

Economic Impact Analysis Virginia Department of Planning and Budget

9 VAC 20-120 – Regulated Medical Waste Management Regulations Department of Environmental Quality

February 9, 2001

The Department of Planning and Budget (DPB) has analyzed the economic impact of this proposed regulation in accordance with Section 9-6.14:7.1.G of the Administrative Process Act and Executive Order Number 25 (98). Section 9-6.14:7.1.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 Virginia Waste Management Board (the board) proposes (1) to exempt certain medical waste from regulations, (2) to change the on-site storage permit requirements for small facilities, (3) to eliminate full permits for off-site medical waste storage, and (4) to replace medical waste packaging and transportation standards with those of other regulatory agencies.

Estimated Economic Impact

Medical wastes generated at facilities such as hospitals, doctor's offices, dentist's offices, and veterinary clinics are subject to specific treatment, storage, and disposal requirements because of public health concerns. These regulations establish standards and procedures for treatment, storage, and disposal of medical waste. Four of the proposed changes may have a significant economic impact.

First, the proposed regulations modify the definition of medical waste. The proposed medical waste regulations employ definitions that are consistent with the Bloodborne Pathogen

Standard established by the Occupational Safety and Health Administration (OSHA) and administered by the Virginia Department of Labor and Industry to regulate the medical waste containing human blood and body fluids. Under the proposed regulations, items that are less likely to release blood and body fluids such as items that have been used for personal hygiene, certain empty items used to collect fluids from or administer fluids to patients, particular items that may have contacted a patient's mucous membranes, and certain absorbent materials containing blood and body fluids but are not saturated are no longer considered as medical waste and are exempted from regulations.

The exemptions of the medical waste specified above from regulations will reduce the amount of waste that must be treated. The Department of Environmental Quality (DEQ) does not know with certainty the amount of reduction in regulated medical waste that will be experienced by the regulated community. However, DEQ expects that the exemptions will amount to a small, but non-negligible amount of medical waste that is no longer required to be treated.

The treatment of medical waste is costly. Facilities can choose to treat their medical waste on-site or they can contract with a private treatment facility. In either case, the medical facility has to incur costs. The treatment costs of medical wastes charged by private treatment facilities in Virginia vary from \$400 to \$640 per ton. By reducing the amount of waste that must be regulated, the proposed regulations are expected to benefit regulated hospitals, doctor's offices, dentist's offices, and veterinary clinics. At the same time, revenues of the firms providing medical waste disposal services are expected to decrease by a smaller magnitude since some of the medical waste has been treated by the generating facilities themselves. Since the amount of reduction in regulated medical waste is not known, the size of the expected benefits to the regulated facilities cannot be estimated.

A potential concern with the exemption of certain medical wastes from regulations is the possibility of an increased chance of citizens' exposure to these medical wastes, and consequently, contracting certain diseases. Exposure to bloodborne pathogens increases the risk of contracting hepatitis B, non-A hepatitis, non-B hepatitis, acquired immune deficiency

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¹ Source: DEQ

syndrome (AIDS), and other bloodborne diseases.² Under the current regulations, only medical waste management personnel are exposed to the proposed exempt medical waste. The proposed regulations are likely to increase the public's exposure, particularly landfill workers, to the proposed exempt medical waste since these wastes are likely to be placed in regular trashcans or dumpsters and sent to landfills instead of being treated at incinerators. However, the proposed exempt materials may have a low chance of transmitting disease. Since these materials are not saturated with blood or body fluids, they are not likely to release blood or body fluids, and consequently, contract diseases to public or landfill workers. Therefore, the public and landfill workers may not be in significantly greater danger. According to a member of the University of Virginia Health Sciences Center, "no health risks to the public are likely to take place" because of the proposed exemptions of specified materials from current medical waste regulations.³ In short, the proposed exemptions of certain medical waste probably will not increase public health risks significantly based on the information currently available. Given that the amount of proposed exempt medical waste is not known, it cannot be determined if the proposed changes will produce net economic benefits to the Commonwealth.

Another potentially significant change involves the way small facilities are regulated. Under the current regulations, limited small clinics and facilities storing less than 64 gallons of medical waste are not required to have a permit by rule for on-site storage. The "limited small clinic" definition is based on the size of the facility itself, i.e., the number of healthcare professionals working. The limited small clinic definition will no longer be used to determine if a small facility is subject to regulations. The proposed regulations use weekly volume of waste generated at the facility as well as the total volume stored to determine if a facility is required to have a permit by rule for storage.

The proposed changes will increase the 64 gallons storage limit for exemption for permit by rule to 200 gallons. A facility generating less than 100 gallons of waste per week and storing less than 200 gallons of waste will be allowed to operate under minimal requirements without obtaining a permit by rule for on-site storage. Additionally, facilities generating more than 100 gallons per week and storing more than 200 gallons of waste on-site will be exempt from

² Occupational Exposure to Bloodborne Pathogens, OSHA Preambles, Section 7, Regulatory Impact and Regulatory Flexibility Analysis, 1992.

³ Source: Telephone conversation with Dr. Barry Farr on February 5, 2001.

obtaining a permit by rule if they provide a designated storage area for all areas of the facility storing greater than 200 gallons of medical waste.

There are different requirements for facilities that are required to obtain a permit by rule and facilities that are not. For example, permitted facilities are required to store the waste in a storage area that is designed in accordance with the regulations, that has access control and signage consistent with the regulation, that has emergency clean up equipment and materials on hand. Permitted facilities are required to keep specific records indicating that waste has been treated and the records also track storage timeframes. Storage at small facilities will simply require the facility to keep the waste stored in a safe and secure manner ensuring the waste cannot spill, or contact workers or the public. In that sense, the proposed regulations are less prescriptive than the current regulations on storage of medical waste. The economic impact of this proposed change will differ between current small facilities and the facilities that are expected to be established in the future.

