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PUBLIC STATEMENT Submitted to

SENATE BANKING AND INSURANCE COMMITTEE
The Honorable Donald C. White, Chairman
The Honorable Michael J. Stack, Democratic Chairman

Presented by
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Blue Cross of Northeastern Pennsylvania

Senate Bill 1199, Printer's No. 1612

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Senate Bill 1199—The Lyme and Related Tick-Borne Disease Education, Prevention and Treatment Act

Blue Cross of Northeastern Pennsylvania (BCNEPA) submits the following public statement on **Senate Bill 1199, Printer's No. 1612** the "Lyme and Related Tick-Borne Disease Education, Prevention and Treatment Act". Similar legislation has been considered in prior legislative sessions and many of the following comments appeared in written testimony that BCNEPA submitted to the House Health and Human Services Committee during previous public hearings that were held in consideration of the same topic.

Development of BCNEPA's medical policies is lead by our physician-run Medical Management Team. Medical Management is responsible for developing sound medical policies that ensure BCNEPA members have access to safe, medically appropriate and cost-effective health care. The team's recommendations are based on the best available data, including the latest medical research and best practices, as well as the experiences of colleagues in other states. It is with this expertise that we submit the following concerns for the Committee's consideration.

It is our position that the mandate included in Senate Bill 1199 would: 1) Codify into statute questionable medical policy that unnecessarily places individuals at risk; 2) Increase the cost of health care without improving outcomes; and, 3) Grant providers an unnecessary and unprecedented exemption from medical liability.

Referral to PHC4

Before addressing the details of Senate Bill 1199, BCNEPA respectfully requests that the Committee refer the legislation to the Pennsylvania Health Care Cost Containment Council (PHC4) for a mandated benefits review of the cost and quality implications associated with open-ended Lyme disease treatment, including the long-term use of antibiotic therapy. PHC4 should analyze the legislation and verify whether the benefits of SB 1199 will outweigh the associated costs forced on insured individuals throughout the state—particularly given that the medical science is inconclusive regarding the safety, efficacy, and medical appropriateness of the treatment protocol suggested in Senate Bill 1199. In addition, with the full impact of federal health care reform on Pennsylvania's health insurance market still unknown, it is vital that we cautiously examine additional health insurance mandates and fully consider the cost implications prior to voting on such legislation.

Mandating Unproven Medical Therapy can Produce Unintended Patient Harm

Senate Bill 1199 seeks to provide coverage for a "chronic" form of Lyme disease by mandating coverage for long-term antibiotic therapy for months or even years. Lyme disease is an infection of the type of bacterium called *Borrelia burgdorferi*, causing a red, circular rash accompanied by muscle and joint pains and other, less common symptoms like arthritis and a slowed heartbeat. While antibiotic therapy is the mainstay of treatment for Lyme disease, this treatment is typically limited to 30 days, with an additional 30 days when warranted. Well controlled clinical trials have not shown that

antibiotic use beyond these timeframes improves outcomes, as is suggested by Senate Bill 1199. In fact, such treatment can jeopardize the safety of the patient and contribute to the rise in antibiotic resistance.

Medical management of Lyme disease can be a lengthy, comprehensive process for both doctor and patient. Many physicians inaccurately diagnose patients experiencing symptoms associated with Lyme disease in a haste to find a treatable diagnosis. Such diagnoses are based on inconsistent and often times inaccurate tests authenticated by non-validated, generally unaccepted guidelines. Furthermore, physicians are left to rely solely on their opinion or clinical experience in diagnosing Lyme disease absent the existence of proven, established medical guidelines. Providing long-term antibiotic therapy to patients based on judgment rather than scientific fact can prolong suffering and cause irreversible harm to patients.

