

Regulatory Analysis Form

(Completed by Promulgating Agency)

**INDEPENDENT REGULATORY
REVIEW COMMISSION**

(All Comments submitted on this regulation will appear on IRRC's website)

(1) Agency: Department of Environmental Protection

(2) Agency Number:

Identification Number: #7-480

IRRC Number:

(3) PA Code Cite: 25 Pa Code Chapters 271, 272, 273, 284, 285, 287, 288, and 299

(4) Short Title: Regulated Medical and Chemotherapeutic Waste

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(6) Type of Rulemaking (check applicable box):

- Proposed Regulation
- Final Regulation
- Final Omitted Regulation

- Emergency Certification Regulation;
- Certification by the Governor
- Certification by the Attorney General

(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less)

The Department of Environmental Protection's (Department) Bureau of Waste Management regulates and oversees the management and disposal of wastes that are generated from the diagnosis, treatment, immunization, or autopsy of human beings and animals.

This final-form rulemaking will bring Pennsylvania's regulated medical and chemotherapeutic waste provisions up to date and consistent with federal requirements. This regulation will:

- Change the terminology from "infectious waste" to "regulated medical waste";
- Exempt certain wastes generated by biologics facilities from the definitions of infectious waste and infectious agent based upon the federal classification of the waste;
- Clarify and streamline the storage, transportation and shipment requirements of regulated medical waste to recognize business practices, and encourage labor and fuel efficiency;
- Incorporate permits-by-rule for processing and treatment of regulated medical waste;
- Allow the use of standard business documentation, including electronic tracking systems, to record the proper processing and disposal of regulated medical waste;
- Allow the transportation of regulated medical waste through the U.S. Postal Service (USPS); and
- Eliminate provisions that relate to areas governed by the Occupational Safety and Health Association (OSHA) to avoid inconsistencies and duplication.

(8) State the statutory authority for the regulation. Include specific statutory citation.

This rulemaking is being made under the authority of the following:

The Solid Waste Management Act (SWMA) (35 P.S. §§ 6018.101 - 6018.1003), which in Section 105(a) (35 P.S. § 6018.105(a)) grants the Board the power and the duty to adopt the rules and regulations of the Department to accomplish the purposes and carry out the provisions of the SWMA. Sections 102(4) and 104(6) of SWMA (35 P.S. §§ 6018.102 and 104), which provide the Department with the power and duty to regulate the storage, collection, transportation, processing, treatment, and disposal of solid waste to protect the public health, safety and welfare.

The Infectious and Chemotherapeutic Waste Disposal Law, which at Section 6019.4(b), (35 P.S. § 6019.4(b)) grants the Board the power and duty to adopt the rules and regulations of the Department to accomplish the purposes and carry out the provisions of the law and which at Section 6019.2(b) (35 P.S. § 6019.2(b)) provides the Department with the authority to review and revise regulations as necessary.

The Administrative Code of 1929 (71 P.S. §§ 510-1 - 510-27), which at Section 1917-A (71 P.S. § 510-17) authorizes and requires the Department to protect the people of this Commonwealth from unsanitary conditions and other nuisances, including any condition that is declared to be a nuisance by any law administered by the Department. Section 1920-A (71 P.S. § 510-20), which grants the Board the power and duty to formulate, adopt and promulgate such rules and regulations as may be determined by the Board for the proper performance of the work of the Department.

(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action.

This regulation is not mandated by any federal law or federal regulation.

This regulation is not mandated by, or related to, any federal or state court decision.

The Pennsylvania Infectious and Chemotherapeutic Waste Disposal Law requires a manifest system to track infectious and chemotherapeutic wastes.

Regulated medical and chemotherapeutic wastes are solid wastes under the Solid Waste Management Act and must be managed in accordance with the rules and regulations pursuant to that Act.

There are no deadlines associated with the regulations.

(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

The regulation of infectious waste (regulated medical waste) and chemotherapeutic waste is necessary to protect the overall health and safety of the public. Blood and bodily fluid have the ability to carry pathogenic organisms that can cause infections and diseases in humans or animals that come into contact with them. Chemotherapeutic drugs are inherently toxic substances. Their toxic effects can pose a threat to otherwise healthy individuals that come into contact with discarded medical devices or supplies used to administer drugs to patients for the treatment of cancer or contain residual amounts of chemotherapeutic substances.

Current regulations are not aligned with nationwide practices and place Pennsylvania at a disadvantage. New streamlined regulations will provide equivalent environmental protection with a more efficient process, which will benefit medical practitioners, medical facilities, transporters of and processors of regulated medical and chemotherapeutic waste (see number (15) for a breakdown of the number of facilities that will benefit). This rulemaking will allow an estimated 16,303 entities managing regulated medical and chemotherapeutic waste to better understand Pennsylvania's requirements and eliminate duplicative and other outdated requirements, as elaborated below:

Labeling

Currently, medical facilities in Pennsylvania are required to have two labels on their waste receptacles, one that reads "infectious waste" to comply with Pennsylvania regulations, and one that reads "regulated medical waste" to comply with Federal requirements. This final-form rulemaking will identify "infectious waste" as "regulated medical waste," making the terminology consistent with federal requirements and thus eliminating the need for two separate labels. This uniform practice should reduce the costs borne by waste generators and other persons managing regulated medical waste because the same containers and labels could be used to satisfy Pennsylvania requirements and the requirements imposed by federal agencies.

