THE GENERAL ASSEMBLY OF PENNSYLVANIA

SENATE BILL

No. 1299 Session of 2015

INTRODUCED BY GREENLEAF, SCAVELLO, ARGALL, TEPLITZ, WOZNIAK, RAFFERTY, COSTA, TARTAGLIONE, AUMENT, BAKER, McGARRIGLE AND BOSCOLA, JUNE 6, 2016

REFERRED TO BANKING AND INSURANCE, JUNE 6, 2016

AN ACT

- 1 Providing for patient access to diagnostics and treatments for
- 2 Lyme disease and related tick-borne illnesses; and requiring
- health care policies to provide certain coverage.
- 4 The General Assembly of the Commonwealth of Pennsylvania
- 5 hereby enacts as follows:
- 6 Section 1. Short title.
- 7 This act shall be known and may be cited as the Lyme Disease
- 8 and Related Tick-Borne Illness Diagnosis and Treatment Act.
- 9 Section 2. Findings.
- 10 The General Assembly finds as follows:
- 11 (1) From 2002 to 2014, Pennsylvania reported a total of
- 12 59,478 confirmed cases of Lyme disease and in 2015 reported
- 13 10,817 new cases (provisional cases to be confirmed in 2016),
- 14 ranking highest in the nation in confirmed cases for the last
- 15 five years.
- 16 (2) In 2015, the Department of Environmental Protection
- 17 published a study that confirmed a high risk of Lyme disease
- in every county of the Commonwealth and that 67 counties had

1 the blacklegged tick.

- (3) Early diagnosis and treatment of these tick-borne illnesses and diseases can greatly reduce the risks of continued symptoms which can affect every system and organ of the human body and often every aspect of life.
 - (4) Between 10% to 40% of Lyme disease patients may go on to suffer from a complex, chronic/persistent disease which is much more difficult to treat.
- There are multiple diagnostic and treatment guidelines for diagnosis and treatment of Lyme disease and tick-borne illness; yet, in 2016, the National Guidelines Clearinghouse (NGC) maintains only the International Lyme and Associated Disease Society's (ILADS) guidelines, which guidelines were updated in 2015 and met the more stringent evidence criteria introduced by the NGC in 2014. These quidelines recommend longer-term courses of antibiotics as an option when deemed necessary by health care professionals. The Infectious Disease Society of America's (IDSA) guidelines were removed from the NGC in 2015 because they were "outdated and not in compliance with current standards."
 - (6) A 2013 Centers for Disease Control and Prevention (CDC) study found that only 39% of individuals with Lyme disease were treated using short-term antibiotic recommendations from the IDSA guidelines. The majority of the individuals were treated for longer periods, more in line with the International Lyme and Associated Disease Society's recommendations.
 - (7) Scientific understanding of these complex tick-borne illnesses is expected to evolve rapidly in the next decade, including diagnosis and treatment options.

- 1 (8) The exercise of the patient's right of self-
- determination is a cornerstone of medical ethics, endorsed by
- 3 the American Medical Association, American College of
- 4 Physicians and other professional medical organizations.
- 5 Patients should be fully informed of their options, taking
- into account the best scientific evidence available,
- 7 especially in emerging diseases, and the physician's clinical
- g judgment and, in light of the patient's values and
- 9 preferences, patients should be informed in order to make the
- 10 best decision for themselves.
- 11 (9) In 2014, the Massachusetts Center for Health and
- 12 Information Analysis (CHIA) found little to no increase in
- insurance costs as a result of expanding coverage to include
- longer-term courses of antibiotics. The expansion by fully-
- insured health plans was projected to result in an average
- annual increase, over five years, to the typical member's
- monthly health insurance premiums of between a negligible
- amount and \$0.13 per year.
- 19 Section 3. Definitions.
- The following words and phrases when used in this act shall
- 21 have the meanings given to them in this section unless the
- 22 context clearly indicates otherwise:
- "Clinical diagnosis." A diagnosis of a patient based
- 24 primarily on information obtained from medical history, a
- 25 physical examination of the patient and review of medical
- 26 records, including laboratory tests and radiologic studies or
- 27 other differential diagnostic testing.
- 28 "Health care professional." A licensed physician,
- 29 physician's assistant, certified registered nurse practitioner
- 30 or other licensed health care professional.