During the General Assembly's consideration of similar legislation during previous sessions, the Infectious Diseases Society of America (IDSA) had sent the General Assembly a letter in opposition to the proposed legislation. The IDSA is a national medical society representing over 8,000 infectious disease physicians and scientists who develop medical practice guidelines intended to assist doctors in diagnosing and treating patient conditions based on high quality, scientifically valid recommendations. In their opposition letter, the IDSA stated that: "Controlled clinical trials have shown no benefit from prolonged antibiotic therapy for the treatment of Lyme disease." Further, IDSA explains that: "Not only does prolonged therapy cause unnecessary patient discomfort, inconvenience, and expense, but most alarmingly, it *may be harmful*."

The IDSA reiterated its concerns in 2007 in a letter to the National Governor's Association encouraging states not to legislate medical policy that sanctions the use of long term antibiotic therapy for Lyme disease treatment. The IDSA further stated: "Of greatest concern are some states' misguided attempts to legislate the prolonged use of antibiotic therapy for Lyme disease. There are no convincing published scientific data that support the existence of chronic Lyme disease...Furthermore, **long term antibiotic therapy may be dangerous, leading to potentially fatal infections in the bloodstream as a result of intravenous treatment.**"

Recently, Lyme disease guidelines developed by the IDSA in 2006 were validated by an independent Review Panel as a result of an investigation brought on by the Connecticut Attorney General. The Attorney General represented Lyme disease patients who criticized the IDSA after their guidelines reported no confirmation of the existence of chronic Lyme disease or that long-term therapy was effective. The Review Panel unanimously agreed that all of the recommendations brought forth in the 2006 guidelines are "medically and scientifically justified". The Review Panel's report also noted: "In the case of Lyme disease, there has yet to be a single high quality clinical study that demonstrates comparable benefit to prolonging antibiotic therapy beyond one month...inherent risks of long-term antibiotic therapy were not justified by clinical benefit." ***The IDSA's statement on the review included this warning: "...there is no convincing evidence for the existence of chronic Lyme infection; and that long-term antibiotic treatment of 'chronic Lyme disease' is unproven and unwarranted. Inappropriate use of antibiotics (especially given intravenously) has been shown to lead to deadly blood infections, serious drug reactions and C. difficile diarrhea, as well as the creation of antibiotic-resistant bacteria or 'superbugs'.*** It makes no

sense to mandate coverage for treatment that is at best questionable and at worst, dangerous for health care consumers.

Senate Bill 1199 is Not Needed – Lyme Disease is a Covered Benefit

BCNEPA currently provides coverage for the treatment of Lyme disease according to the recommendations of the IDSA (attached). There is general consensus on the diagnosis and treatment of Lyme disease in academic centers throughout the United States. However, there are no well controlled scientific trials that support the treatment of “chronic Lyme disease” or even the existence of “chronic Lyme disease”, as is supported by the most recent review of the IDSA Lyme disease guidelines developed in 2006. Diagnosing and treating a condition for which there is no consensus and for which well controlled trials show no benefit seems to be the area of expertise for self-described “Lyme Specialists” who practice medicine that is not evidence based. This leaves great potential for inappropriate treatment, misappropriation of medical resources, and potential harm to patients. In addition, with the passage of federal health care reform there will be a continued push for greater use of evidence based medicine and a reduction in the use of clinical practices that demonstrate little to no efficacy for patients and add unnecessary costs to the health care system.

Benefit Mandates Increase Costs – Fall Heavily on Small Business

Senate Bill 1199 specifically states that health insurers shall provide coverage that includes long-term therapies and treatment as prescribed by the patient’s attending physician. Long-term therapies are defined in the bill as those that are longer than four weeks in duration. Not only is this type of treatment dangerous to the patient, it is costly.

The cost of treating a single Lyme disease patient with long-term antibiotics is estimated to range between \$5,000 and \$7,000 per month or between \$60,000 and \$84,000 per member per year under managed care. These numbers could fluctuate somewhat depending on whether the patient has someone capable of learning to administer the intravenous (IV) antibiotic on a daily basis at home instead of at a provider’s office. Treatment that exceeds one year is not an unusual occurrence with certain Lyme disease “specialists.” It must be noted that cost estimates would be much higher for non-participating providers who can bill whatever they wish and balance-bill the member for anything BCNEPA, or another insurer, does not cover.