DEQ estimates that about 60 existing facilities storing waste on-site will no longer be required to have a permit by rule under the proposed regulations. Thus, these less prescriptive requirements are likely to reduce the record keeping costs and other operating costs of about 60 existing facilities by a small margin. However, the proposed changes are not likely to affect these existing permit by rule holders through associated permit costs and designated storage area requirements. The facilities with permit by rule will not save any permit related costs since the permits are issued permanently and not renewed over the years. Their permits will be void. Also, permit holders are already required to have designated storage areas under the current regulations and are not likely to incur additional costs because of storage area requirements so they will not incur any additional costs under these provisions.

The main effect of this proposed change will be on the small facilities that are expected to be established in the future. DEQ has been receiving one permit application for on-site storage over about every one to two year period. Under the proposed regulations, no facility is expected to apply for permit by rule for on-site storage. Thus, one facility every one or two year period may benefit from the proposed changes in the sense that they will not be required to have a permit by rule for storage, and consequently, will not incur associated permit costs. A permit by rule is issued after certain reports are prepared and evaluated. Permit applicants usually hire a

private consultant to prepare reports for the permit. Certifications that the facilities meet the siting and design standards in the regulation, an operations plan, and an emergency contingency plan are required. Consultants charge about \$10,000-\$12,000 to prepare reports for an application for a permit by rule. DEQ does not charge any fee for a permit by rule. Thus, one facility over every one or two year period will avoid costs associated with obtaining a permit. Additionally, by eliminating the permit by rule for onsite storage facilities, DEQ will save a small amount of administrative costs associated with evaluating about one permit application every one or two year period. Thus, this proposed change is expected to benefit regulated facilities and DEQ. No additional costs to society are expected.

Third, the proposed regulations will eliminate a specific type of permit for off-site storage/treatment. Currently, DEQ mostly issues a type of permit known as permit by rule. Another type of permit is a full permit. A permit by rule is issued if the applicant demonstrates that a standard set of requirements is fulfilled. The full permit is issued on a case by case basis. Currently, off-site facilities are given the option to apply for either of the two permits. The board is proposing to eliminate the full permit option. A full permit has more extensive requirements than the permit by rule. For example, a lot more detail is required in a full permit application particularly in the area of design plans detailing existing site conditions, profiling views of proposed features and utilities and roadways. A full permit is one way to enhance public perception among many other ways. For example, facilities may voluntarily choose to provide the information on the safety measures taken to the public to enhance public perception even if it is not required. DEQ indicates that only one off-site facility holds a full permit whereas the two other off-site facilities chose to apply for a permit by rule. Thus, the removal of full permit option will apply to only one current off-site facility. This one facility will lose its option to keep its full permit, but will not incur monetary costs. Additionally, the proposed changes will help DEQ to achieve more standardized permit procedures and reduce regulatory language.

This proposed change will force all of the future off-site permit applicants to obtain a permit by rule which is less costly than a full permit.⁵ Consultant costs of preparing an application package for a permit by rule for off-site storage vary from \$10,000 to \$12,000. Consultant costs for the preparation of an application for a full permit for off-site storage vary

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⁴ Source: DEQ

from \$50,000 to \$70,000. Also, a full permit applicant must pay for an application fee. The full permit fee for medical waste off-site storage is \$3,300 and there is no fee for a permit by rule. Thus, the costs associated with preparing an application package are lower by \$43,300 to \$61,300 for a permit by rule than the costs for a full permit.

Fourth, the board proposes to replace medical waste packaging and transportation standards with the current standards of other regulatory agencies by referencing their standards. Currently, packaging requirements for medical waste differ from the other standards enforced by the Virginia Department of Labor and Industry. The differences in packaging requirements relate to the bag specification standards as well as the labeling requirements for the bags. By referencing these other standards in the proposed regulations, the regulated community will have to comply with only one set of packaging regulations. In addition, there are minor differences between the state transportation standards established in this regulation and the federal transportation standards established by the U.S. Department of Transportation. The federal Department of Transportation requirements preempt any state requirements that are not the same as the federal requirements. Because of the proposed changes, reported confusion experienced by the regulated community relating to the different packaging and transportation standards are likely to be eliminated in the future. Thus, incorporating other agency standards for packaging and transportation of medical waste by reference is expected to benefit the regulated facilities.

Businesses and Entities Affected

The proposed regulations are likely to affect approximately 175 hospitals, 784 animal hospitals, all doctors and dentists offices, and three firms providing private medical waste disposal services to the regulated facilities in Virginia. The total number of doctors and dentists offices is not known, but there are approximately 26,728 medical doctors and 5,274 dentists in Virginia. In addition, about 250 to 350 landfill workers at approximately 67 landfills in Virginia may be affected. Moreover, about 60 current on-site storage permit by rule holders, and one current off-site storage full permit holder are expected to be affected. It is also likely that about one potential on-site medical waste storage facility over every one or two year period will be affected by the proposed regulations.

⁵ ibid.

Localities Particularly Affected

All localities are expected to be affected throughout the Commonwealth.

Projected Impact on Employment

The proposed regulations may have a small negative impact on employment in the waste disposal industry due to decreased business volume of medical waste disposal services. However, since the rule will lower the costs associated with collecting and disposing of medical waste, it will increase profits of certain firms in the medical industry. The net effect of these two changes is not known.

Effects on the Use and Value of Private Property

The value of three private medical waste disposal facilities may decrease by a very small amount due to decreased demand for medical waste disposal. But, the value of regulated medical firms is likely to increase as their profits increase due to lower disposal costs. The net economic impact of these two changes is unclear.