2020 -- H 7840

========
LC004806
========

S T A T E O F R H O D E I S L A N D

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2020

A N A C T

RELATING TO INSURANCE -- ACCIDENT AND SICKNESS INSURANCE POLICIES

Introduced By: Representative Julie A. Casimiro

Date Introduced: February 26, 2020

Referred To: House Health, Education & Welfare

It is enacted by the General Assembly as follows:

SECTION 1. Purpose and legislative findings.

(a) Purpose. It is the policy of the state of Rhode Island not to permit introduction of pollutants into the ground waters and water systems of the state or otherwise to be discharged in concentrations which are known to be toxic, carcinogenic, mutagenic, or teratogenic as the same are defined in the Rhode Island department of environmental management groundwater quality rules and the rules and regulations for hazardous waste management. More specifically, the Rhode Island department of environmental management, in regulation #DEM OWM-HW 01-14, most recent revision dated January 7, 2014, defines certain antineoplastic or cytotoxic chemotherapy agents and drugs as "Extremely Hazardous Waste."

(b) Findings.

(1) The Drug Quality and Security Act (H.R. 3204) is a new federal law that amended the Federal Food, Drug, and Cosmetic Act to grant the Food and Drug Administration more authority to regulate and monitor the manufacturing and handling of compounded drugs. This bill was written in response to the New England Compounding Center meningitis outbreak that took place in 2012, which killed sixty-four (64) people. The bill was signed into law by President Obama on November 27, 2013.

(2) This act mandated that the FDA order the United States Pharmacopeia (USP) to set standards for compounding drugs. USP 800 was published in 2017 and took effect December 1, 2019. These standards require the control of certain cytotoxic chemotherapy drugs from the time

they arrive at the pharmacy, all the way through excretion of the drugs by the patient.

(3) This mandate puts an enormous financial burden on the Rhode Island hospital system, insurance companies, Medicaid and the people of Rhode Island. This cost should be carried by the producers of therapies that are used in combination with cytotoxic drugs as well as the producers of cytotoxic drugs

(4) This federal mandate requires that the waste follow all federal, state, and local regulations including #DEM OWM-HW 01-14 which defines "Extremely Hazardous Waste."

(5) It is acknowledged by medical experts that bodily wastes of patients undergoing chemotherapy treatment may contain levels of chemicals that are toxic, carcinogenic, mutagenic or teratogenic for a certain period of time, to such an extent that the World Health Organization defines genotoxic waste as chemotherapy drug waste including urine, feces and vomit from patients, which may contain potentially hazardous amounts of the administered cytostatic drugs or of their metabolites, and which should be considered genotoxic for at least forty-eight (48) hours and sometimes up to one week after drug administration. According to the World Health Organization, ten percent (10 %) of known carcinogens are chemicals used to cure cancer.

(6) While, according to the American Society of Clinical Oncology, the cost of one additional cancer patient resulting from the exposure to these harmful chemicals is approximately one hundred seventy thousand dollars ($170,000) per treatment year, the cost of the implementation of cytotoxic chemical safety protocols is estimated to be less than two percent (2%) of that cost.

(7) The World Health Organization further states that any discharge of genotoxic waste into the environment could have disastrous ecological consequences. The World Health Organization places the responsibility for genotoxic waste on the chief pharmacist and further states that the chief pharmacist also has the special responsibility of ensuring that genotoxic products are used safely, and that genotoxic waste is managed safely.

(8) The European Commission, Executive Agency for Health and Consumers undertook a comprehensive "Study on the environmental risks of medicinal products" which was released in June of 2014, drafted by BIO Intelligence Service, a division of Deloitte Consulting LLP, reviewing the prevalence of contaminants in drinking water and noting the extreme dangers arising from improper disposal of cytotoxic chemotherapy drugs.