Storage

In Pennsylvania, medical facilities are currently required to seal medical waste disposal containers, such as boxes or bags, for disposal within 30 days of placing the first waste item in the container. This final-form rulemaking will allow generators to store regulated medical and chemotherapeutic waste for a longer time period: 30 days after the date the container is full or sealed, whichever occurs first. This will provide the generator with more control over the length of time the waste is stored on-site and promotes more efficient business practices by reducing the need to transport partially filled containers. This change encourages transporter labor savings and fuel efficiency, while maintaining the integrity of Pennsylvania's regulated medical waste management and disposal requirements.

Transportation and Shipping

The final-form rulemaking streamlines the transportation and shipment requirements for regulated medical and chemotherapeutic waste in several respects. The amendments allow generators, transporters and those involved in storage, processing and disposal of regulated medical and chemotherapeutic waste to use standard business documentation, including electronic tracking systems, to demonstrate compliance with the regulations instead of the currently prescribed, but outdated, paper manifest. The rulemaking includes provisions for the manifest requirement to be satisfied with a shipping paper, log or electronic tracking system that provides the required information, allowing the generator to track its waste in accordance with current industry practices. This provision will allow the generators and haulers to choose which tracking option is best to satisfy their compliance needs.

Additionally, the rulemaking allows authorized waste haulers, under certain conditions, to transport containerized regulated medical and chemotherapeutic wastes along with other containerized wastes in the same vehicle. This will reduce the number of trips needed to transport waste from generators that have both regulated medical and chemotherapeutic waste and other wastes requiring disposal, increasing fuel efficiency and reducing the hauling costs borne by the generators.

The rulemaking also allows the shipment of regulated medical waste through the USPS, in accordance with its program and requirements. Currently, sharps from small quantity generators may be sent through

the mail. This rulemaking will broaden the authorization to include other types of regulated medical waste, providing facilities more options for transporting their regulated medical waste to a processing or disposal site.

(11) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

The Department is not aware of any provisions in the final-form rulemaking that are more stringent than federal requirements.

(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?

The rulemaking reflects a global change in terminology from "infectious waste" to "regulated medical waste," which is consistent with how federal agencies identify this waste stream. By making the terminology consistent with federal requirements, containers used for collection, storage and transportation could be used, processed and reused without the need for any additional marking or labeling requirements. Additionally, the changes in the manifesting system should allow easier transport between states and decrease the amount of paperwork that generators and transporters would need to complete in order to comply with Pennsylvania's regulations. Rather than continuing to use a dedicated Department form and require that copies of that form accompany the waste shipment, the manifesting requirements can now be met with a generic shipping paper, log or electronic tracking system accompanying the waste stream, provided it includes all the required information.

(13) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

The rulemaking is not expected to affect any other regulations of the Department.

The Department of Corrections and health centers operated by the Department of Health will be regulated under this final-form rulemaking. The benefits of the rulemaking will be realized by these facilities in the same manner that they will be realized by all generators, processors and transporters of regulated medical and chemotherapeutic waste (see numbers 15, 17 & 18).

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)

In April of 2008, the Department conducted a Regulatory Review Meeting with representatives of the following groups: Stericycle, Inc., the nation's largest medical waste transportation and disposal company serving hospitals, dentist offices, long-term care facilities, medical laboratories, and physician's offices, including those that qualify as a small business; the American Red Cross; Thomas Jefferson University Hospital/Greater Philadelphia American Society Healthcare Environmental Services; Children's Hospital of Philadelphia; University of Pennsylvania Health System; University of Pennsylvania; Pugliese Associates; and Johnson & Johnson Pharmaceutical Research and Development.

In September of 2011, the Department's Solid Waste Advisory Committee (SWAC) considered the proposed amendments to these regulations and urged the Department to present them to the Environmental Quality Board for action.

In November of 2012, the Department presented this proposed rulemaking to the Department's Small Business Compliance Advisory Committee (SBCAC). The SBCAC is comprised of nine small business owners and other representatives from around the state, including the Department's Small Business Ombudsman. The committee voiced support for this rulemaking and wrote a letter of support, stating that these regulations will benefit small and rural health facilities by helping them to comply with regulatory requirements for management of regulated medical and chemotherapeutic waste.

The Department also contacted the Pennsylvania Medical Society, the Pennsylvania Dental Association, and the Pennsylvania Veterinary Medical Association regarding the proposed amendments. All were provided copies of the draft proposed rulemaking approved by the SWAC in 2011, as well as a summary of the proposed changes. The Department met with a representative of the Pennsylvania Medical Society on January 29, 2013, to discuss the regulatory changes proposed and additional opportunities for outreach to small businesses through the organization. In addition, the Department will continue to work with these organizations to provide outreach and support to doctors, dentists and veterinarians that will be subject to the final-form rulemaking.

Furthermore, the Department reached out randomly to a number of private medical facilities in an attempt to conduct the cost savings analysis for this regulation. These facilities include: Summit Health Chambersburg Hospital, Pinnacle Health Camp Hill Family Care, Phoenix Wellness Center, Mechanicsburg Family Dentistry, Cameron County Health Center, Cameron County Dental Center, Johnsonburg Dental Center, and Mountaintop Area Medical Center. All facilities expressed that the final-form rulemaking will benefit their operations. None of the facilities surveyed indicated that it would impact their regulated medical and chemotherapeutic waste disposal procedures negatively (see number 19).

The Department worked cooperatively with representatives of the impacted biologics facilities during the development of the final rulemaking and was able to incorporate revisions into the final rulemaking that satisfy the comments submitted on behalf of the biologics facilities while maintaining a high level of protection for public health and the environment.

