in the early stages of Lyme disease recover completely¹⁴, however, symptoms can last for more than 6 months in some cases. This is sometimes called “chronic Lyme disease” but is properly known as “Post-Treatment Lyme Disease Syndrome” (PTLDS).¹⁵ Studies have estimated the percentage of cases which meet the case definition of PTLDS at 6-months to be as high as 35% of cases,¹⁶ although this is still debated and the CDC states that it represents a small percentage of cases.¹⁷

In addition to the statutory criteria, the Committee also asked that the review provide an analysis of:

- The extent to which coverage of the diagnosis and treatment of Lyme disease is included in the State’s essential benefits package and the manner in which the bill may expand this coverage.
- The impact of amending LD 1417 to require coverage of short-term and long-term antibiotic therapy as proposed by Rep. Fredette.
- The impact of amending LD 1417 to require coverage for the diagnosis and treatment of Lyme disease by naturopathic physicians or other out-of-network providers.
- If the bill expands coverage beyond the essential benefits package, the estimated costs to the State to defray the costs of including the coverage in qualified health plans.

The extent to which coverage of the diagnosis and treatment of Lyme disease is included in the State’s essential benefits package and the manner in which the bill may expand this coverage.

LD 1417 mandates that health insurance carriers cover diagnosis, short-term, and long-term antibiotic therapy. According to our survey results, carriers in Maine cover certain diagnostic tests and short-term antibiotic therapy, which they define as less than 28 days. Anthem also covers additional care for

¹³ Marzec, Natalie S. MD, et al. “Serious Bacterial Infections Acquired During Treatment of Patients Given a Diagnosis of Chronic Lyme Disease — United States.”

¹⁴ Centers for Disease Control and Prevention. “Lyme Disease Treatment.” 2016. <https://www.cdc.gov/lyme/treatment/index.html>. Accessed October 16, 2017.

¹⁵ Centers for Disease Control and Prevention. “Post-Treatment Lyme Disease Syndrome.” 2017. <https://www.cdc.gov/lyme/postlds/index.html>. Accessed October 16, 2017.

¹⁶ Aucott, John N. et al. “Post-Treatment Lyme Disease Syndrome Symptomatology and the Impact on Life Functioning: Is There Something Here?” 2013. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3548099/>. Accessed October 17, 2017.

¹⁷ Centers for Disease Control and Prevention. “Post-Treatment Lyme Disease Syndrome.”

continued symptoms associated with Post-Treatment Lyme Disease Syndrome (PTLDS), which does not include long-term antibiotic therapy.

Carriers currently cover the diagnostic tests consistent with recommendations of the Centers for Disease Control and Prevention (CDC). LD 1417 may have the impact of mandating carriers to cover all diagnostic tests including those carriers believe are experimental and investigational.

Carriers typically do not cover antibiotic therapy lasting longer than 28 days. We believe LD 1417 will have the impact of mandating that carriers cover antibiotic therapy, which is considered experimental and investigational, for an indefinite amount of time.

The impact of amending LD 1417 to require coverage of short-term and long-term antibiotic therapy as proposed by Rep. Fredette.

The original bill stated, “A carrier offering or renewing a health plan in this State shall provide coverage for the diagnosis and short-term and long-term treatment of Lyme disease. An increase in enrollee cost sharing to achieve compliance with this section may not be implemented.” The amendment specified short-term and long-term antibiotic therapy as opposed to short-term and long-term treatment of Lyme disease.

The original bill could have the effect of requiring coverage for virtually any test or treatment for Lyme disease or Post Treatment Lyme Disease Syndrome (PTLDS). With the amendment, the bill has the effect of requiring coverage for virtually any antibiotic treatment for an indefinite duration. While the bill’s language is still quite broad, specifying antibiotic therapy narrows the scope.

The impact of amending LD 1417 to require coverage for the diagnosis and treatment of Lyme disease by naturopathic physicians or other out-of-network providers.

According to our survey of carriers, providers with appropriate state licensure, and accreditation/certification from an appropriate accrediting organization, which includes naturopathic physicians, providing treatment that is not experimental, investigational, and is medically necessary are covered. In addition, out-of-network providers would be paid according to the out-of-network coverage. In cases where HMO plans do not cover out-of-network services healthcare, expenses may be impacted, if the network does not include naturopaths.

If the bill expands coverage beyond the essential benefits package, the estimated costs to the State to defray the costs of including the coverage in qualified health plans.

According to our survey of carriers, their understanding is that the State would be required to pay the costs associated with the expansion in the diagnostic tests that would be covered, as well as the costs associated with requiring coverage of long-term antibiotic therapy.

We do not have adequate information on which diagnostic tests are not covered by each carrier or what percentage of patients would use these tests, so we are unable to quantify this impact. We believe, however, that the impact would be minimal because the prices of the tests posted on IGeneX website¹⁸ are consistent with cost of other Lyme disease diagnostic tests.¹⁹ We have also assumed all short-term antibiotic treatments are already covered, so we assume no increase in cost for the diagnosis and first month of treatment. As discussed later in this report, we estimate the additional cost for long-term antibiotic therapy, depending on the length of treatment, to be between \$0.14 and \$0.75 per member per month for individual coverage and between \$0.14 and \$0.76 per member per month for small group coverage.²⁰ Based on the projected member months for 2018 for plans offered on-Exchange this would total approximately \$98,000 to \$542,000 per year for individual coverage and \$6,000 to \$35,000 per year for small group coverage for a grand total of \$104,000 to \$577,000.

III. Social Impact

A. Social Impact of Mandating the Benefit

1. The extent to which the treatment or service is utilized by a significant portion of the population.

The CDC used national surveillance data to compile a list of reported cases of Lyme disease from 2005 to 2015 by state and locality. In 2015, the data collection showed 28,453 confirmed cases of Lyme disease in the US, with another 9,616 probable cases.²¹ In Maine alone, this amounted to 993 confirmed cases and 208 probable cases. However, there is skepticism about the surveillance data being reported to the CDC and underreporting of Lyme disease is estimated to be 6 to 12-fold.²² A majority of these cases will be treated successfully with short-term antibiotic therapy; however, those with symptoms that persist (PTLDS) would likely utilize a longer-term antibiotic therapy. Studies have estimated the percentage of cases which meet the case definition of PTLDS at 6-months to be as high as 35% of cases.²³

¹⁸ IGeneX, Inc. "Price List." 2017. <https://www.igenex.com/wp-content/uploads/2017/04/IGeneX-Price-List.pdf>. Accessed October 19, 2017.

¹⁹ Wormser, Gary P. et al. "Comparative Cost-Effectiveness of Two-Tiered Testing Strategies for Serodiagnosis of Lyme Disease with Noncutaneous Manifestations." 2013. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3838032/>. Accessed October 19, 2017.

²⁰ We estimate a range of \$0.15 to \$0.82 per member per month for the large group market, however, large group policies are not considered QHPs and are therefore not considered in the cost to the state.

²¹ Centers for Disease Control and Prevention. "Lyme Disease Tables."

²² Aucott, John N. et al. "Post-Treatment Lyme Disease Syndrome Symptomatology and the Impact on Life Functioning: Is There Something Here?"

²³ Aucott, John N. et al. "Post-Treatment Lyme Disease Syndrome Symptomatology and the Impact on Life Functioning: Is There Something Here?"

According to a report developed by the Maine Bureau of Insurance 13,982 claims were submitted to carriers in 2016 for Lyme disease, of which 12,995 were paid for a total paid amount of \$1,604,775.29.²⁴

2. The extent to which the service or treatment is available to the population.

According to the CDC, patients treated with appropriate antibiotics in the early stages of Lyme disease usually recover rapidly and completely.²⁵ Lyme disease cases are treated with antibiotics commonly used for oral treatment which include doxycycline, amoxicillin, or cefuroxime axetil. Patients with certain neurological or cardiac forms of illness may require intravenous treatment with drugs such as ceftriaxone or penicillin. This was verified in an article on Johns Hopkins Arthritis Center which stated, “In general, early Lyme disease in adults is treated with doxycycline 100 mg orally twice daily or amoxicillin 500 mg orally three times daily for 20 to 30 days. Doxycycline should not be used in children under age nine years or pregnant women. Other antibiotic choices include phenoxymethyl penicillin, tetracycline, cefuroxime axetil, erythromycin, or azithromycin, with the latter two considered to be second line choices.”²⁶

The antibiotics used to treat Lyme disease are among the most commonly prescribed antibiotics and are widely available to the public.²⁷ For patients that require intravenous treatment, such as for nervous system problems or severe heart symptoms,²⁸ outpatient treatment may be required which would require a visit to a medical facility and make care more difficult for some patients.

