Economic Impact Analysis
Virginia Department of Planning and Budget

12 VAC 5-90 – Virginia Department of Health (State Board of)
Disease Reporting and Control
May 13, 2003

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 2.2-4007.G of the Administrative Process Act and Executive Order Number 21 (02). Section 2.2-4007.G requires that such economic impact analyses include, but need not be limited to, 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. The analysis presented below represents DPB's best estimate of these economic impacts.

Summary of the Proposed Regulation

The proposed amendments to the regulations will (1) allow reporting of infectious diseases through secure electronic transmissions, (2) require research laboratories to report dangerous microbe and pathogen supplies, (3) update the reportable disease list and requirements, (4) reduce the reporting time frame for diseases that are public health concerns, (5) establish additional reporting requirements for suspected active cases of tuberculosis, and (6) require all private laboratories to submit the specimens associated with a number of diseases to the state laboratory for additional testing.

Estimated Economic Impact

These regulations contain disease-reporting requirements for hospitals, laboratories, nursing homes, and physicians. The list of notifiable diseases includes approximately 70 infectious diseases, toxic effects, and conditions. Surveillance of notifiable diseases is an essential part of public health policy. It allows public health officials to monitor infectious diseases, to identify emerging problems, and to develop an immediate response to the emerging

problems. Virginia Department of Health (the department) receives about 35,000 notifications annually. Of these reports, approximately 25,000 are for sexually transmitted diseases.

In addition to its essential role in public health policy, disease surveillance appears to be very cost effective. The reporting costs are usually small and may include a telephone call, filling out a form, mailing or faxing a form, or reporting through other approved electronic means. The potential benefits however appear to be substantial. For example, notification of unusual emergence of bloody diarrhea (a notifiable disease in Washington) in 1993 allowed Washington State Department of Health to identify the hamburgers at a fast food chain restaurant as the cause of the outbreak.[1] As a result, 250,000 potentially contaminated hamburgers were removed and an estimated 800 cases of infection were prevented. Cooking tests revealed non-compliance with temperature requirements and led to change in restaurant policy nationwide. Also, disease surveillance provides data about incidences of diseases in the community, helps identify unusual trends, promotes early detection and treatment, and prevents unnecessary treatment or treatment of wrong diseases.

Cost effectiveness of disease reporting could be attributed to the nature of communicable diseases. Each occurrence of reportable communicable diseases not only poses health risks to the individual person, but also adds to the risk of an outbreak. Thus, notification of an infectious disease provides benefits to the individual as well as to the community as a whole. In other words, each report indicates an occurrence of an infectious disease and consequently each report has the potential to prevent multiple occurrences of the same disease and provide substantial savings in healthcare and other types of prevention costs.

Recognizing the public health consequences, the Code of Virginia provides up to $10,000 fine a day for incidences not reported. In practice, however, this requirement is not currently enforced due to concerns about the enforcement costs. Indeed, enforcement costs would be tremendous if all records in each physician office are audited. However, it may be possible to develop other types of cost effective enforcement mechanisms. If a cost effective enforcement strategy increases the chances of a physician being found in violation of the statutory requirement and being fined accordingly, an increase in compliance would be expected. This

[1] Denise, Koo, 1999, "The Role of Providers and Health Plans in Infectious Disease Surveillance," American College of Physicians, vol. 2, no. 5, pp. 247-252.

would certainly help reducing underreporting of notifiable diseases, which is the most significant problem in public health disease monitoring and surveillance.