On March 6, 2014, the SWAC reviewed the comments received on the proposed rulemaking, including the Department's proposed responses and possible revisions to the proposed regulations. SWAC provided constructive feedback on potential impacts the proposed amendments would have on municipal waste management facilities. The Department considered SWAC's concerns in developing the final rulemaking.

On June 5, 2014, SWAC discussed the final amendments. Although the SWAC did not have a quorum, of the eight members in attendance, all supported moving the rulemaking to the EQB for consideration and publication as final.

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

Types of facilities affected:

All generators, processors and transporters of regulated medical or chemotherapeutic waste currently regulated by the Department would be required to comply with the final-form rulemaking. Generators and processors of regulated medical and chemotherapeutic waste include providers of medical care, such as hospitals, physician offices, veterinary offices, home health care providers, nursing facilities, dentist offices, blood collection agencies, biologics facilities, laboratories, and research facilities.

The Department assumes that a portion of these affected facilities are small businesses, as defined in Section 3 of the Regulatory Review Act. This Act defines a small business in the medical industry based on the dollar amount of gross annual receipts generated by the business. This dollar amount is different for each type of facility. A facility that shows gross annual receipts less than the figures shown below is defined as a “small business” under the Regulatory Review Act.

- Hospital <\$34.5 million gross annual receipts
- Waste Collection <\$12.5 million
- Doctor’s Office <\$10 million
- Dentist Office <\$7 million
- Veterinary Office <\$7 million
- Nursing Home <\$13.5 million
- Medical Lab <\$13.5 million

Section 3 of the Regulatory Review Act defines a small business in the vaccine and biological manufacturing industry and the biotechnology research and development industry by the number of employees. A business that has fewer employees than the figures shown below is defined as a “small business” under the Regulatory Review Act.

- Biological Products Manufacturing <500 employees
- Research and Development in Biotechnology <500 employees

Number of facilities affected:

The Department estimates there are approximately 16,303 entities across Pennsylvania managing regulated medical and chemotherapeutic waste. These entities include generators, processors and transporters of regulated medical and chemotherapeutic waste. This estimation is based on the following data obtained from the Department’s Bureau of Waste Management and Bureau of Radiation Protection, the Pennsylvania Department of Health, the Pennsylvania Department of Corrections, and the U.S. Census Bureau. In parenthesis is the accompanying 2012 NAICS code, along with the amount of gross annual receipts to indicate the threshold for small business consideration, as provided in the Regulatory Review Act.

Generators (16,232 total facilities)

According to the Department of Health, currently in Pennsylvania there are:

- 190 hospitals (622110; less than \$35.5 million);
- 6,000 doctor’s offices with in-house laboratories (621111; less than \$10 million);
- 11 outpatient rehabilitation facilities (621498; less than \$19 million);
- 95 outpatient physical therapy facilities (621498; less than \$19 million);
- 64 rural health clinics (621111; less than \$10 million);
- 13 birth centers (621410; less than \$10 million);

- 5 pediatric extended care centers;
- 613 nursing home facilities (623110; less than \$25.5 million);
- 272 renal dialysis centers (621492; less than \$35.5 million);
- 188 intermediate care facilities;
- 106 psychiatric residential treatment facilities (622210; less than \$35.5 million); and
- 340 independent laboratories (621511; less than \$30 million).

The Department used data from the Bureau of Radiation Protection’s licensing of X-Ray machines to obtain information on the number of the following businesses currently operating in Pennsylvania:

- 5,715 dentist offices (621210; less than \$7 million);
- 556 podiatrist facilities (621391; less than \$7 million);
- 918 chiropractor offices (621310; less than \$7 million); and
- 867 veterinarian offices (541940; less than \$7 million).

According to the Department of Corrections, in Pennsylvania there are:

- 26 state correctional institutions;
- 14 community corrections centers; and
- 70 county prisons.

According to the U.S. Census Bureau, as of 2011 in Pennsylvania, there were:

- 23 biological products manufacturing facilities (325414; less than 500 employees); and
- 146 biotechnology research and development facilities (541711; less than 500 employees)

NAICS code 325414 is titled “Biological Products (except Diagnostic) Manufacturing.” All facilities utilizing this NAICS code are manufacturing facilities, including, but not limited to, manufacturers of agar culture media, allergens, allergenic extracts (except diagnostic substances), anti-venoms, vaccines, blood derivatives, and plasmas.

NAICS code 541711 is titled “Research and Development in Biotechnology.” All facilities utilizing this NAICS code are research facilities, including, but not limited to, biotechnology research and development laboratories; services in biology, botany, agriculture, bacteriology, environmental science, food science, genetics, industrial research, medical sciences, and veterinary sciences biotechnology research and development laboratories; protein engineering research and experimental development laboratories; and recombinant DNA research and experimental development laboratories.

Based on the NAICS descriptions for biologics and biotechnology facilities, it is likely that a significant portion of the facilities listed are not generating regulated medical waste. Therefore the number of facilities affected by the final-form rulemaking is less than the total number of facilities classified under the two NAICS codes. In addition, even though biotechnology-related research may be conducted at hospitals, the U.S. Census Bureau does not classify hospitals within NAICS Code 541711. Hospitals are classified under NAICS Code 622110 (General Medical and Surgical Hospitals).

Processors

Currently, there are 25 facilities operating under permits issued by the Department to process infectious and chemotherapeutic waste. Of those 25 facilities, 11 are operating under a general permit; 11 are operating under an individual permit; and 3 are operating under a permit-by-rule. However, the number of processors operating in Pennsylvania is difficult to estimate because the term “processors” by

definition includes waste transfer facilities; facilities engaged in the disinfection, incineration, shredding, and encapsulation of regulated medical and chemotherapeutic waste, including those facilities which may operate under the permit-by-rule provisions of the regulations; as well as some generators, such as hospitals, doctors' offices, dentists' offices, veterinary practices and other patient care facilities that are processing their own waste. Therefore, there is some overlap between the number of generators of infectious and chemotherapeutic waste and the number of processors of those wastes, since in some instances the generators and the processors are the same entity.