In cases where symptoms persist, there is debate about ongoing symptoms and treatment. For long-term treatment, there appears to be no established treatment capable of completely eradicating the infection and treatment failures are reported with all current regimens.²⁹

²⁴ Maine Bureau of Insurance. “Report on 2016 Claims for Treatment of Lyme Disease and Other Tick-Borne Illnesses.” 2017. http://www.maine.gov/pfr/legislative/documents/2016_Tickborne_Report.pdf. Accessed November 2, 2017.

²⁵ Centers for Disease Control and Prevention. “Lyme Disease Treatment.”

²⁶ Johns Hopkins Arthritis Center. “Lyme Disease Treatment.”

²⁷ Anderson, L. PharmD. “Antibiotics Guide.” 2016. <https://www.drugs.com/article/antibiotics.html>. Accessed October 16, 2017.

²⁸ Healthwise Staff. “Antibiotics for Lyme Disease.” 2014. <https://www.webmd.com/arthritis/antibiotics-for-lyme-disease>. Accessed October 17, 2017.

²⁹ Centers for Disease Control and Prevention. “Lyme Disease Treatment.”

3. *The extent to which insurance coverage for this treatment is already available.*

Currently, all carriers that we surveyed indicated that they cover diagnosis and short-term treatment when medically necessary, subject to standard plan cost sharing.

Aetna

Aetna currently provides coverage for diagnosis and treatment of Lyme disease consistent with the recommendations of the Centers for Disease Control and Prevention and the Infectious Diseases Society of America. Aetna's clinical bulletin policy indicates that Aetna considers outpatient intravenous antibiotic therapy medically necessary in adult and pediatric members with the diagnosis of Lyme disease only when it is based on the clinical presentation of signs and symptoms compatible with the disease and supported by a positive serologic and/or cerebrospinal fluid (CSF) titer by indirect immunofluorescence assay (IFA), Prevue Borrelia burgdorferi antibody detection assay, or enzyme-linked immunosorbent assay (EIA), which itself is validated by a positive Western Blot Test. Once a definitive diagnosis of Lyme disease is established, Aetna will cover a 4-week oral antibiotic therapy or 4-week outpatient intravenous antibiotic therapy under certain conditions such as cardiac involvement, neurological involvement, pregnancy, or failure to respond to oral antibiotic therapy.

Anthem Blue Cross and Blue Shield

Anthem provides coverage for the diagnosis and treatment of Lyme disease in accordance with evidence based medicine and generally accepted standards of care. Covered services include EIA and Western Blot testing, short-term (up to four weeks) oral antibiotic therapy, short term IV antibiotic therapy for those for whom it is medically necessary, and additional care for continued symptoms associated with Post-Treatment Lyme Disease Syndrome (PTLDS, which is sometimes incorrectly referred to as "long-term Lyme disease" or "chronic Lyme disease"), which does not include long-term antibiotic therapy.

Cigna

Cigna already provides coverage for the diagnosis and short-term antibiotic treatment of Lyme disease, which we define as up to 28 days of treatment.

Community Health Options

Health Options' plans provide coverage for medically necessary services, including short-term and long-term treatment of Lyme disease when not subject to a policy exclusion. The benefits are subject to standard plan cost sharing which could include deductibles, coinsurance, co-payments subject to a maximum out of pocket limitation.

Health Options noted that currently there are basically two treatment regimens that are considered medically necessary for the treatment of Lyme disease. They are a 10-day course for early stage disease and a 28-day course for later stage disease. There is no definition of long-term treatment in the bill. Any extension beyond the 28-day course of treatment for later stage disease would be an expansion of coverage.

Harvard Pilgrim Health Care

Harvard Pilgrim covers medically necessary use of parenteral antibiotics (i.e., drugs administered by intramuscular [IM] or intravenous [IV] injection) that is clinically indicated for treatment of Lyme and other Tick-Borne Diseases (e.g., Human Granulocytic Anaplasmosis, and Babesiosis).

Covered parenteral (IM or IV) therapy must be:

- Reasonable and medically necessary based on the member’s condition, complexity of requested service(s), and accepted standards of clinical practice;
- An essential part of active treatment of the member’s medical condition, and ordered under a plan of care established and reviewed regularly by the attending physician caring for the member; and
- Furnished by provider(s) with appropriate state licensure, and accreditation/certification from an appropriate accrediting organization.

United Healthcare Insurance Company

Coverage is for the use of parenteral antibiotics, such as ceftriaxone, cefotaxime, or penicillin G, for a period of up to 28 days. This is proven and medically necessary for treating Lyme disease. The mandate would expand the current coverage period.

4. If coverage is not generally available, the extent to which the lack of coverage results in a person being unable to obtain the necessary health care treatment.

If diagnosis and short-term antibiotic therapy was not covered by insurance it is reasonable to assume patients who could not afford the diagnostic test or antibiotic medication may not receive proper care, but the survey data indicates that short-term therapy is currently covered.

For long-term antibiotic therapy, which is not covered by insurance, patients who could not afford the therapy may not receive proper care, although the effectiveness of such treatment is still being debated. Nonetheless, we can assume fewer patients will pursue long-term treatment due to the cost impact.

Testimony by Rhonda Buker indicated she paid more than \$5,000 out-of-pocket for long-term treatment over the course of a few months. Victoria Delfino also testified that she spends thousands of dollars out-of-pocket each year for treatment and knows many who do the same. In addition, testimony by Rhonda Buker and Victoria Delfino indicated their Lyme disease specialists, often called “Lyme literate” doctors, do not accept insurance because they would not be reimbursed for the length of an appointment. We note, however, there is nothing in the bill to address the limit on a length of appointment for a Lyme literate

doctor. In addition, there is debate as to the effectiveness of Lyme literate doctors.³⁰

5. If coverage is not generally available, the extent to which the lack of coverage involves unreasonable financial hardship.

According to a retrospective study on medical claims, Lyme disease is associated with \$2,968 higher total health care costs and 87% more outpatient visits over a 12-month period compared to those with no Lyme disease exposure. Among those with Lyme disease, having one or more PTLDS-related diagnosis is associated with \$3,798 higher total health care costs and 66% more outpatient visits over a 12-month period per person.³¹ Considering that insurance will typically only cover the first 28 days of treatment, this could represent a significant financial burden.

The 2016 median household income in Maine is \$53,079.³² The \$3,798 higher total health care costs would represent 7.2% of the 2016 median household income. This could be considered a financial hardship for some Maine citizens.

6. The level of public demand and the level of demand from providers for this treatment or service.

As discussed previously, Maine is one of the states most impacted by Lyme disease. With over 1,000 new cases in Maine annually (which may be understated) and with the serious consequences of Lyme disease being left untreated, there is a high level of public demand for diagnosis and treatment of Lyme disease. Long-term antibiotic therapy, which is currently not covered by insurance, is less in demand. The CDC in the past has stated that 10-20%³³ of Lyme disease patients experience PTLDS and the International Lyme and Associated Diseases Society has stated that this number is 40%.³⁴

7. The level of public demand and the level of demand from the providers for individual or group coverage of this treatment.

³⁰ Sun, Lena H. "Dangerous unproven treatments for 'chronic Lyme disease' are on the rise." 2015. https://www.washingtonpost.com/news/to-your-health/wp/2017/06/15/dangerous-unproven-treatments-for-chronic-lyme-disease-cause-are-on-the-rise/?_hscenc=p2ANqtz-8JadzjySCa0GekEbIN7xGQGzsJnT8w9ByTahWx3slUNTFib18cwLHBDm0qFKZDJU7rvCNiSelfoyu9QkACz-iMBMAdRQ&_hsmi=53209539&utm_campaign=KHN%3A%20First%20Edition&utm_content=53209539&utm_medium=email&utm_source=hs_email&utm_term=.f4cbc18133ea. Accessed October 16, 2017.

³¹ Adrion, Emily R. et al. "Health Care Costs, Utilization and Patterns of Care Following Lyme Disease." 2015. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4317177/>. Accessed October 18, 2017.

³² Guzman, Gloria G. "Household Income: 2016." 2017. <https://www.census.gov/content/dam/Census/library/publications/2017/acs/acsbr16-02.pdf>. Accessed October 17, 2017.