(9) Dr. Christian G. Daughton, former chief of environmental chemistry for the United States Environmental Protection Agency, notes in a paper entitled "Eco-directed sustainable prescribing: feasibility for reducing water contamination by drugs" published in the journal "Science of the Total Environment" on June 3, 2014, that generally, the best practice for lowering the level of drugs in our environment is reduction of dosages, but that "[c]ertain drug classes

(especially cytotoxic chemotherapeutics) may not be amenable to this approach; the best control measure for such highly toxic drugs may simply be the prevention of urine and feces from entering sewers."

(10) The federal Occupational Safety and Health Administration ("OSHA") is the main federal agency charged with the enforcement of safety and health legislation. OSHA, in concert with the National Institute for Occupational Safety and Health ("NIOSH") and the Joint Commission on Healthcare, an independent, not-for-profit organization that accredits and certifies more than twenty thousand (20,000) health care organizations and programs in the United States, stated in a 2011 letter to every hospital in the country that "[e]very day in healthcare settings across America, workers are exposed to hundreds of powerful drugs used for cancer chemotherapy, antiviral treatments, hormone regimens and other therapies. While these drugs are used to relieve and heal patients, many of them present serious hazards to the health and safety of your workers. Some of these drugs have been known to cause cancer, reproductive and developmental problems, allergic reactions, and other adverse effects that can be irreversible even after low-level exposures."

(11) Further, because of the risk of ongoing exposure to these extremely hazardous excreted drugs, the American Cancer Society has published a comprehensive list of safety precautions regarding the in-home personal hygiene for individuals undergoing chemotherapy and their families.

(12) Therefore, for the protection of both the public health and the environment, the general assembly shall require that standards are set forth pursuant to these sections to address this serious health and safety issue.

SECTION 2. Chapter 27-18 of the General Laws entitled "Individual Health Insurance Coverage" is hereby amended by adding thereto the following section:

27-18-85. Cancer patient safety and environmental protection.

(a) Chemotherapy precautions following treatment. All physicians, pharmacists, or other health care professionals licensed in the state of Rhode Island authorized to prescribe and/or administer chemotherapy treatment shall:

(1) Provide written notice from the prescribing pharmacist to each patient undergoing such treatment as to the hazards posed to patients and their families of extremely hazardous excretions, including, but not limited to, urine, vomit, and feces, for a period following treatment as generally determined by the food and drug administration label accompanying said chemotherapy drug or drugs. To the extent such notices are generally consistent with those now provided for patients undergoing treatment with radioactive drugs, or consistent with the recommendations of the World Health Organization with regard to cytotoxic drugs, or otherwise consistent with similar standards

that may be approved by the department of environmental management in the context of a product stewardship plan adopted pursuant to chapter 19.16 of title 23, then the prescribing pharmacist will not be held liable for the form of such notice;

(2) Participate in an approved product stewardship program for the collection, safe and proper disposal of extremely hazardous wastes, including cytotoxic drugs and related byproducts and wastes adopted pursuant to chapter 19.16 of title 23 in order that providers and patients can safely collect and contain extremely hazardous excretions for a period of time as determined by the United States Food and Drug Administration ("FDA") and referenced on the relevant FDA prescription insert(s).

(b) Cytotoxic drug producers shall provide for the costs of managing and safely disposing of the health care waste identified in this section in accordance with chapter 19.16 of title 23.

(c) Receipt of notice from the party administering chemotherapy drugs or their agent responsible for proper disposal of the hazardous wastes by the prescribing pharmacist or chief pharmacist that the wastes have been disposed of in accordance with a product stewardship plan shall satisfy the responsibility of the prescribing pharmacist hereunder.

(d) For the purposes of this section, extremely hazardous excretions shall mean any excretion from a patient on a regimen of chemotherapy agents that are antineoplastic or cytotoxic, and which may be excreted during the period of administration or the time period referenced in subsection (c)(2) of this section, including, but not limited to, drugs listed in the NIOSH list of antineoplastic and other hazardous drugs, as the same may be updated or amended from time to time.

SECTION 3. Chapter 27-18.5 of the General Laws entitled "Nonprofit Hospital Service Corporations" is hereby amended by adding thereto the following section:

27-18.5-11. Cancer patient safety and environmental protection.