Transporters

Currently, there are 46 transporters of infectious and chemotherapeutic waste licensed by the Department. For solid waste collection (NAICS 562111) the maximum gross annual receipts allowable by definition for a small business is \$35.5 million.

Small Businesses:

Because the definition of a small business in the medical industry is based primarily on the gross annual receipts of the individual company, an exact number of small businesses affected by this regulation cannot be identified by the Department with any certainty. However, some assumptions and estimates can be made. The Department assumes that all 64 rural health facilities and most of the transporters qualify as small businesses. Of the other facilities, the Department assumes that a portion of each would qualify as a small business. Regardless of the amount shown in gross receipts each year, each facility will have more options for storage, transportation and disposal of their regulated medical and chemotherapeutic waste from this final-form rulemaking; thereby providing the regulated community with additional efficiencies that are not available under the existing regulations.

How they will be affected:

Terminology

By changing the terminology from "infectious waste" to "regulated medical waste," generators and transporters will no longer be required to have two labels on each waste container nor two signs on each truck in order to be compliant with both federal requirements and Pennsylvania requirements. This change in terminology will align Pennsylvania's regulations with federal requirements and reduce costs for this portion of the regulated community, particularly when waste is disposed of out-of-state.

Disposal and On-site Storage

Currently, generators of infectious and chemotherapeutic waste are required to seal and dispose of containers within 30 days of first placing waste in the container. Many generators have cited difficulty in keeping track of the date when waste was first placed in the container and have expressed frustration that they are required to dispose of and transport partially full bags and containers. This final-form rulemaking will allow generators to seal containers of regulated medical and chemotherapeutic waste when they are full and allow them to store the waste on-site for an additional 30 days after the container is full or sealed, whichever occurs first. This provision will reduce the costs borne by generators by eliminating the disposal of partially full containers.

Manifesting

The ability to use standard business documentation, including electronic tracking systems, to demonstrate compliance with the regulations will provide benefits to both generators and transporters of regulated medical and chemotherapeutic waste. Currently, a paper manifest is required to accompany the waste shipment to ensure that the waste is being disposed of in the manner intended by the generator. This is an

outdated method of waste tracking. This regulation will allow the generator and the transporter to utilize whichever system (shipping paper, log or electronic tracking) that works best for their needs.

Fuel Efficiency

Additionally, both generators and transporters of regulated medical and chemotherapeutic waste will benefit from the fuel efficiency achieved by being able to transport containerized regulated medical and chemotherapeutic waste along with other containerized waste in the same vehicle. Current regulations require infectious and chemotherapeutic waste to be transported in separate vehicles from municipal waste. This change will reduce the number of trips needed to transport waste from generators that have regulated medical and chemotherapeutic waste and other types of waste that require disposal, thus further reducing fuel costs.

Additional Options - Shipping

Currently, sharps from small quantity generators may be sent through the USPS's Medical Waste Program. This final-form rulemaking will allow generators to ship other types of regulated medical chemotherapeutic waste in any amount or volume through the USPS's Medical Waste Program, provided that certain conditions are satisfied, including mailing standards and other relevant USPS regulations. This provision is consistent with federal regulations and regulations of other states and will allow generators more options for disposing of their regulated medical waste.

Permits-by-rule for Processing Facilities

The final-form rulemaking will provide 7 permits-by-rule for qualifying processing facilities. Autoclaves, incinerators, and steam superheated water disinfection operators, along with regulated medical and chemotherapeutic waste aggregation facilities and certain transfer facilities, may qualify for permits-by-rule instead of having to obtain individual or general permits for processing. These permits-by-rule will allow facilities to operate under standard requirements contained in the regulations and will eliminate the need for these facilities to submit individual or general permit applications to the Department.

Biologics Facilities

The Department recognizes that improvements in practices and technologies employed in biologics facilities have increased the safety of vaccine viruses such that many vaccine agents that were once infectious have been attenuated to the point that they are no longer capable of being communicated by replication or invasion in healthy humans. The EPA, in its Medical Waste Tracking Act, has excluded from the definition of "cultures and stocks" those materials that do not pose an appreciable risk of causing disease, including materials classified as Biosafety Level 1 (BSL-1), citing the Centers for Disease Control's (CDC) *Biosafety in Microbial and Biomedical Laboratories* (BMBL), as guidance in determining what constitutes an "infectious agent." The CDC defines BSL-1 as "the basic level of protection and is appropriate for agents that are not known to cause disease in normal, healthy humans." An exception has been added to the definition of "infectious waste" for wastes generated by biologics facilities that have not come in contact with agents classified as BSL 2-4. Similar language has been included in the definition of "infectious agent," which excludes agents classified as BSL-1 by a biologics facility. This provides flexibility and cost savings for biologics facilities in managing their waste.

(16) List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.

See the “number of facilities affected” section in number (15) for a breakdown of the estimated 16,303 entities that will be affected by this final-form rulemaking. All generators, processors and transporters of regulated medical and chemotherapeutic waste will be required to comply with this rulemaking. These facilities are currently required to comply with the Department’s regulations relating to infectious and chemotherapeutic waste. The final-form rulemaking does not increase the number of entities that have to comply with the Department’s regulations.