³³ Lyme Disease.org. "Chronic Lyme Disease."

³⁴ International Lyme and Associated Diseases Society. "ILADS About Lyme."

Antibiotic therapy lasting longer than 28 days is typically not covered by insurance and must be paid out-of-pocket. Because the long-term treatment of Lyme disease is complex and experimental at this point, the sponsor of LD 1417 argued that mandating long-term treatment by insurance would allow the medical community to continue to search for a treatment while giving patients a currently available treatment option.

However, there are concerns about the general language in the bill that some believe could be easily manipulated to the detriment of Lyme disease patients and more education is required. One person commented that a recent Lyme disease bill passed in Massachusetts has not gone as planned and more work is required before it could be considered a success. There was also concern that the language refers solely to Lyme disease and does not reference other tick-borne diseases.

8. The level of interest in and the extent to which collective bargaining organizations are negotiating privately for the inclusion of this coverage by group plans.

No information is available.

9. The likelihood of meeting a consumer need as evidenced by the experience in other states.

Other states that cover long-term treatment of Lyme disease are Rhode Island, Connecticut, and Massachusetts.

Rhode Island passed a law in 2004 that requires every individual or group hospital or medical expense insurance policy or individual or group hospital or medical service plan to provide for long-term Lyme disease treatment.³⁵ BCBSRI calculated the impact of the Lyme disease mandate at \$0.02 per-member-per-month (PMPM) in 2010. Inflated to 2014 dollars, the expected impact of this mandate on premiums in Rhode Island increases slightly to \$0.03 PMPM.³⁶

Connecticut passed a similar law, which requires not less than 30 days of intravenous antibiotic therapy, 60 days of oral antibiotic therapy, or both, and further treatment if recommended by a rheumatologist,

³⁵ State of Rhode Island General Assembly. "House Passes Lyme Disease Bill." 2014. <http://www.rilin.state.ri.us/pressrelease/Lists/PressReleaseData/DispForm.aspx?ID=969>. Accessed October 18, 2017.

³⁶ Rhode Island Office of the Health Insurance Commissioner. "A Review of Rhode Island's Mandated Benefits and Recommendations for Future Reviews." 2014. <http://www.ohic.ri.gov/documents/HIAC-Mandated-Benefits-Report-May-2014.pdf>. Accessed October 18, 2017.

infectious disease specialist, or neurologist.³⁷ Connecticut's 2014 estimate was \$0.34 PMPM.³⁸

Massachusetts overrode a veto by their governor to mandate that health insurers begin paying for long-term antibiotic treatment for Lyme disease in 2016.³⁹ Massachusetts included a mandated benefit review in 2014, which stated, "Requiring coverage for this benefit by fully-insured health plans would result in an average annual increase, over five years, to the typical member's monthly health insurance premiums of between a negligible amount (0.00%) and \$0.13 (0.02%) per year."⁴⁰

Minnesota has a statute that states "Every health plan, including a plan providing the coverage specified in section 62A.011, subdivision 3, clause (10), must cover treatment for diagnosed Lyme disease."⁴¹ It also specifies that a health plan may not impose deductible, co-payment, waiting period, or other special restrictions on Lyme disease treatment that is not applied to non-preventive treatment in general.

New York passed three bills providing further education on Lyme disease including requiring a state board to put out a report by May 2018 on the impact of requiring insurers to provide long-term coverage for tick-borne illness.⁴²

The Pennsylvania legislature recently voted for House Bill 174, which will move into the senate. This bill would cover long-term treatment of Lyme disease but did not provide a fiscal impact of the bill.⁴³

10. The relevant findings of the state health planning agency or the appropriate health system agency

³⁷ Kaminski Leduc, Janet L. "State Mandated Health Insurance Benefits." 2009. <https://www.cga.ct.gov/2009/rpt/2009-R-0317.htm>. Accessed October 18, 2017.

³⁸ UCONN Health. "Review of Connecticut Mandated Health Insurance Benefits 2014." 2014. http://www.ct.gov/cid/lib/cid/Mandated_Health_Insurance_Benefits_Reviews_for_the_2015.pdf. Accessed October 18, 2017.

³⁹ Freyer, Felice J. "Legislature overrides Baker veto on Lyme treatment coverage." 2016. <https://www.bostonglobe.com/metro/2016/08/01/legislature-orders-insurers-cover-long-term-lyme-treatment-overriding-baker-veto/YBZ3DGaUy8bHRWMYyOyQdM/story.html>. Accessed October 18, 2017.

⁴⁰ Center for Health Information and Analysis. "Mandated Benefit Review of H.B. 989: An Act Relative to Lyme Disease Treatment Coverage." 2014. <http://www.canlyme.com/wp-content/uploads/2014/05/h989-mbr-lyme-disease%20Mass.pdf>. Accessed October 18, 2017.

⁴¹ The Office of Revisor of Statutes. "2017 Minnesota Statutes." 1996. <https://www.revisor.mn.gov/statutes/?id=62A.265>. Accessed November 2, 2017.

⁴² Riback, Lindsey. "Lyme disease battle: NY Senate approves bills." 2017. <http://www.lohud.com/story/news/politics/politics-on-the-hudson/2017/05/16/ny-senate-approves-lyme-fighting-bills/101755842/>. Accessed October 18, 2017.

⁴³ Hook, Jim. "Bill pushing insurers, doctors to act on Lyme disease moves to Senate." 2017. <http://www.publicopiniononline.com/story/news/local/2017/05/20/lawmakers-push-insurers-doctors-act-lyme-disease/101769072/>. Accessed October 18, 2017.

relating to the social impact of the mandated benefit.

State agencies did not provide findings pertaining to the proposed legislation.

11. The alternatives to meeting the identified need.

The following are the responses from commercial insurance carriers to the Bureau's request for information. We are not opining on the validity of the following assumptions or conclusions, but rather are repeating them as provided.

Community Health Options

As an alternative to the currently proposed mandate, although we believe no mandate is necessary, we would find appropriate a mandate for a 10-day course of antibiotics for early stage disease and up to a 28-day course of treatment with antibiotics for later stage disease based on medical necessity. We recommend that providers following experimental or investigational treatment protocols work closely with researchers on this serious disease, but that no coverage be mandated for those treatments.

The other carriers noted that they do not have any alternatives to suggest.

12. Whether the benefit is a medical or a broader social need and whether it is inconsistent with the role of insurance and the concept of managed care.

The benefit is a medical need and coverage required by LD 1417 is not inconsistent with the role of insurance to provide medically necessary services for a condition. However, this mandate may step outside the role of insurance in that it requires carriers to reimburse providers for long-term Lyme disease treatments, which have not been shown to be medically necessary or to improve symptoms.⁴⁴

13. The impact of any social stigma attached to the benefit upon the market.

Individuals with Lyme disease have testified that they often feel stigmatized by physicians who are unable to diagnose or treat the condition. Some believe they are misdiagnosed with other conditions, thus delaying treatment. Bill Young, a resident that testified at the public hearing described his family "trials of trying to find someone who would listen and help." He also said, that physicians "don't know how to treat it and often think it is all psychological."⁴⁵

14. The impact of this benefit upon the other benefits currently offered.

⁴⁴ Centers for Disease Control and Prevention. "Research into Prolonged Treatment for Lyme Disease." 2017. <https://www.cdc.gov/lyme/treatment/prolonged/index.html>. Accessed October 18, 2017.

⁴⁵ Young, Bill. "Testimony on LD 1417" <http://www.mainelegislature.org/legis/bills/getTestimonyDoc.asp?id=71492>. Accessed December 11, 2017.

The insurance carriers that we surveyed already cover certain diagnostic tests and certain short-term treatment for Lyme disease. This bill would likely mandate the insurance companies to cover all diagnostic tests and all short-term treatment methods, even though they are currently covered without the mandate.

This bill would also expand coverage to include for long-term Lyme disease treatment, which could extend treatment indefinitely. Because there is no standard of care for PTLDS, services that are considered experimental or investigational would need to be covered.

15. The impact of the benefit as it relates to employers shifting to self-insurance and the extent to which the benefit is currently being offered by employers with self-insured plans.

As premiums increase due to mandated benefits, some employers choose to self-insure in order to have more control over the benefits that they provide to employees and control the cost of health insurance premiums. Since this mandate will have a minimal impact on premiums it is unlikely this will impact any shifting to self-insurance.