The department believes that hospitals and laboratories in Virginia do a good job complying with these regulations. Physicians are believed to report rare and serious diseases accurately. However, the department believes that more common and less serious diseases may be underreported in Virginia, as is the case nationwide. A comprehensive survey of the literature reveals that infectious disease reporting completeness in the United States is disease specific and varies from 9% to 99%.[2] Reporting completeness for tuberculosis, AIDS, and sexually transmitted diseases as a group (79%) is found to be much higher than for all other diseases as a group (49%). The reasons for underreporting generally include the physicians' lack of understanding the importance of health surveillance, the role of the provider as a source of information, the role of the health department, the lack of knowledge as to what diseases are notifiable and how to report them to proper authorities, the assumption that someone else will report the case, the lack of awareness of the legal requirement, insufficient reward for reporting or penalty for not reporting, and concerns about time involvement and patient confidentiality.[3]

The presence of underreporting creates a room for significant economic improvement if cost effective strategies could be developed to improve disease reporting. For example, physicians may be encouraged to report through distributions of educational materials, telephone numbers, forms, and information on legal requirements as currently done by the department. In addition to these efforts, however, an automated disease reporting and surveillance system and a cost effective enforcement mechanism may further improve disease reporting. While the implementation of such measures may require additional public resources, given the current situation, it appears that the return on each dollar spent to reduce underreporting within a well

[2] Doyle, Timothy J., et al., 2002, "Completeness of Notifiable Infectious Disease Reporting in the United States: An Analytical Literature Review," American Journal of Epidemiology, vol. 155, no. 9, pp. 866-874.

[3] Denise (1999)

Doyle (2002)

Squires, Susan G., et al., 1998, "Improved Disease Reporting: A Randomized Trial of Physicians," Canadian Journal of Public Health, vol. 89, no. 1, pp. 66-69.

Peate, Ian, 1999, Infectious Diseases: Statutory Notification and Surveillance, British Journal of Nursing, vol. 8, no. 14, pp. 943-947.

MacDonald, Jean K., et al., 1997, "Active and Passive Surveillance for Communicable Diseases in Child Care Facilities, Seattle-King County, Washington," American Journal of Public Health, vol. 87, no. 12, pp. 1951-1955.

designed strategy would easily justify the additional costs and improve the health and safety of Virginians.

One of the proposed changes will allow reporting of diseases by means of secure electronic transmission. Currently the department is working on implementing an electronic disease reporting system which could be an improvement over the paper based system in place. However, this change would also allow an automatic disease reporting system, which could be the integral part of the strategy in reducing underreporting in addition to educating physicians and strengthening enforcement. Current status of provider and laboratory based information management systems makes it possible to establish an automated disease reporting and surveillance system. Such a system would reduce dependence on individual provider behavior for disease surveillance (one of the most important shortfalls of traditional methods of reporting as explained above) without compromising patient privacy and confidentiality. Thus, an automated system has the potential to improve quality and timeliness of disease reporting.

For example, the Hawaii Department of Health implemented an automated disease reporting system for laboratories and achieved very desirable outcomes.[4] This system automatically extracts disease information from laboratory's information system every day and transfers the encrypted information to the health department. It is found that the automated system increased the number of reports received by 2.3 times relative to the traditional reporting mechanisms, shortened the time for submitting reports by 3.8 days, and resulted in a more complete reporting in terms of the data fields required to be reported on each form. Such a system would require non-negligible investment in programmer time and in electronic equipment to operationalize the system, but would also provide ongoing cost savings in terms of personnel time required to fill out the forms, make telephone calls etc. associated with the traditional reporting methods.

In short, consistent with national data, infectious disease underreporting is a significant problem in Virginia. Underreporting causes insufficient allocation of public resources in disease prevention and creates healthcare costs that could be avoided. The reasons for underreporting appear to be the lack of physician understanding and education, the reliance on individual

[4] Effler, Paul, et al., 1999, "Statewide System of Electronic Notifiable Disease Reporting from Clinical Laboratories: Comparing Automated Reporting with Conventional Methods," Journal of American Medical Association, vol. 282, no. 19, pp. 1845-1850.

provider behavior, and lack of enforcement. An automated electronic reporting system supplemented by other cost effective strategies to educate physicians and to improve compliance by enforcing existing laws seems to have the potential to be the cornerstone of a cost effective strategy to improve infectious disease reporting. Although initiation of such strategies would require significant start up costs, the savings in terms of avoided healthcare costs and long-term cost savings from an effective automated system could easily exceed the initial implementation costs.