(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

The Department expects the final-form rulemaking to reduce the costs borne by all generators, processors and transporters of regulated medical or chemotherapeutic waste by allowing transporters to haul regulated medical and chemotherapeutic waste with municipal wastes in the same vehicle and allowing facilities more time to completely fill containers prior to sending them for disposal. The rulemaking encourages labor and fuel efficiency and reduces costs associated with multiple pick-ups and transportation of partially full containers, as currently prescribed in the existing regulations.

Other than biologics facilities, the Department expects the largest financial and economic benefit of the rulemaking to be realized by small medical facilities located in rural areas. Currently, these businesses must pay for the transportation of regulated medical and chemotherapeutic wastes and municipal wastes separately, meaning that two trips are necessary to regularly haul the facilities’ wastes. In addition, small facilities must remove and dispose of containers of regulated medical and chemotherapeutic waste within 30 days of waste first being placed into the containers, resulting in many partially full containers being shipped for disposal. The rulemaking alleviates the requirement for wastes to be collected in two separate vehicles and allows businesses to completely fill containers of regulated medical and chemotherapeutic waste before they must be shipped off-site for disposal.

The final-form rulemaking allows generators, transporters and those involved in storage and processing of regulated medical and chemotherapeutic waste to use standard business documentation, including electronic tracking, to demonstrate compliance with the regulations instead of the currently prescribed and outdated method of a paper manifest. The rulemaking also provides an alternative transportation and disposal option for all medical facilities by allowing these facilities to ship waste through the mail where authorized by the USPS. The USPS allows small facilities to ship regulated medical waste based on need rather than on a prescribed regulatory frequency or schedule.

The rulemaking allows businesses to manage regulated medical and chemotherapeutic wastes more efficiently, while maintaining the equivalent level of protection to public safety and the environment that is currently realized under the existing regulations.

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

No adverse effects are expected from the final-form rulemaking, while the benefits are numerous.

The benefits of this regulation involve increased flexibility for generators, processors and transporters of regulated medical and chemotherapeutic waste. These regulations create consistency with U.S. Department of Transportation requirements by changing the term “infectious waste” to “regulated

medical waste.” The shift in terminology will simplify the labeling and signage requirements and reduce costs, in addition to ensuring consistency.

Generators will benefit from the flexibility of scheduling disposal of their medical waste as needed instead of on a prescribed disposal schedule. They will also be able to utilize shipping options through the USPS.

The final-form rulemaking encourages labor and fuel efficiency by allowing haulers to transport regulated medical and chemotherapeutic waste with municipal wastes in the same vehicle. Transporters will also benefit by eliminating unnecessary trips to rural parts of the state to pick up waste, as the final-form rulemaking will allow waste to be disposed of on an as-needed basis.

This final-form rulemaking will allow transporters of medical waste to use standard business documentation, including electronic tracking, to demonstrate compliance with regulations instead of the currently prescribed and outdated method of a paper manifest.

Qualifying processors will be able to utilize permits-by-rule instead of individual or general permits for their facilities.

(19) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

Generators

The realized savings for generators will depend on the amount of regulated medical and chemotherapeutic waste that a facility generates, the frequency with which the waste is disposed and the contracted costs associated with disposing the waste. This will vary from generator to generator.

The Department reached out to different types of facilities to gauge the cost savings that each could expect from the regulation.

- *Biologics facilities (NAICS 325414)*: The Department worked closely with Merck Sharp and Dohme Corporation (Merck) in response to the comments it provided on the proposed regulation. Merck expressed that the requirements in Pennsylvania were more stringent than in all the other states in which Merck has operations; this meant at least two main waste streams generated by their facility in Pennsylvania were still being handled as infectious waste, while in other states the same wastes could be managed in a less costly manner. For example, in one manufacturing process alone, Merck generates approximately 12,000 plastic bottles per week that were used to grow vaccine viruses; disposing of these bottles as infectious waste costs Merck over \$2 million a year. As a result, this put Merck at a financial disadvantage. The Department was able to accommodate the requests of Merck and made several changes to the proposed regulation to provide more flexibility not only to Merck, but to all biologics facilities doing business in Pennsylvania, thereby providing these facilities with a savings in management and disposal costs.
- *Medium-sized hospital*: In conversations with Summit Health Chambersburg Hospital, a medium-sized hospital, it indicated to the Department that infectious and chemotherapeutic waste is picked up four times a week. Stericycle, Inc. (the waste hauler used) charges \$35 per box,

whether it is full or not. Due to the volume of medical waste generated, a medium-sized hospital, such as Summit Health Chambersburg Hospital, is unable to waiver from this pickup schedule and therefore does not expect to see savings from the provisions included in the rulemaking.