16. The impact of making the benefit applicable to the state employee health insurance program.

Anthem stated they have little experience to review for the state employee plans, so the assumptions used to develop the cost implications for the bill and amendment are the same as those used for their Large Group segment. They also stated due to the extremely broad nature of the bill, they are unable to develop a meaningful estimate of the cost implications of the bill. The mandate could require Anthem to cover a subset of diagnostic tests (IGeneX, Inc. test kits), which are not currently covered. Anthem assumed a five-year period of long-term antibiotic therapy with 75% of members receiving antibiotics orally and 25% receiving them intravenously. Below is the PMPM cost estimate provided by Anthem:

State Employee Health Plan	PMPM
Long-term antibiotic therapy	\$15.80
Diagnostic tests	\$0.88
Total	\$16.68

IV. Financial Impact

B. Financial Impact of Mandating Benefits

1. The extent to which the proposed insurance coverage would increase or decrease the cost of the service or treatment over the next five years.

The expansion in coverage is for antibiotics that are commonly used for many conditions. It is unlikely that the cost of these antibiotics would be impacted.

2. The extent to which the proposed coverage might increase the appropriate or inappropriate use of the treatment or service over the next five years.

The mandate would likely increase the use of long-term antibiotic therapy for Lyme disease. The appropriateness of such treatment is still being debated.

Anthem Blue Cross and Blue Shield

The proposed mandate is extremely broad. The bill does not define the scope or duration of the Lyme disease treatments for which coverage would be required. In addition, it does not provide that the treatments be evidence-based or consistent with generally accepted standards of care, nor does it provide that the treatments be medically necessary. As a result, virtually any test or treatment that someone could assert to be a test or treatment for Lyme disease or PTLDS would be covered under the legislation as drafted, regardless of whether it is supported by medical science or consistent with generally accepted standards of care. This will substantially expand coverage well beyond what is covered today, despite the fact that many of the services that would be covered under the mandate, including long-term antibiotic therapy, have been expressly rejected and are considered to be inappropriate tests and treatments by the U.S. Centers for Disease Control and Prevention, and the National Institute of Allergy and Infectious Disease, and the Infectious Diseases Society of America within the National Institute of Health.

Rhonda Buker Testimony⁴⁶

One of Ms. Rhonda Buker's concerns is that the language in this bill is too general in nature and could easily be manipulated to the detriment of Lyme disease patients.

Victoria Delfino Testimony⁴⁷

Ms. Victoria Delfino is concerned that the language in this Bill is too simple for a very complex matter. Both the Lyme disease diagnosis and treatment are complex and controversial. She fears this simple bill language could be influenced by special interest groups in ways that would be harmful to Lyme disease patients in Maine.

⁴⁶ Buker, Rhonda. "LD 1417 Testimony." 2017. <http://www.mainelegislature.org/legis/bills/getTestimonyDoc.asp?id=71496>. Accessed October 16, 2017.

⁴⁷ Delfino, Victoria. "LD 1417 Testimony." 2017. <http://www.mainelegislature.org/legis/bills/getTestimonyDoc.asp?id=71497>. Accessed October 16, 2017.

Diane Farnum Testimony⁴⁸

LD 1417 is very broad based, has ambiguous language, and refers solely to Lyme disease and none of the other tick-borne illnesses found in Maine.

3. The extent to which the mandated treatment or service might serve as an alternative for more expensive or less expensive treatment or service.

According to the CDC, alternative treatments include IV infusions of hydrogen peroxide, immunoglobulin therapy, hyperbaric oxygen therapy, electromagnetic frequency treatments, garlic supplements, colloidal silver, and stem cell transplants, none of which have shown evidence of effectiveness.⁴⁹ These treatments are typically considered experimental and investigational and are not currently covered by insurance. Anthem mentioned that they do cover some treatments for PTLDS, however, they did not specify treatments they cover. We do not believe these alternative treatments would be covered by the amended bill, because the language specifies antibiotic therapy.

The Maine Bureau of Insurance prepared a report which contained a table showing the number of claims submitted for antibiotic therapy and other treatment for Lyme disease.⁵⁰ In 2016, 2,803 antibiotic therapies were paid for with an average paid claim amount of \$83.51, compared to 10,199 paid claims for alternative treatments with an average paid claim amount of \$134.58. So not only are alternative treatments experimental or investigational, they also may be more expensive than antibiotic therapies.

4. The methods that will be instituted to manage the utilization and costs of the proposed mandate.

There is no language in the bill that prohibits medical management. Carriers will be able to limit services to those that they determine are medically necessary. If treatment is not having an impact, the medical management would be able to discontinue treatment.

5. The extent to which insurance coverage may affect the number and types of providers over the next five years.

In public testimony on the bill it was stated that Lyme literate doctors do not take insurance because insurance companies will not reimburse them for the length of time they need to spend with a patient in order to give them good care. We do not see anything in the bill that will address time limits on doctor visits for Lyme disease treatment, so the bill may not impact the number of Lyme literate doctors.

⁴⁸ Farnum, Diane. "LD 1417 Testimony." 2017.

<http://www.mainelegislature.org/legis/bills/getTestimonyDoc.asp?id=71495>. Accessed October 16, 2017.

⁴⁹ Marzec, Natalie S. MD, et al. "Serious Bacterial Infections Acquired During Treatment of Patients Given a Diagnosis of Chronic Lyme Disease — United States."

⁵⁰ Maine Bureau of Insurance. "Report on 2016 Claims for Treatment of Lyme Disease and Other Tick-Borne Illnesses."

According to the Washington Post, “Clinicians who call themselves “Lyme literate” are often self-anointed; there is no special training program and no requirement to be board certified in infectious disease.”⁵¹ In addition, Lyme literate doctors may subject patients to a host of unproven treatments, which would not be covered by the bill.⁵²

The proposed amendment to the bill may require coverage of naturopaths that are not currently mandated providers. The effect of mandating naturopaths will be part of a separate report by the Bureau of Insurance provided for LD 1030, An Act to Require Nondiscrimination Policies in Providing Health Insurance. However, as noted above, covered treatment by naturopaths is currently covered by in-network naturopaths.

6. The extent to which the insurance coverage of the health care service or providers may be reasonably expected to increase or decrease the insurance premium or administrative expenses of policyholders.

Aetna

Aetna’s actuarial department has estimated an increase in premiums of \$0.10 per member per month (PMPM) to cover the additional services if the mandate went into effect. They do not anticipate an increase in administrative expenses. This cost estimate applies to Small Group as well as Large Group. Aetna does not offer individual coverage in Maine.

Anthem Blue Cross and Blue Shield

Anthem Blue Cross and Blue Shield indicated the cost of additional diagnostic tests and long-term antibiotic therapies not covered today would represent a significant premium increase. They indicated they currently cover certain diagnostic tests, but do not cover a small subset of diagnostic tests including those offered by IGeneX, Inc., which would represent an additional cost. They also considered the long-term antibiotic therapy (through oral and intravenous methods) which they say could vary greatly based on length of treatment but used five years as a proxy. The costs PMPM are shown below.

	Individual	Small Group	Large Group
Long-term antibiotic therapy	\$22.60	\$16.00	\$15.80
Diagnostic tests	\$1.26	\$0.89	\$0.88
Total	\$23.86	\$16.90	\$16.68

Cigna

The estimated claim cost for the current coverage of diagnosis and short-term treatment of Lyme disease is about \$0.50 PMPM. Internal research would estimate that the cost could increase by 40% if coverage was extended to include long-term treatment.

⁵¹ Sun, Lena H. “Dangerous unproven treatments for ‘chronic Lyme disease’ are on the rise.”

⁵² Sun, Lena H. “Dangerous unproven treatments for ‘chronic Lyme disease’ are on the rise.”

Community Health Options

Community Health Options estimates no impact from the current bill. They anticipate significant increases in the cost of treatment of Lyme disease particularly if long-term antibiotic therapy as referenced in 32 MRS Section 3282-B is required to be covered in all cases without regard to whether the treatment is experimental or investigational or medically necessary. Unlimited treatment with no constraints could permit unfettered fraud, waste, and abuse particularly by out-of-network and out-of-state medical providers. There are, of course, increased administrative expenses in attempting to coordinate care with non-network providers in regions of the country where our experience with specialists and treatment facilities is limited. This makes coordination more challenging. It also requires more effort to educate providers regarding the operations of our plan.