In addition, pursuant to section 32.1-35 of the Code of Virginia, the department proposes to establish regulations for reporting of dangerous microbes and pathogens. Approximately 10 biotechnical research laboratories in Virginia will be subject to the proposed new rules. The types of microbes and pathogens that must be reported are select agents and toxins outlined in federal regulations. The department will initially collect information on the type, quantity, and location of these microbes and pathogens as well as the objective of the work and the identification of persons with access to each agent. Based on this information, the department will create a select agent and toxin registry. The laboratories will be required to send a copy of federal forms filed with Centers for Disease Control addressing destruction or transfer of these agents at their facilities within 7 days of their submission to the federal agency so that the state registry can be updated. More importantly, the research laboratories will be required to report to the department suspected release, loss, or theft of any select agent or toxin within 24 hours by the most rapid means available.

The main purpose of these requirements is the surveillance of dangerous microbe or pathogen supplies at research laboratories and rapid identification of potential public health risks. Intentional or unintentional release of these agents or toxins may have devastating consequences. For example, the biological attacks involving intentional distribution of anthrax spores through the mail system after September 2001 infected 22 people, killed five of those who were infected, caused authorities to advise more than 10,000 people to take post exposure treatment because they were at risk of contracting anthrax, caused an additional 20,000 people to start post exposure treatment until authorities reassured that exposure for them was unlikely, and worried

coworkers, friends, and family members of those who were exposed.[5] Unquantified full-scale economic effect of this terrorist activity was probably much greater than just the treatment costs and loss of five human lives.

The most significant benefit of the proposed rapid reporting is to establish an early warning mechanism for the Commonwealth's public health officials to protect civilians who are at risk in the event of an unexpected change in the supply of these bio-chemicals held at research laboratories. Quantification of the benefits of such a low-frequency high-risk event is beyond the scope of this report and cannot be made at this time. However, the costs of the initial reporting to establish and maintain the registry is expected to be small as this will require communication of already available information for federal reporting purposes to the Virginia Department of Health. Similarly, the cost of rapid reporting of unexpected changes in the supply of select agents through telephone or fax should be small relative to potential benefits should such an event occur.

The proposed changes will also modify the reportable disease list and requirements in several ways. Regulated entities will be required to report suspected or confirmed cases of diseases caused by an agent that may have been used as a weapon to the department within 24 hours. Additionally, the department proposes to add 16 diseases, toxic effects, or conditions to the list for rapid reporting.[6] Also, seven of the already notifiable diseases will be required to be reported within 24 hours rather than 3 days. Moreover, the sections for laboratories explaining the types of tests used to confirm the reportable diseases and the types of diseases hospitals, nursing homes, assisted living facilities, and correctional facilities required to report will be updated.

The requirements for notification of diseases evolve overtime as new scientific information becomes available and as new threats to public health emerge.[7] The proposed changes will update the disease list and requirements so that the new scientific information is utilized and emerging threats are better addressed. Particularly for biological agents, inadequate

[5] Herberding, Julie L., et al., 2002, "Bioterrorism Preparedness and Response: Clinicians and Public Health Agencies as Essential Partners," Journal of American Medical Association, vol. 287, no. 7, pp. 898-900.
[6] These are anthrax, botulism, cholera, diphtheria, haemophilus influenzae infection, hepatitis A, measles, meningococcal infection, all types of outbreaks, pertussis, plague, poliomyelitis, psittacosis, rabies in human or animal, active tuberculosis, and yellow fewer.

disease reporting may result in delayed recognition of a bioterrorism attack and ineffective response to bioterrorism or other public health emergencies.[8] On the other hand, increasing the number of diseases that must be reported, increasing the number of diseases that must be reported rapidly, and requiring new test methods to confirm suspected cases will likely introduce some administrative costs on regulated entities. However, the potential benefits are probably more than enough to outweigh the additional reporting costs.