- *Medium-sized physician's office:* Pinnacle Health Camp Hill Family Care indicated to the Department that, on average, two full boxes of infectious waste are transported for disposal every other week. Since its hauler charges a flat fee per box, and the facility generates enough waste that it does not dispose of partially full boxes, a medium-sized physician's office, such as Pinnacle Health Camp Hill Family Care, does not expect to see savings due to the provisions included in the rulemaking.
- *Small physician's office:* The Department spoke with Phoenix Wellness Center, a small physician's office, regarding management of its medical waste. This office has its transporter pick up infectious waste once a month, whether the box is full or not. Under the final-form rulemaking, it would be able to develop a schedule based on when its container is full, stretching out its pickup times and ensuring that all loads are full. If one box costs \$35 a month and they stretch the pickup to every 2 months, they could save \$210 a year ($\35×6 months of eliminated half full pickups).
- *Dentist's office:* Most dentist offices do not generate as much infectious waste as a doctor's office, but are still required to comply with the regulations regarding this waste stream. According to Mechanicsburg Family Dentistry, who serves a large clientele, it has infectious waste picked up every four weeks. Sometimes the boxes are not completely full. Smaller generators, like dentists, will benefit from the provisions which allow generators to wait until the container is full before being required to seal and dispose of it. They will also have another option to mail it through the USPS Medical Waste Program as needed, instead of having a dedicated pickup schedule.
- *Rural Dentist Facility:* Cameron County Dental Center and Johnsonburg Dental Center, small dentist offices in rural areas, indicated to the Department that they have their infectious waste picked up every two months and pay \$86.53 per pickup. These offices each spend \$519.18 per year ($\86.53×6 pickups) for infectious waste disposal. Under final-form rulemaking, each office could reduce its pickup schedule to every 6 months or longer, resulting in a savings of at least \$346.12 each year. Both offices also expressed interest in utilizing the USPS Medical Waste Program for transportation to a processing or disposal site on an as-needed basis.
- *Rural Health Facility:* The Mountaintop Area Medical Center and Cameron County Health Center both spoke with the Department regarding the management of their infectious waste. Both stated that infectious waste is picked up every two months, regardless of whether the box is full. Pickup is offered once per month; however, the facilities do not generate enough infectious waste for a monthly schedule. The facilities each spend \$86.53 per box, significantly more than other urban or suburban facilities. Rural facilities are expected to be some of the biggest beneficiaries of this regulation, based on their size (less regulated medical waste generated) and location (farther to drive for pickups). Through this rulemaking, they will have the additional option of shipping regulated medical waste through the USPS Medical Waste Program as needed, instead of having a dedicated pickup schedule.

Cost savings analysis per generator type:

- *Biologics facilities (NAICS 325414)* : Merck indicated in its comments to the Department that disposal of the approximately 12,000 plastic bottles generated in one of their manufacturing processes costs over \$2 million per year; under the final-form rulemaking, this yearly cost would be greatly decreased, as these bottles will be able to be disposed in a less expensive manner. Combined with the savings that would also be realized for other waste streams generated at biologics facilities, the potential cost savings could exceed \$2 million per year.

Using the above assumptions, biologics facilities would collectively save
($\$2 \text{ million}$) x (23 facilities) = $\$46,000,000$ per year.

- *Large and medium-sized hospital*: No additional costs, but no savings.
- *Medium-sized physician's office*: No additional costs, but no savings.
- *Small physician's office*: According to the above, a small physician's office will potentially save \$210 per year. Based on estimates of the number of health facilities affected by the regulations (see number 15 for a breakdown of affected facilities), for this cost-savings analysis, the Department assumed that a total of 3,841 facilities would generate a similar amount of waste as the small physician's office identified above, and therefore, these facilities would realize similar cost-savings. The Department conservatively estimated that one-quarter of all physicians' offices would be considered small. (1,500 of the 6,000 doctors' offices with in-house laboratories (1/4 of all doctors' offices); all 556 podiatrist facilities; all 918 chiropractic facilities; and all 867 veterinary facilities).

Using the above assumptions, small physicians' offices would collectively save
($\$210$) x (3,841 facilities) = $\$806,610$ per year.

- *Dentist's office*: According to the outreach conducted and described above, the Department conservatively estimated that 75% of all dentists' offices would generate a similar amount of waste as the small physicians' offices. Therefore, of the 5,715 dentists' offices currently operating in Pennsylvania (given in number 15), 4,286 offices are assumed to generate a quantity of medical waste similar to that generated by a small physician's office for the purpose of this cost analysis.

Using the above assumptions, these dentists' offices would collectively save
($\$210$) x (4,286 facilities) = $\$900,060$ per year.

- *Rural Dentist's offices*: The Department conservatively estimated that 25% of all dentists' offices are rural dentist facilities. Therefore, of the 5,715 dentists' offices currently operating in Pennsylvania (given in number 15), 1,429 offices are assumed to generate a quantity of medical waste similar to that generated by a rural dentist facility for the purpose of this cost analysis.

Using the above assumptions, these dentists' offices would collectively save
($\$346.12$) x (1,429 facilities) = $\$494,605.48$ per year.

- *Rural Health Facilities:* According to the above, a rural health facility will potentially save \$346.12 per year. Based on estimates of the number of rural health clinics affected by the regulation (see number 15 for a breakdown of affected facilities), for this cost-savings analysis, the Department assumed that all 64 rural health clinics would realize the cost savings identified above for rural health facilities.

Using the above assumptions, rural health facilities would collectively save
 $(\$346.12) \times (64 \text{ facilities}) = \$22,151.68$ per year.

Therefore, the total estimated annual savings for generators is approximately
 $(\$46,000,000) + (\$806,610) + (\$900,060) + (\$494,605.48) + (\$22,151.68) = \$48,223,427.16$.

Transporters

Currently, a generator must have a separate pick up of their infectious and chemotherapeutic waste at least every 30 days. Most transporters charge a flat fee based on number of boxes or weight of infectious and chemotherapeutic waste, not based on the number of times they visit a facility. Transporters will benefit from being able to make fewer trips, by picking up more waste on each trip. They will also benefit from being able to transport regulated medical and chemotherapeutic waste in the same vehicle as other wastes generated from the same facility.

According to Stericycle, Inc., increases in generator storage time will save an average of two unnecessary trips per transporter per week. That is approximately 100 trips per transporter per year.

$(100 \text{ trips}) \times (46 \text{ transporters}) = 4,600$ unnecessary trips eliminated.