Harvard Pilgrim Health Care

If amended, the estimated impact of this mandate is \$0.18 PMPM. This cost was estimated using HPHC claims data for covering the diagnosis and long-term antibiotic treatment of Lyme disease where such coverage is mandated. Additionally, they expect these results to be consistent across all groups (Individual/Small/Large). This estimate is driven entirely by increased claims; as part of their standard procedure in analyzing the impact of mandates they do not include any impact from administrative or additional costs. Therefore, in order to remain consistent in how they conduct their mandate analysis, they did not include any increase in non-medical costs.

United Healthcare Insurance Company

UHIC expects a 0.1% increase in costs if long-term antibiotic treatment of Lyme disease is covered. This amount is consistent across all group sizes. All increases are due to an increase in claim costs – they are not expecting an increase in administrative expenses.

Our Estimate

Obviously, the cost is highly dependent upon the length of antibiotic treatment, so we have developed a range for our cost estimates for 2, 5, and 11 months of long-term treatment. Because the first month is covered, this amounts to 3, 6, and 12 months of total antibiotic treatment. Although one carrier surmised that the antibiotic treatment could continue for several years, this may be harmful to a patient’s health and we have found no studies where treatment continued longer than one year. We have assumed patients would discontinue treatment or opt for a different treatment after one year. Medical management can also be used to ensure that the appropriate length of treatment is followed for the patient’s safety.

Our estimate of cost is below:

Additional months of antibiotic treatment (After 1 month of short-term antibiotic therapy)	Individual Market PMPM	Small Group Market PMPM	Large Group Market PMPM
2-months	\$0.14	\$0.14	\$0.15

5-months	\$0.34	\$0.35	\$0.37
11-months	\$0.75	\$0.76	\$0.82

For our cost estimate above, we started with 3-year incidence rate in Maine from the CDC website.⁵³ However, during our research we discovered that many sources believe these CDC numbers are underreported. One article estimated the underreporting to be 6 to 12-fold.⁵⁴ We assumed the underreporting was 6-fold. We used 2016 membership from the National Association of Insurance Commissioners (NAIC) Supplemental Health Care Exhibit (SHCE) for all carriers in Maine to calculate the expected 2016 insured cases of Lyme disease.

There is a large variation in the estimates of the proportion of Lyme disease patients that will experience PTLDS. The CDC in the past has stated 10-20%⁵⁵ of patients experience PTLDS and the International Lyme and Associated Diseases Society has stated this number is 40%.⁵⁶ We have assumed the midpoint between these estimates and assumed 28% will experience PTLDS.

We then assumed 3 major antibiotics would be used for long-term treatment. We assumed Doxycycline would be the primary oral antibiotic used,⁵⁷ and at a cost of \$82.38 for 20 capsules of 100mg⁵⁸, which would be taken twice daily,⁵⁹ this amounts to a cost per day of \$8.24. We assumed Amoxicillin would be used for patients who could not use Doxycycline including pregnant women and children under 9.⁶⁰ At a cost of \$15.31 for 30 capsules of 500mg⁶¹, which would be taken three times daily⁶², this amounts to a

⁵³ Centers for Disease Control and Prevention. "Lyme Disease Tables." <https://www.cdc.gov/lyme/stats/tables.html>. Accessed October 16, 2017.

⁵⁴ Aucott, John N. et al. "Post-Treatment Lyme Disease Syndrome Symptomatology and the Impact on Life Functioning: Is There Something Here?" 2013. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3548099/>. Accessed October 16, 2017.

⁵⁵ Lyme Disease.org. "Chronic Lyme Disease." <https://www.lymedisease.org/lyme-basics/lyme-disease/chronic-lyme/>. Accessed October 16, 2017.

⁵⁶ International Lyme and Associated Diseases Society. "ILADS About Lyme." <http://www.ilads.org/lyme/lyme-quickfacts.php>. Accessed October 17, 2017.

⁵⁷ Burrascano Jr., Joseph J. MD. "Diagnostic Hints and Treatment Guidelines for Lyme and Other Tick Borne Diseases." 2002. http://www.chroniclymedisease.com/burrascano_lyme_treatment_guidelines

⁵⁸ GoodRx. "Doxycycline Hyclate." <https://www.goodrx.com/doxycycline-hyclate>. Accessed October 18, 2017.

⁵⁹ Johns Hopkins Arthritis Center. "Lyme Disease Treatment." <https://www.hopkinsarthritis.org/arthritis-info/lyme-disease/lyme-disease-treatment/>. Accessed October 18, 2017.

⁶⁰ Johns Hopkins Arthritis Center. "Lyme Disease Treatment."

⁶¹ GoodRx. "Amoxicillin." <https://www.goodrx.com/amoxicillin?drug-name=amoxicillin>. Accessed October 18, 2017.

⁶² Johns Hopkins Arthritis Center. "Lyme Disease Treatment."

cost per day of \$1.53. Lastly, we assumed some patients would be prescribed intravenous antibiotics, for which we assumed Ceftriaxone would be utilized⁶³ at 2 gm daily.⁶⁴ The average wholesale price for ceftriaxone 2 gm is \$68.84.⁶⁵ Consistent with our carrier survey to Anthem Blue Cross we assumed 75% antibiotics would be oral and 25% would be IV. We then assumed 5% would use Amoxicillin for the conditions explained above. Therefore, our weights were 70% Doxycycline, 25% Ceftriaxone, and 5% Amoxicillin. We note that the costs represented above are higher than insurance companies would pay after contracting.

For the costs paid by the insurance companies after cost-sharing, we calculated the average projected paid-to-allowed ratio for the five companies that had the highest market share in Maine in 2016 and who also submitted ACA rate filings in the individual and small group markets. This resulted in a 74% ratio in the individual market, and 75% in the small group market, which we believe is reasonable. For the large group market where this information was not available, we used actuarial judgment to determine an 85% ratio.

In order to add non-benefit expenses, we used actuarial judgment to assume a marginal loss ratio of 85% for the individual and small group markets, and 90% for the large group market. We used higher target loss ratios than a traditional loss ratio since the only additional costs associated with this benefit are the marginal costs for claim adjudication and expenses that are a function of premium.

Using the average premium determined from the NAIC 2016 SHCE, we determined a percent of premium estimates below:

Additional months of antibiotic treatment (After 1 month of short-term antibiotic therapy)	Individual Market % of premium	Small Group Market % of premium	Large Group Market % of premium
2-months	0.03%	0.03%	0.03%
5-months	0.09%	0.09%	0.07%
11-months	0.19%	0.19%	0.16%

7. The impact of indirect costs, which are costs other than premiums and administrative costs, on the question of the cost and benefits of coverage.

⁶³ Centers for Disease Control and Prevention. “Lyme Disease Treatment.” 2016. <https://www.cdc.gov/lyme/treatment/index.html> . Accessed October 16, 2017.

⁶⁴ Johns Hopkins Arthritis Center. “Lyme Disease Treatment.”

⁶⁵ Bartlett, J. et al. “Average Wholesale Prices (AWP) for Commonly-Used Intravenous Antibiotics, by dose, per day.” 2005. http://www.med.umich.edu/lrc/therademo/course_topics_refs/refs/infection/selection/AWP-IVs.pdf. Accessed October 16, 2017.

There will not be any additional cost effect beyond benefit and administrative costs.

8. The impact on the total cost of health care, including potential benefits and savings to insurers and employers because the proposed mandated treatment or service prevents disease or illness or leads to the early detection and treatment of disease or illness that is less costly than treatment or service for later stages of a disease or illness.

Although insurance companies already cover diagnosis and short-term treatment for Lyme disease, not all diagnostic tests and forms of treatment may be covered. It is unknown if this would lead to earlier diagnosis or higher quality of care. Long-term antibiotic therapy is not covered and research has not shown that it will affect later stages of PTLDS.

Aetna

Aetna is not aware of any studies that document potential savings through facilitating other treatments. They do not anticipate potential benefits or savings in conjunction with the proposed mandate and would add that long-term treatment with antibiotics has not been proven effective.

Anthem Blue Cross and Blue Shield

Anthem does not believe that there are any potential benefits or savings associated with the proposed mandate.

United Healthcare Insurance Company

No benefits are expected other than possible customer satisfaction in having the benefit covered.

9. The effects of mandating the benefit on the cost of health care, particularly the premium and administrative expenses and indirect costs, to employers and employees, including the financial impact on small employers, medium-sized employers and large employers.

There is concern that the broad language of the bill will lead to more inappropriate use of health care services which would have the effect of increasing premiums.

10. The effect of the proposed mandates on cost-shifting between private and public payers of health care coverage and on the overall cost of the health care delivery system in this State.