The department also proposes to reduce the reporting time frame for diseases that must be reported within 7 days to 3 days. The timeliness of reporting is a major factor in disease surveillance. This change is expected to shorten the time frame the department becomes aware of the infectious disease occurrence and acts to prevent the further spread. A rapid response would provide some savings in healthcare costs by avoiding an outbreak and improve health and safety of people who would otherwise be exposed to the disease. On the other hand, hospitals, laboratories, and physicians would probably incur some additional costs. These costs may be the result of increased frequency of reporting which could require a change in disease reporting procedure already in place at these facilities. While the potential benefits seem to be disease specific, potential costs would probably vary from facility to facility depending on the reporting system in place.

Pursuant to the statutory requirements, another change requires additional reporting from physicians and medical care facilities for suspected active cases of tuberculosis. An initial report is required comprising identity of the patient, basic demographic characteristic of the patient, and any pertinent medical information. This report is updated within 1-2 weeks with information on the test results and drugs administered. Subsequent reporting is required when any changes occur in the status of the patient, the treatment, or in test results. The purposes of these additional requirements include making sure that the patient does not develop a drug resistance and reducing exposure to this airborne disease. The department receives notifications for about 300-400 cases of tuberculosis annually. Similar to the other infectious disease requirements, the potential benefits of the reporting of readily available information would probably exceed the administrative costs of reporting.

[7] Roush, Sandra, et al., 1999, "Mandatory Reporting of Diseases and Conditions by Health Care Professionals and Laboratories," Journal of American Medical Association, vol. 282, no. 2, pp. 164-170.

Finally, all private laboratories will be required to submit the specimens associated with a number of diseases to the state laboratory for additional testing. This requirement currently applies only to laboratories operating in a medical facility. The purpose of the additional testing by state laboratory is to further identify the more specific characteristics of the culture that cannot be done in a regular laboratory. For example, the state laboratory has the capability to identify the genetic code of *E. coli* bacteria or the type of *salmonella* virus. This type of additional information helps the department to effectively respond to reports it receives. Although this requirement may allow the department to more effectively prevent outbreaks, it will probably introduce some costs to several more laboratories for shipment of specimens to the state laboratory.

Businesses and Entities Affected

The proposed regulations apply to approximately 100 hospitals, 150 laboratories, 250 nursing homes, and about 20,000 physicians.

Localities Particularly Affected

The proposed regulations are not expected to affect any locality more than others.

Projected Impact on Employment

The short-term economic impact of proposed changes on labor demand will likely be positive. Hospitals, nursing homes, laboratories, and physician offices will start reporting more diseases to the department and a number of diseases will have to be reported rapidly. In addition, the research laboratories will start reporting supply of dangerous microbes or pathogens for the purpose of establishing a statewide registry and maintaining it over time. There will also be additional reporting for active cases of tuberculosis and additional shipping of specimens to the public health officials. However, the proposed changes will also allow the use of electronic reporting means. If an automated disease reporting system is implemented, there is likely to be a decrease in labor demand due to the labor-intensive nature of current paper reporting system in place. Thus, overall long-run economic effect of these changes could be a decrease in labor demand if and when an automated reporting system is implemented.

[8] Horton, Heather H., et al., 2002, "Critical Biological Agents: Disease Reporting as a Tool for Determining Bioterrorism Preparedness," Journal of Law, Medicine, and Ethics, no. 30, pp. 262-266.

Effects on the Use and Value of Private Property

Similarly, the proposed additional reporting requirements will introduce some administrative costs and may reduce the profits and the value of privately owned regulated entities in the short-run. However, there is a possibility that, if implemented, an automated system could provide savings in administrative costs over time, increase profits, and increase the value of private hospitals, nursing homes, laboratories, and physician offices that are subject to the proposed requirements.