- 1 "Lyme disease." Signs or symptoms compatible with acute,
- 2 late-stage, persistent infection with Borrelia burgdorferi or
- 3 complications related to such infection or with such other
- 4 strains of Borrelia, including, but not limited to, B.
- 5 miyamotoi, B. mayonii, B. garinii and B. afzelii, that are
- 6 recognized by the Centers for Disease Control and Prevention as
- 7 a cause of Lyme disease. The term includes infection that meets
- 8 the surveillance criteria established by the Centers for Disease
- 9 Control and Prevention and other acute and persistent
- 10 manifestations of such an infection as determined by a health
- 11 care professional.
- 12 "Related tick-borne illness." The presence of signs or
- 13 symptoms compatible with infection with bartonella,
- 14 babesiosis/piroplasmosis, anaplasmosis, ehrlichiosis, Rocky
- 15 Mountain spotted fever, rickettsiosis or other tick-
- 16 transmissible illness or complications related to the
- 17 infections. The term does not include Lyme disease.
- 18 "Surveillance criteria." The set of case definition
- 19 standards established by the Centers for Disease Control and
- 20 Prevention for the purposes of consistency in research or for
- 21 evaluating trends in the spread of various diseases, but which
- 22 the Centers for Disease Control and Prevention does not intend
- 23 to be used by health care professionals for individual patient
- 24 diagnoses.
- 25 Section 4. Legislative intent.
- 26 It is the intent of the General Assembly to ensure that
- 27 patients have access to available and emerging diagnostics and
- 28 treatment options for Lyme disease and related tick-borne
- 29 illnesses as prescribed by attending health care professionals.
- 30 Section 5. Treatment.

- 1 A licensed health care professional may order diagnostic
- 2 testing and prescribe, administer or dispense antibiotic therapy
- 3 of the duration they determine appropriate for the patient, for
- 4 the therapeutic purpose of eliminating or controlling a
- 5 patient's infection or symptoms upon making a clinical diagnosis
- 6 that the patient has Lyme disease or a related tick-borne
- 7 illness or displays symptoms consistent with a clinical
- 8 diagnosis of Lyme disease or related tick-borne illnesses and by
- 9 documenting the diagnosis and treatment in the patient's medical
- 10 records.
- 11 Section 6. Required coverage.
- 12 (a) Duty to provide.--
- 13 (1) Except as provided in subsection (b), every health
- care policy which is delivered, issued for delivery, renewed,
- 15 extended or modified in this Commonwealth by a health insurer
- shall cover the prescribed treatment for Lyme disease or
- 17 related tick-borne illnesses if the diagnosis and treatment
- 18 plan are documented in the patient's medical record.
- 19 Treatment plans may include short or longer durations of
- antibiotic or antimicrobial treatments, as prescribed by the
- 21 patient's attending health care professional.
- 22 (2) Longer-term antibiotic treatment otherwise eligible
- for benefits under this section shall not be denied coverage
- solely because the treatment may be characterized as
- 25 unproven, experimental or investigational in nature for the
- treatment of Lyme disease and related tick-borne illnesses.
- 27 (b) Exception. -- Subsection (a) shall not apply to any of the
- 28 following types of insurance:
- 29 (1) Hospital indemnity.
- 30 (2) Accident.

- 1 (3) Specified disease.
- 2 (4) Disability income.
- 3 (5) Dental.
- 4 (6) Vision.
- 5 (7) Medicare and Medicare Advantage.
- 6 (8) Any federally funded plans, including TRICARE,
- formerly CHAMPUS, covering military personnel and dependents,
- 8 Veterans Administration and the Federal Employee's Health
- 9 Benefit Plan.
- 10 (9) Self-insured plans, subject to Federal law.
- 11 (10) Other limited insurance benefit plans.
- 12 Section 7. Immunity.
- 13 (a) General rule. -- No health care professional may be
- 14 subject to disciplinary action by the health care professional's
- 15 licensing board solely for diagnosing Lyme disease or related
- 16 tick-borne illnesses or for prescribing, administering or
- 17 dispensing longer-term antibiotic therapies for the therapeutic
- 18 purpose of eliminating infection or controlling a patient's
- 19 symptoms when the patient is clinically diagnosed with Lyme
- 20 disease or related tick-borne illnesses, if the diagnosis,
- 21 treatment plan and ongoing monitoring has been documented in the
- 22 patient's medical record.
- 23 (b) Construction. -- Nothing in this section shall be
- 24 construed to deny the right of a licensing board to deny, revoke
- 25 or suspend the license of or to discipline any health care
- 26 professional who:
- 27 (1) prescribes, administers or dispenses longer-term
- antibiotic therapy for a nontherapeutic purpose;
- 29 (2) fails to monitor ongoing care of a patient receiving
- 30 longer-term antibiotics; or

- 1 (3) fails to keep complete and accurate records of the
- 2 diagnosis, treatment and response to treatment of a patient
- 3 receiving longer-term treatment relating to Lyme disease or
- 4 related tick-borne illnesses.
- 5 Section 8. Effective date.
- 6 This act shall take effect immediately.