These additional services are not currently covered by MaineCare or other public payers. Therefore, there should be no cost-shifting.

V. Medical Efficacy

C. The Medical Efficacy of Mandating the Benefit

1. The contribution of the benefit to the quality of patient care and the health status of the population, including any research demonstrating the medical efficacy of the treatment or service compared to the alternative of not providing the treatment or service.

Early diagnosis and short-term antibiotic treatment has been accepted as an effective treatment for Lyme disease. The CDC states, “Patients treated with appropriate antibiotics in the early stages of Lyme disease usually recover rapidly and completely.”⁶⁶ Health insurance companies cover certain diagnostic tests and short-term antibiotic therapies.

Long-term antibiotic therapy has not produced consistent improvement in patient’s symptoms. The CDC cites four placebo controlled studies performed by the National Institute of Allergy and Infectious Diseases which show little to no improvement.⁶⁷ One study concluded, “treatment with intravenous and oral antibiotics for 90 days did not improve symptoms more than placebo.”⁶⁸ Another study concluded, “Those receiving antibiotics reported greater improvement in fatigue than those on placebo. However, no benefit to cognitive function was observed. Six of 55 patients had serious adverse events associated with the study and 4 required hospitalization, 3 for IV line infections, and 1 for severe allergic reaction.”⁶⁹ One of the more recent studies indicated that “12 weeks of therapy with either doxycycline or clarithromycin plus hydroxychloroquine yielded no additional benefit over placebo with respect to serial mental and physical health-related quality-of-life measures that spanned the duration of the study through 38 weeks after the active study drugs or placebo were discontinued.”⁷⁰

In addition, long periods of antibiotics may be harmful and the CDC has published a report describing cases of septic shock, osteomyelitis, *Clostridium difficile* colitis, and paraspinal abscess resulting from treatments for chronic Lyme disease.⁷¹ Studies have shown that prolonged courses of intravenous

⁶⁶ Centers for Disease Control and Prevention. “Lyme Disease Treatment.”

⁶⁷ Centers for Disease Control and Prevention. “Research into Prolonged Treatment for Lyme Disease.”

⁶⁸ Klempner, Mark S. MD, et al. “Two Controlled Trials of Antibiotic Treatment in Patients with Persistent Symptoms and a History of Lyme Disease.” 2001. <http://www.nejm.org/doi/full/10.1056/NEJM200107123450202> . Accessed October 19, 2017.

⁶⁹ Centers for Disease Control and Prevention. “Research into Prolonged Treatment for Lyme Disease.”

⁷⁰ Melia, Michael T. MD, et al. “Time for a Different Approach to Lyme Disease and Long-Term Symptoms.” 2016. <http://www.nejm.org/doi/citedby/10.1056/NEJMe1502350#t=article>. Accessed October 19, 2017.

⁷¹ Marzec, Natalie S. MD, et al. “Serious Bacterial Infections Acquired During Treatment of Patients Given a Diagnosis of Chronic Lyme Disease — United States.”

antibiotics can often result in serious harm, including death.⁷² According to the Washington Post, “While antibiotics are effective for many conditions, unnecessary antibiotics provide no benefit and actually put patients at risk for serious harm, especially if used for extended periods. The drugs kill beneficial bacteria and allow drug-resistant ones to dominate, and intravenous treatments can introduce new infections.”⁷³

2. If the legislation seeks to mandate coverage of an additional class of practitioners:

The bill will not apply to an additional class of practitioners.

VI. Balancing the Effects

D. The Effects of Balancing the Social, Economic, and Medical Efficacy Considerations

1. The extent to which the need for coverage outweighs the cost of mandating the benefit for all policyholders.

Experts agree that it is important to treat this condition as early as possible to increase the likelihood of successful outcomes. However, our survey shows that insurance carriers are already providing coverage for diagnosis and short-term therapy. More research is needed on the efficacy of the long-term coverage.

2. The extent to which the problem of coverage can be resolved by mandating the availability of coverage as an option for policyholders.

It is likely that only those who would benefit from the services would purchase the coverage. This would result in an alternative coverage that would cost more than the additional cost of services because of the administrative charges that would be added to benefit costs. This cost would be reduced if the option were only available when the coverage was initially purchased, but it would then be less effective because many individuals would not anticipate needing the coverage and, therefore, would not purchase it.

3. The cumulative impact of mandating this benefit in combination with existing mandates on costs and availability of coverage.

NovaRest, Inc. estimates that the premium impact of LD 1417 would range from \$0.14 to \$0.82 per member per month or from 0.03% to 0.19% of premium.

⁷² Sun, Lena H. “Dangerous unproven treatments for ‘chronic Lyme disease’ are on the rise.”

⁷³ Sun, Lena H. “Dangerous unproven treatments for ‘chronic Lyme disease’ are on the rise.”

The estimated cost of current Maine mandates is detailed in Appendix A. For most of these mandates, our estimate is based on the net impact on premiums as estimated at the time the mandate was enacted. Four of the mandates – mental health, substance abuse, chiropractic, and screening mammograms – require carriers to report annually the number of claims paid for these benefits and the estimates are based on that data. The true cost for the Maine mandates are impacted by the fact that:

1. Some services would be provided and reimbursed in the absence of a mandate.
2. Certain services or providers will reduce claims in other areas.
3. Some mandates are required by Federal law.

VII. Appendices

Appendix A: Cumulative Impact of Mandates

Bureau of Insurance Cumulative Impact of Mandates in Maine Report for the Year 2016

This report provides data for medical insurance coverage of mandates as required by 24-A M.R.S.A. §2752 and compiled by the Bureau of Insurance. While some data was provided through annual mandate reports by insurers, other figures were estimated as a part of the proposed mandates study. The following provides a brief description of each state mandate and the estimated claim cost as a percentage of premium. Many of these mandates are now required by the federal Affordable Care Act (ACA). In addition, the ACA requires benefits covered by the benchmark plan which includes all state mandates to be covered by all individual and small group plans effective January 1, 2014. A summary chart is provided at the end of this report.

- ♦ **Mental Health** (Enacted 1983)

Mental health parity for group plans in Maine became effective July 1, 1996, and was expanded in 2003. The percentage of mental health group claims paid has been tracked since 1984 and has historically been between 3% - 4% of total group health claims and was reported as 3.8% in 2016. Mental health claims stayed in this range despite the fact that an expansion of the list of conditions for which parity is required was fully implemented in 2005.

Mental health parity was only a mandated offer for individual plans until it was included in the essential health benefits for ACA (Affordable Care Act) individual and small group plans beginning 2014. The Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA) amended the PHS Act, ERISA, and the Code to provide increased parity between mental health and substance use disorder benefits and medical/surgical benefits and extended parity to all individual plans. As expected, mental health claims have stabilized back to a lower level of 2.6% in 2016 after meeting pent-up demand of 9.4% in 2015.

- ♦ **Substance Abuse** (Enacted 1983)

Maine's mandate only applied to group coverage. Effective October 1, 2003, substance abuse was added to the list of mental health conditions for which parity is required. Effective on

January 1, 2014 the federal Affordable Care Act requires substance abuse treatment benefits for individual and small group plans as part of the essential health benefits. The percentage of claims paid for group plans has been tracked since 1984. Substance abuse claims paid decreased from 0.7% in 2015 to 0.4% in 2016 of the total group health claims. Individual substance abuse health claims decreased from 5.8% in 2015 to 2.5% in 2016. As expected, substance abuse claims have leveled out as pent-up demand is met and carriers manage utilization.

♦ ***Chiropractic*** (Enacted 1986)

This mandate requires coverage for the services of chiropractors to the extent that the same services would be covered if performed by a physician. Using annual experience reports from the carriers, the percentage of claims paid has been tracked since 1986 and, in 2016, was 1.01% of total health claims. Prior to 2014, the level has typically been lower for individual than for group. Individual claims at 1.42% continue to exceed group 0.87% in 2016. We estimate the current combined levels going forward. Although it is likely that some of these costs would have been covered even in the absence of a mandate, we have no basis for estimating how much. We have included the entire amount, thereby overstating the impact of the mandate to some extent.

♦ ***Screening Mammography*** (Enacted 1990)

This mandate requires that benefits be provided for screening mammography. We estimate the current combined levels of 0.70% going forward. Coverage is required by ACA for preventive services.