According to information obtained from transporters, a typical trip consists of 50 miles.

The average total transport cost (including labor) is approximately \$80 per hour to operate a standard box truck. An average speed of 35 mph is used, resulting in a cost of approximately \$2.30/mile.

The average total transport cost (including labor) for tractor/trailer shipments is \$95.00 per hour. An average speed of 55 mph is used, resulting in a cost of approximately \$1.75/mile.

Therefore, the average transportation cost is approximately \$2 per mile.

Using the above assumptions, transporters would save $(\$2) \times (50 \text{ miles}) \times (4600 \text{ trips}) = \$460,000$ per year.

When added to the estimated annual savings for generators, the total estimated annual savings for generators and transporters is $(\$460,000) + (\$48,223,427.16) = \$48,683,427.16$

Signs on transportation vehicles would need to be replaced within two years of the regulation taking effect. Most transporters have adequate signage already, as it is required in most of the surrounding states.

Assuming half of the transporters will need the signage update, and the cost is \$500 to replace or add required signs, the regulated community will spend:

$(1/2) \times (46 \text{ transporters}) \times (\$500) = \$11,500.$

See number (23) for a breakdown of the projected yearly savings versus costs of the final-form rulemaking.

(20) Provide a specific estimate of the costs and/or savings to the **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

Local government facilities, such as health centers and county prisons, are generators of medical waste, and therefore, said facilities will be subject to the final-form rulemaking. The savings realized for generators will depend on the amount of regulated medical and chemotherapeutic waste that a facility generates, the frequency with which the waste is disposed and the contracted costs associated with disposing the waste (see number 19).

These facilities will no longer need to use labels that satisfy differing federal regulations. Allowing haulers to transport regulated medical and chemotherapeutic waste with municipal wastes in the same vehicle and allowing facilities more time to completely fill containers and vehicles before it must be placed into service will reduce the overall costs of transportation and disposal. The final-form rulemaking encourages aggregation and consolidation of waste; encourages labor and fuel efficiency; reduces costs associated with multiple pick-ups and transportation of partially full containers, as currently prescribed in the existing regulations; and allows the utilization of standard business documentation, such as electronic tracking, to show compliance with the regulations, instead of the outdated method of paper manifests.

The rulemaking is not expected to impose any additional regulatory costs on local governments.

(21) Provide a specific estimate of the costs and/or savings to the **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

State government facilities, such as state-supported hospitals, local Department of Health facilities and the Department of Correction's state correctional facilities are generators of medical waste, and therefore, those facilities will be subject to the final-form rulemaking. The savings realized for generators will depend on the amount of regulated medical and chemotherapeutic waste that a facility generates the frequency with which the waste is disposed and the contracted costs associated with disposing the waste (see number 19).

These facilities will no longer need to use labels that satisfy differing federal regulations. Allowing haulers to transport regulated medical and chemotherapeutic waste with municipal wastes in the same vehicle and allowing facilities more time to completely fill containers and vehicles before it must be placed into service, will reduce the overall costs of transportation and disposal. The final-form rulemaking encourages aggregation and consolidation of waste; encourages labor and fuel efficiency; reduces costs associated with multiple pick-ups and transportation of partially full containers, as currently prescribed in the existing regulations; and allows the utilization of standard business documentation, such as electronic tracking, to show compliance with the regulations, instead of the outdated method of paper manifests.

The rulemaking is not expected to impose any additional direct regulatory costs on state governments, except those nominal costs the Commonwealth will incur to provide training, outreach and technical assistance to the regulated community. It is not anticipated that any new staffing resources will be necessary.

(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

No additional legal, accounting or consulting procedures, nor additional reporting, recordkeeping or other paperwork are required for implementation of the regulation for the regulated community.

The final-form rulemaking allows generators and businesses involved in the transportation, storage and processing of regulated medical and chemotherapeutic waste to use standard business documentation, including electronic tracking, to demonstrate compliance with the regulations instead of the currently prescribed and outdated method of a paper manifest. The use of alternative documentation provides the Department with the same information contained in a paper manifest, while reducing the amount of paperwork required of regulated entities.

Paperwork will be reduced by the creation of permits-by-rule for qualifying facilities in the final-form rulemaking. The permits-by-rule will eliminate the need to issue individual or general permits to those facilities, reducing reporting, record keeping and paperwork submissions to the Department for those qualifying facilities, while reducing the amount of paperwork managed by the Department in authorizing the operation of facilities permitted-by-rule.

(23) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

The dollar amounts below are taken from number (19) above and rounded to whole dollar amounts. See number (19) above for a breakdown of the estimated costs and annual savings associated with the proposed rulemaking.

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	\$ 48.2 million	\$ 48.2 million	\$ 48.2 million	\$ 48.2 million	\$ 48.2 million	\$ 48.2 million
Regulated Community	\$ 48.2 million	\$ 48.2 million	\$ 48.2 million	\$ 48.2 million	\$ 48.2 million	\$ 48.2 million
Local Government						
State Government						
Total Savings	\$ 48.2 million	\$ 48.2 million	\$ 48.2 million	\$ 48.2 million	\$ 48.2 million	\$ 48.2 million
COSTS:						
Regulated Community	\$ 11,500	0	0	0	0	0

Local Government	0	0	0	0	0	0
State Government	0	0	0	0	0	0
Total Costs	\$ 11,500	0	0	0	0	0
REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses						

(23a) Provide the past three year expenditure history for programs affected by the regulation.