If the mandate is enacted, BCNEPA would be forced to include an actuarial estimate of the added cost of covering open-ended Lyme disease treatment for our members in our health insurance premiums. The added cost is despite the fact that appropriate treatment is already being covered under our health plan *and* despite the fact that the specific inclusion of coverage for long-term antibiotic therapies make the proposal not only costly but proven medically unsound.

We also call the Committee’s attention to the fact that benefit mandates are not applied equally among insurance plans. Specifically, state mandates do not apply to self-funded plans that are regulated federally by ERISA and do not have to comply with state-imposed mandates. It should be noted that self-funded plans are typically large employers. Several years ago, the Pennsylvania Insurance Department calculated that,

one of every two Pennsylvanians that had health insurance was covered by a self-insured plan. Thus, state mandated benefits were applying to only one of every two insured Pennsylvanians.

Since small and medium sized businesses are unable to self-insure they bear the brunt and cost of all state imposed mandates. This magnifies the negative cost impact of bills such as Senate Bill 1199. Small and mid-sized employers as well as individual policy holders—those that are already struggling to afford health insurance—will bear the full cost impact of this mandate. The premiums for these policies will increase because the added benefit of open-ended Lyme disease treatment will generate additional costs for treatment that does not withstand medical scrutiny.

Enactment of an open-ended benefit mandate for an area of medicine that has been prone to questionable practice lacking a standard of care and which has been proven to fall short of medical consensus will do nothing to improve cost or quality.

Disease-Specific Liability Protection is Poor Public Policy

Another concern with Senate Bill 1199 is Section 7 in which medical providers who administer long-term Lyme disease therapies are granted immunity from medical liability. Proponents of the bill contend that such protection is necessary due to the fact that Lyme disease is often difficult for physicians to diagnose. We disagree that disease-specific protection is necessary for physicians and believe that this legislation sets a negative precedent in terms of the potential inclusion of other medical conditions. In the case of Lyme disease or **any** medical condition, if there is a misdiagnosis, a determination of negligence is based upon whether or not the treating physician provided competent care within the acceptable standard of care for treatment of the disease in question. Demonstrating that the care delivered did not rise to the acceptable standard of care is often difficult to prove, therefore, we believe that no additional or special provider protections are necessary.

We further contend that inclusion of the medial liability provision in the proposed legislation is further evidence of the lack of sound medical practice and treatment for Lyme disease. If the diagnosis and treatment standards for this disease were clear and well-accepted by the medical community, no additional medical liability protections would be necessary.

Conclusion

When reviewing Senate Bill 1199, we respectfully request that the members of the Senate Banking and Insurance Committee carefully consider the following:

- The lack of consensus for the diagnosis and management of chronic Lyme disease demonstrates that the effectiveness of the proposed mandate – including long-term antibiotic therapy – is questionable and in some cases may be medically dangerous for patients.
- This bill, if enacted, will be a throwback to an era of medicine that preceded the current practice of “evidence based medicine.” In an era of health care reform,

- we cannot afford the cost and wasted resources associated with practicing medicine without sound scientific guidelines.
- The legislation ignores the needs of those who purchase health insurance and want to maintain access to quality, affordable health care. In addition, the cost burden of this mandate will be borne by small employers and individuals – those purchasers too small to self-insure and least able to absorb the costs of premium increases.
 - Providing immunity from medical liability for those who administer long-term Lyme disease treatment is an unnecessary legal protection and reinforces the fact that the legislation is based upon questionable medical policy.

In closing, BCNEPA opposes Senate Bill 1199, the net effect of which will be to adversely affect the cost and availability of health care coverage in the Commonwealth with no subsequent quality improvement.