♦ ***Dentists*** (Enacted 1975)

This mandate requires coverage for dentists' services to the extent that the same services would be covered if performed by a physician. It does not apply to HMOs. A 1992 study done by Milliman and Robertson for the Mandated Benefits Advisory Commission estimated that these claims represent 0.5% of total health claims and that the actual impact on premiums is "slight." It is unlikely that this coverage would be excluded in the absence of a mandate. We include 0.1% as an estimate.

♦ ***Breast Reconstruction*** (Enacted 1998)

This mandate requires coverage for reconstruction of both breasts to produce a symmetrical appearance after a mastectomy. At the time this mandate was being considered in 1995, one carrier estimated the cost at \$0.20 per month per individual. We do not have a more recent estimate. We include 0.02% in our estimate of the maximum cumulative impact of mandates.

- ♦ ***Errors of Metabolism*** (Enacted 1995)

This mandate requires coverage for metabolic formula and prescribed modified low-protein food products. At the time this mandate was being considered in 1995, Blue Cross estimated the cost at \$0.10 per month per individual. We do not have a more recent estimate. We include 0.01% in our estimate.

- ♦ ***Diabetic Supplies*** (Enacted 1996)

This mandate requires that benefits be provided for medically necessary diabetic supplies and equipment. Based on data collected in 2006, most carriers reported that there would be no cost increase or an insignificant cost increase because they already provide this coverage. Based on our report we estimate 0.2%.

- ♦ ***Minimum Maternity Stay*** (Enacted 1996)

This mandate requires that if a policy provides maternity benefits, the maternity (length of stay) and newborn care benefits must be provided in accordance with “Guidelines for Prenatal Care.” Based on carrier responses indicating that they did not limit maternity stays below those recommended, we estimate no impact.

- ♦ ***Pap Smear Tests*** (Enacted 1996)

This mandate requires that benefits be provided for screening Pap smear tests. HMOs would typically cover these costs and, for non-HMO plans, the relatively small cost of this test would not in itself satisfy the deductible, so there would be no cost unless other services were also received. We estimate a negligible impact of 0.01%. Coverage is required by ACA for preventive services.

- ♦ ***Annual GYN Exam Without Referral*** (Enacted 1996)

This mandate only affects HMO plans and similar plans, and it requires the provision of benefits for annual gynecological exams without prior approval from a primary care physician. To the extent the Primary Care Physician (PCP) would, in absence of this law, have performed the exam personally rather than referring to an OB/GYN, the cost may be somewhat higher; therefore, we include 0.1%.

- ♦ ***Breast Cancer Length of Stay*** (Enacted 1997)

This mandate requires that benefits for breast cancer treatment be provided for a medically appropriate period of time as determined by the physician in consultation with the patient. Group claims in 2016 were 1.58% compared to individual claims at 1.32% with the combined impact remaining level with past years at 1.5%.

♦ ***Off-label Use Prescription Drugs*** (Enacted 1998)

This mandate requires coverage of off-label prescription drugs in the treatment of cancer, HIV, and AIDS. Our 1998 report stated a "high-end cost estimate" of about \$1 per member per month (0.6% of premium) if it is assumed there is currently no coverage for off-label drugs. Because the HMOs claimed to already cover off-label drugs, in which case there would be no additional cost; and, providers testified that claims have been denied on this basis, we include half this amount, or 0.3%.

♦ ***Prostate Cancer*** (Enacted 1998)

This mandate requires prostate cancer screenings. Our report estimated additional claims cost would approximate \$0.10 per member per month. With the inclusion of administrative expenses, we would expect a total cost of approximately \$0.11 per member per month, or approximately 0.07% of total premiums. Coverage is required by ACA for preventive services.

♦ ***Nurse Practitioners and Certified Nurse Midwives*** (Enacted 1999)

This law mandates coverage for nurse practitioners and certified nurse midwives and allows nurse practitioners to serve as primary care providers. This mandate is estimated to increase premium by 0.16%.

♦ ***Coverage of Contraceptives*** (Enacted 1999)

This mandate requires health plans that cover prescription drugs to cover contraceptives. Our report estimated an increase of premium of 0.8%.

♦ ***Registered Nurse First Assistants*** (Enacted 1999)

This mandate requires health plans that cover surgical first assistants to cover registered nurse first assistants if an assisting physician would be covered. No material increase in premium is expected.

♦ ***Access to Clinical Trials*** (Enacted 2000)

This mandate requires that coverage be provided for an eligible enrollee to participate in approved clinical trials. Our report estimated a cost of 0.19% of premium.

♦ ***Access to Prescription Drugs*** (Enacted 2000)

This mandate only affects plans with closed formularies. Our report concluded that enrollment in such plans is minimal in Maine and therefore the mandate will have no material impact on premiums.

- ♦ ***Hospice Care*** (Enacted 2001)

No cost estimate was made for this mandate because the Legislature waived the requirement for a study. Because carriers generally covered hospice care prior to the mandate, we assume no additional cost.

- ♦ ***Access to Eye Care*** (Enacted 2001)

This mandate affects plans that use participating eye care professionals. Our report estimated a cost of 0.04% of premium.

- ♦ ***Dental Anesthesia*** (Enacted 2001)

This mandate requires coverage for general anesthesia and associated facility charges for dental procedures in a hospital for certain enrollees for whom general anesthesia is medically necessary. Our report estimated a cost of 0.05% of premium.

- ♦ ***Prosthetics*** (Enacted 2003)

This mandate requires coverage for prosthetic devices to replace an arm or leg. Our report estimated a cost of 0.03% of premium for groups over 20, and a cost of 0.08% of premium for small employer groups and individuals.

- ♦ ***LCPCs*** (Enacted 2003)

This mandate requires coverage of licensed clinical professional counselors. Our report on mental health parity indicated no measurable cost impact for coverage of LCPCs.

- ♦ ***Licensed Pastoral Counselors and Marriage & Family Therapists*** (Enacted 2005)

This mandate requires coverage of licensed pastoral counselors and marriage & family therapists. Our report indicated no measurable cost impact for this coverage.

- ♦ ***Hearing Aids*** (Enacted 2007)

This mandate requires coverage for a hearing aid for each ear every 36 months for children age 18 and under. The mandate was phased-in between 2008 and 2010, and our report estimated a cost of 0.1% of premium.

- ♦ ***Infant Formulas*** (Enacted 2008)

This mandate requires coverage for amino acid-based elemental infant formulas for children two years of age and under, regardless of delivery method. This mandate is effective January 2009, and our report estimated a cost of 0.1% of premium.

- ♦ ***Colorectal Cancer Screening*** (Enacted 2008)

This mandate requires coverage for colorectal cancer screening. This mandate is effective January 2009. No carriers stated they denied coverage prior to this mandate; therefore, our report estimated no impact on premium. Coverage is required by ACA for preventive services.

- ♦ ***Independent Dental Hygienist*** (Enacted 2009)

This mandate requires individual dental insurance or health insurance that includes coverage for dental services to provide coverage for dental services performed by an independent practice dental hygienist. This mandate applies only to policies with dental coverage; therefore, there is no estimated impact on medical plan premiums.

- ♦ ***Autism Spectrum Disorders*** (Enacted 2010)

This mandate was effective January 2011 and required all contracts to provide coverage for the diagnosis and treatment of autism spectrum disorders for individuals five years of age or under. It was expanded to age 10 for January 2014 effective dates. A recent report estimated a cost of 0.3% of premium once the mandate is fully implemented if it included those under age 10. Based on that estimate and recently reported experience we are estimating this going forward.

- ♦ ***Children's Early Intervention Services*** (Enacted 2010)

This mandate requires all contracts to provide coverage for children's early intervention services from birth to 36 months for a child identified with a developmental disability or delay. This mandate was effective January 2011, and our report estimated a cost of 0.05% of premium.

- ♦ ***Chemotherapy Oral Medications*** (Enacted 2014)

Policies that provide chemotherapy treatment must provide coverage for prescribed orally administered anticancer medications equivalent to the coverage for IV or injected anticancer medication. No material increase in premium is expected.

- ♦ ***Bone Marrow Donor Testing*** (Enacted 2014)

Reimbursement for human leukocyte antigen testing to register as a bone marrow donor. Limited to \$150 per lifetime. May not be applied to any deductible or other cost share. No material increase in premium is expected.

- ♦ ***Dental Hygienist*** (Enacted 2014)

Coverage for services provided by a dental hygiene therapist for policies with dental coverage. No material increase in premium is expected.