Program	FY -3	FY -2	FY -1	Current FY
Environmental Program Management (#161-10382)	\$28,881,000	\$27,755,000	\$24,965,000	\$26,297,000
Environmental Protection Operations (#160-10381)	\$78,021,000	\$77,359,000	\$74,547,000	\$76,221,000

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

- (a) An identification and estimate of the number of small businesses subject to the regulation.
- (b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.
- (c) A statement of probable effect on impacted small businesses.
- (d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

The Department does not believe that this rulemaking will have any adverse impact on small businesses.

(25) List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.

There are no special provisions in the final-form rulemaking for any specific social or economic sectors. The largest financial and economic benefit of the rulemaking is expected to be realized by the small

medical facilities located in rural areas. Currently, these businesses must pay for the collection and transportation of regulated medical/chemotherapeutic wastes and municipal wastes separately, meaning that two trips are necessary to regularly haul the facilities' wastes. In addition, small facilities must remove and dispose of containers of regulated medical and chemotherapeutic waste within 30 days of wastes first being placed into the containers, resulting in many partially full containers being shipped for disposal. The final-form rulemaking allows businesses to completely fill containers of regulated medical and chemotherapeutic waste before they must be shipped off-site for disposal and alleviates the requirement for wastes to be collected in two separate vehicles. As a result, the final-form rulemaking will make compliance easier for these small facilities without reducing the level of protection to public health and the environment. All regulated facilities will be able to use the USPS program to ship regulated medical waste for disposal. That program provides an on-demand or as-needed approach for shipping regulated medical waste rather than a prescribed schedule.

(26) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

No program alternatives were considered.

(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

- a) The establishment of less stringent compliance or reporting requirements for small businesses;

This final-form rulemaking will affect all generators, processors and transporters of regulated medical and chemotherapeutic waste, including small businesses. These regulations will allow all generators to store regulated medical and chemotherapeutic waste on-site for longer periods of time. They will be able to ship regulated medical and chemotherapeutic waste when their containers are full, instead of in accordance with a prescribed schedule. This will result in fewer pick-ups of partially full containers. These regulations provide permits-by-rule for processors and extend the amount of time processors can hold regulated medical and chemotherapeutic waste prior to processing. Generators and transporters will also be able to utilize standard business documentation, including electronic tracking or shipping logs, to demonstrate compliance with the regulations, instead of the currently prescribed, but outdated method of a paper manifest.

- b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;

There are no schedules or deadlines for compliance or reporting requirements except for all regulated facilities will be required to comply with the regulations, if approved.

- c) The consolidation or simplification of compliance or reporting requirements for small businesses;

Compliance and reporting requirements were simplified for businesses that qualify for permits-by-rule including those considered small businesses. The final-form rulemaking allows these facilities to operate under a standard set of regulatory requirements that eliminate the need of a facility to apply for an individual or general permit. Regulatory compliance is further simplified in the rulemaking by allowing

generators and transporters to utilize standard business documentation, including electronic tracking or shipping logs, to track their waste disposal, instead of the currently prescribed, but outdated method of a paper manifest.

- d) The establishment of performing standards for small businesses to replace design or operational standards required in the regulation; and

The final-form rulemaking provides 7 permits-by-rule for qualifying facilities, which allow these facilities to operate under a standard set of requirements without reducing the level of protection for public health or the environment.

- e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

Small businesses are not exempted from any of the requirements of this regulation. All businesses are given additional options for the transportation to a processing or disposal site of regulated medical and chemotherapeutic waste, such as utilizing the USPS Medical Waste Program.

(28) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

The following article recommends the renaming of *Bacillus stearothermophilus* to *Geobacillus stearothermophilus*:

International Journal of Systematic and Evolutionary Microbiology, Vol 51, 433-446, Copyright © 2001

- A copy of the article is attached to this form. (Attachment 1)

The following article recommends the reclassification of bioindicator strains *Bacillus subtilis* DSM 675 and *Bacillus subtilis* DSM 2277 as *Bacillus atrophaeus*:

International Journal of Systematic and Evolutionary Microbiology *January 2001 51:35-7*

- A copy of the article is attached to this form. (Attachment 2)

The following link will redirect you to a publication by the United Nations, regarding health care waste, which recommends using mycobacteria only as an indicator of disinfection. According to the publication, Mycobacteria are the toughest to neutralize and therefore the best indicator:

<http://gefmedwaste.org/downloads/Guidance%20on%20Microbiological%20Challenge%20Testing%20for%20Medical%20Waste%20Autoclaves-%20November%202010.pdf>

- A copy of the publication is attached to this form. (Attachment 3)

The following link will redirect you to a fact sheet regarding steam autoclaves, written by the EPA. The fact sheet provides guidelines for bacterial reductions and temperature requirements:

<http://www.epa.gov/osw/nonhaz/industrial/medical/mwpdfs/alt/autoclav.pdf>

- A copy of the fact sheet is attached to this form. (Attachment 4)

(29) Include a schedule for review of the regulation including:

- | | |
|---|--------------------|
| A. The date by which the agency must receive public comments: | <u>Summer 2013</u> |
| B. The date or dates on which public meetings or hearings will be held: | <u>N/A</u> |
| C. The expected date of promulgation of the proposed regulation as a final-form regulation: | <u>Spring 2014</u> |
| D. The expected effective date of the final-form regulation: | <u>Fall 2014</u> |
| E. The date by which compliance with the final-form regulation will be required: | <u>Fall 2014</u> |
| F. The date by which required permits, licenses or other approvals must be obtained: | <u>N/A</u> |

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

This regulation will be reviewed in accordance with the sunset review schedule published by the Department to determine whether the regulation effectively fulfills the goals for which it was intended.