



Economic Impact Analysis Virginia Department of Planning and Budget

12 VAC 5-90 – Regulations for Disease Reporting and Control
Virginia Department of Health
November 7, 2013

Summary of the Proposed Amendments to Regulation

The Regulations for Disease Reporting and Control provide information about the process and procedures for reporting diseases to the Virginia Department of Health (VDH), including what diseases must be reported, who must report them and other details related to public health reporting and disease control. The Virginia Board of Health proposes to: 1) add two diseases and subtract one from the reportable disease list, 2) add three conditions to the list of conditions for which specimens must be shipped to the Department of General Services Division of Consolidated Laboratory Services (DCLS), and make numerous other changes for clarity and to reflect current practice.

Result of Analysis

The benefits likely exceed the costs for all proposed changes.

Estimated Economic Impact

The specific changes being proposed are necessary to ensure the regulations comply with recent changes in the practice of public health pertaining to the reporting of diseases in humans that are potentially transmitted from environmental sources (e.g., babesiosis and leptospirosis) as well as to update the list of laboratory tests that can be used to identify reportable disease findings and of specimens needing further testing to reflect advances in laboratory technology. Further amendments are necessary to clarify definitions and ensure consistency of the regulatory language, such as to standardize the reporting requirements for those who are required to report. Minor changes are also proposed to the section on the reporting of dangerous microbes to align the regulatory requirements with federal requirements. The benefits of the proposed amendments

stem from the improvement in information on which actions can be taken to minimize the spread of disease in Virginia.

The Board proposes to add babesiosis and leptospirosis and remove monkeypox from the reportable disease list. According to VDH, babesiosis and leptospirosis are quite rare and monkeypox has never been found in the Commonwealth. Thus this proposed change will in net likely cause a very small increase in laboratory staff time spent on reporting

Another proposed change will newly require the shipping of specimens to DCLS if positive tests are found for: 1) HIV, 2) Vibrio infection, or 3) when a clinical specimen yields evidence indicating the presence of a select agent or toxin as defined by federal regulations in 42 CFR Part 73. VDH estimates that approximately 2,400 positive HIV lab tests are confirmed each year in Virginia. Annually there are about 30 Vibrio infections and fewer than ten for select agents in the Commonwealth.

Private and Public labs that do HIV testing currently ship remnant sample (that is, serum that is remaining after they have finished their testing) to the federal Centers for Disease Control and Prevention (CDC)-designated lab voluntarily and at zero cost to the shipping lab. The samples are tested to determine recency of the HIV infection; thus this lab is referred to as the recency lab. One state lab (NY) does all of the testing for the country and works with the labs that do confirmatory testing for HIV to provide for them to ship their remnant samples to the recency lab using CDC funds. CDC has supported this program since 2004. As long as CDC funds continue to be available, this proposed amendment would not have any costs to laboratories in Virginia.

There is currently no federal funding to pay for the shipping of the Vibrio and select agent specimens. Statewide there will likely be fewer than 40 times per annum where such a specimen would need to be shipped.¹ Also, if labs are already shipping other specimens to DCLS at the same, the lab could potentially just add the specimen in question to the package and not incur additional costs. Nevertheless, there will likely be occasions where a shipment must be made due to the detection of Vibrio or a select agent.

¹ As mentioned, VDH estimates that there are about 30 Vibrio infections and fewer than ten for select agents annually in the Commonwealth

Businesses and Entities Affected

VDH estimates that up to 100 laboratories may be affected by the changes proposed in laboratory reporting requirements; however, not all will offer the types of testing that must be reported. These laboratories are already reporting disease information to the health department, and the additions should have minimal impact. Some of the affected laboratories, including those in hospitals, would meet the definition of a small business.

Localities Particularly Affected

The proposed amendments do not disproportionately affect particular localities.

Projected Impact on Employment

The proposed amendments will not likely affect employment.

Effects on the Use and Value of Private Property

The proposal to add *Vibrio* infection and the presence of a select agent or toxin² to the list of conditions for which specimens must be shipped to DCLS will create some occasions where private laboratories must expend additional dollars on shipping.

Small Businesses: Costs and Other Effects

The proposal to add *Vibrio* infection and the presence of a select agent or toxin³ to the list of conditions for which specimens must be shipped to DCLS will create some occasions where small private laboratories must expend additional dollars on shipping.

Small Businesses: Alternative Method that Minimizes Adverse Impact

Short of providing a subsidy or other outside reimbursement, there is no clear alternative method that would reduce the additional shipping costs for some small laboratories while still accomplishing the policy goal of improved information on which to actions can be taken to minimize the spread of disease in Virginia.

Real Estate Development Costs

The proposed amendments do not affect real estate development costs.

² As defined by federal regulations in 42 CFR Part 73.

³ Ibid.

Legal Mandate

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.04 of the Administrative Process Act and Executive Order Number 14 (10). Section 2.2-4007.04 requires that such economic impact analyses include, but need not be limited to, a determination of the public benefit, the projected number of businesses or other entities to whom the regulation would apply, the identity of any localities and types of businesses or other entities particularly affected, the projected number of persons and employment positions to be affected, the projected costs to affected businesses or entities to implement or comply with the regulation, and the impact on the use and value of private property. Further, if the proposed regulation has an adverse effect on small businesses, Section 2.2-4007.04 requires that such economic impact analyses include (i) an identification and estimate of the number of small businesses subject to the regulation; (ii) the projected reporting, recordkeeping, and other administrative costs required for small businesses to comply with the regulation, including the type of professional skills necessary for preparing required reports and other documents; (iii) a statement of the probable effect of the regulation on affected small businesses; and (iv) a description of any less intrusive or less costly alternative methods of achieving the purpose of the regulation. The analysis presented above represents DPB's best estimate of these economic impacts.