♦ ***Abuse-Deterrent Opioid Analgesic Drugs*** (Enacted 2015)

Coverage for abuse-deterrent opioid analgesic drugs on a basis not less favorable than that for opioid analgesic drugs that are not abuse-deterrent and are covered by the health plan. No material increase in premium is expected.


COST OF EXISTING MANDATED HEALTH INSURANCE BENEFITS

Year Enacted	Benefit	Type of Contract Affected	Est. Maximum Cost as % of Premium
1975	Must include benefits for dentists' services to the extent that the same services would be covered if performed by a physician.	All Contracts	0.10%
1983	Benefits must be included for treatment of alcoholism and drug dependency .	Groups	0.40%
		Individual	2.50%
1975 1983 1995 2003	Benefits must be included for Mental Health Services , including psychologists and social workers.	Groups	3.80%
		Individual	2.60%
1986 1994 1995 1997	Benefits must be included for the services of chiropractors to the extent that the same services would be covered by a physician. Benefits must be included for therapeutic, adjustive, and manipulative services.	Group	0.87%
		Individual	1.42%
1990 1997	Benefits must be made available for screening mammography .	Group	0.68%
		Individual	0.76%
1995	Must provide coverage for reconstruction of both breasts to produce symmetrical appearance according to patient and physician wishes.	All Contracts	0.02%
1995	Must provide coverage for metabolic formula and up to \$3,000 per year for prescribed modified low-protein food products.	All Contracts	0.01%
1996	If policies provide maternity benefits, the maternity (length of stay) and newborn care benefits must be provided in accordance with "Guidelines for Prenatal Care."	All Contracts	0
1996	Benefits must be provided for medically necessary equipment and supplies used to treat diabetes and approved self-management and education training.	All Contracts	0.20%
1996	Benefits must be provided for screening Pap tests .	All	0.01%
1996	Benefits must be provided for annual gynecological exam without prior approval of primary care physician.	Group managed care	0.10%
1997	Benefits provided for breast cancer treatment for a medically appropriate period of time determined by the physician in consultation with the patient.	All Contracts	1.51%
1998	Coverage required for off-label use of prescription drugs for treatment of cancer, HIV, or AIDS.	All Contracts	0.30%
1998	Coverage required for prostate cancer screening .	All Contracts	0.07%

LD 1417, An Act to Require Insurance Coverage for the Diagnosis and Treatment of Lyme Disease

1999	Coverage of nurse practitioners and nurse midwives and allows nurse practitioners to serves as primary care providers.	All Managed Care Contracts	0.16%
1999	Prescription drug must include contraceptives .	All Contracts	0.80%
1999	Coverage for registered nurse first assistants .	All Contracts	0
2000	Access to clinical trials .	All Contracts	0.19%
2000	Access to prescription drugs .	All Managed Care Contracts	0
2001	Coverage of hospice care services for terminally ill.	All Contracts	0
2001	Access to eye care .	Plans with participating eye care professionals	0.04%
2001	Coverage of anesthesia and facility charges for certain dental procedures.	All Contracts	0.05%
2003	Coverage for prosthetic devices to replace an arm or leg	Groups >20	0.03%
		All other	0.08%
2003	Coverage of licensed clinical professional counselors	All Contracts	0
2005	Coverage of licensed pastoral counselors and marriage & family therapists	All Contracts	0
2007	Coverage of hearing aids for children	All Contracts	0.1%
2008	Coverage for amino acid-based elemental infant formulas	All Contracts	0.1%
2008	Coverage for colorectal cancer screening	All Contracts	0
2009	Coverage for independent dental hygienist	All Contracts	0
2010	Coverage for autism spectrum	All Contracts	0.3%
2010	Coverage for children's early intervention services	All Contracts	0.05%
2014	Coverage for chemotherapy oral medications	All Contracts	0
2014	Coverage for human leukocyte antigen testing	All Contracts	0
2014	Coverage for dental hygienist	All Contracts	0
2015	Coverage for abuse-deterrent opioid analgesic medications	All Contracts	0
	Total cost for groups larger than 20:		9.89%
	Total cost for groups of 20 or fewer:		9.94%
	Total cost for individual contracts:		11.47%

Appendix B: Letter from the Committee on Insurance and Financial Services with Proposed Legislation

<p>SENATE</p> <p>RODNEY L. WHITEMORE, DISTRICT 28, CHAIR DANA L. DOW, DISTRICT 13 EVERETT BROWNIE CARSON, DISTRICT 24</p> <hr/> <p>COLLEEN MCCARTHY REED, LEGISLATIVE ANALYST VERONICA SNOW, COMMITTEE CLERK</p>		<p>HOUSE</p> <p>MARK LAWRENCE, SOUTH BERNARD, CHAIR HEIDI E. BROOKS, LEWISTON GINA M. MELARAGNO, ALBANY BENJAMIN T. COLLINGS, PORTLAND HEATHER S. SANBORN, PORTLAND RAYMOND A. WALLACE, DEER ISLAND JOHN JOSEPH PICCHIOTTI, FARMFIELD ROBERT A. FOLEY, BRISTOL DWAYNE W. PRESCOTT, BATHING GARREL ROBERT CRAIG, GREENER</p>
<p>STATE OF MAINE ONE HUNDRED AND TWENTY-EIGHTH LEGISLATURE COMMITTEE ON INSURANCE AND FINANCIAL SERVICES</p>		
<p>June 9, 2017</p>		
<p>Marti Hooper Senior Insurance Analyst Life and Health Division Bureau of Insurance 34 State House Station Augusta, Maine 04333</p>		
<p>Dear Ms. Hooper:</p>		
<p>Title 24-A Maine Revised Statutes Annotated, Section 2752 requires the Joint Standing Committee on Insurance and Financial Services to submit legislation proposing health insurance mandates to the Bureau of Insurance for review and evaluation if there is substantial support for the mandate among the committee after a public hearing on the proposed legislation. Pursuant to that statute, we request that the Bureau of Insurance prepare a review and evaluation of LD 1417, An Act to Require Insurance Coverage for the Diagnosis and Treatment of Lyme Disease.</p>		
<p>A copy of the bill is enclosed. Please prepare the evaluation using the guidelines set out in Title 24-A § 2752. In addition, we ask that the Bureau provide an analysis of the following issues:</p>		
<ul style="list-style-type: none">• The extent to which coverage of the diagnosis and treatment of Lyme disease is included in the State's essential benefits package and the manner in which the bill may expand this coverage;• The impact of amending LD 1417 to require coverage of short-term and long-term antibiotic therapy as proposed by Rep. Fredette (attached);• The impact of amending LD 1417 to require coverage for the diagnosis and treatment of Lyme disease by naturopathic physicians or other out-of-network providers; and• If the bill expands coverage beyond the essential benefits package, the estimated costs to the State to defray the costs of including the coverage in qualified health plans.		

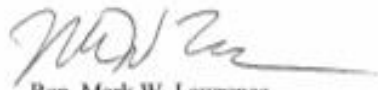
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Please submit the report to the committee before January 1, 2018. If you have any questions, please do not hesitate to contact us or our legislative analyst, Colleen McCarthy Reid.

Sincerely,



Sen. Rodney L. Whittemore
Senate Chair



Rep. Mark W. Lawrence
House Chair

cc: Rep. Kenneth Fredette
Members, Joint Standing Committee on Insurance and Financial Services

Appendix D: LD 1417 Amendment

REP. Fredette - PROPOSED AMENDMENT TO LD1417

An Act To Require Insurance Coverage for the Diagnosis and Treatment of Lyme Disease

(Changes to the bill are underlined)

Sec. 1. 24-A MRSA §4320-K is enacted to read:

§4320-K. Coverage for diagnosis and treatment of Lyme disease.

1. Definitions. As used in this section, unless the context otherwise indicates, the following terms have the following meanings:

A. "Diagnosis" means a diagnosis that is based on knowledge obtained through medical history and physical examination of a patient, alone or in conjunction with testing that provides supportive data for the diagnosis.

B. "Long-term antibiotic therapy" as defined in 32 MRSA Sec. 3282-B(1)(A).

C. "Lyme disease" as defined in 32 MRSA Sec. 3282-B(1)(B).

2. A carrier offering or renewing a health plan in this State shall provide coverage for the diagnosis and short-term and long-term antibiotic therapy treatment of Lyme disease. An increase in enrollee cost sharing to achieve compliance with this section may not be implemented.

SUMMARY

This bill requires a carrier offering or renewing a health plan in the State to provide coverage to diagnose and treat Lyme disease.