(a) Chemotherapy precautions following treatment. All physicians, pharmacists, or other health care professionals licensed in the state of Rhode Island authorized to prescribe and/or administer chemotherapy treatment shall:

(1) Provide written notice from the prescribing pharmacist to each patient undergoing such treatment as to the hazards posed to patients and their families of extremely hazardous excretions, including, but not limited to, urine, vomit, and feces, for a period following treatment as generally determined by the food and drug administration label accompanying said chemotherapy drug or drugs. To the extent such notices are generally consistent with those now provided for patients undergoing treatment with radioactive drugs, or consistent with the recommendations of the World Health Organization with regard to cytotoxic drugs, or otherwise consistent with similar standards

that may be approved by the department of environmental management in the context of a product stewardship plan adopted pursuant to chapter 19.16 of title 23, then the prescribing pharmacist will not be held liable for the form of such notice;

(2) Participate in an approved product stewardship program for the collection, safe and proper disposal of extremely hazardous wastes, including cytotoxic drugs and related byproducts and wastes adopted pursuant to chapter 19.16 of title 23 in order that providers and patients can safely collect and contain extremely hazardous excretions for a period of time as determined by the United States Food and Drug Administration ("FDA") and referenced on the relevant FDA prescription insert(s).

(b) Cytotoxic drug producers shall provide for the costs of managing and safely disposing of the health care waste identified in this section in accordance with chapter 19.16 of title 23.

(c) Receipt of notice from the party administering chemotherapy drugs or their agent responsible for proper disposal of the hazardous wastes by the prescribing pharmacist or chief pharmacist that the wastes have been disposed of in accordance with a product stewardship plan shall satisfy the responsibility of the prescribing pharmacist hereunder.

(d) For the purposes of this section, extremely hazardous excretions shall mean any excretion from a patient on a regimen of chemotherapy agents that are antineoplastic or cytotoxic, and which may be excreted during the period of administration or the time period referenced in subsection (c)(2) of this section, including, but not limited to, drugs listed in the NIOSH list of antineoplastic and other hazardous drugs, as the same may be updated or amended from time to time.

SECTION 4. Chapter 27-19 of the General Laws entitled "Nonprofit Medical Service Corporations" is hereby amended by adding thereto the following section:

27-19-77. Cancer patient safety and environmental protection.

(a) Chemotherapy precautions following treatment. All physicians, pharmacists, or other health care professionals licensed in the state of Rhode Island authorized to prescribe and/or administer chemotherapy treatment shall:

(1) Provide written notice from the prescribing pharmacist to each patient undergoing such treatment as to the hazards posed to patients and their families of extremely hazardous excretions, including, but not limited to, urine, vomit, and feces, for a period following treatment as generally determined by the food and drug administration label accompanying said chemotherapy drug or drugs. To the extent such notices are generally consistent with those now provided for patients undergoing treatment with radioactive drugs, or consistent with the recommendations of the World Health Organization with regard to cytotoxic drugs, or otherwise consistent with similar standards

that may be approved by the department of environmental management in the context of a product stewardship plan adopted pursuant to chapter 19.16 of title 23, then the prescribing pharmacist will not be held liable for the form of such notice;

(2) Participate in an approved product stewardship program for the collection, safe and proper disposal of extremely hazardous wastes, including cytotoxic drugs and related byproducts and wastes adopted pursuant to chapter 19.16 of title 23 in order that providers and patients can safely collect and contain extremely hazardous excretions for a period of time as determined by the United States Food and Drug Administration ("FDA") and referenced on the relevant FDA prescription insert(s).

(b) Cytotoxic drug producers shall provide for the costs of managing and safely disposing of the health care waste identified in this section in accordance with chapter 19.16 of title 23.

(c) Receipt of notice from the party administering chemotherapy drugs or their agent responsible for proper disposal of the hazardous wastes by the prescribing pharmacist or chief pharmacist that the wastes have been disposed of in accordance with a product stewardship plan shall satisfy the responsibility of the prescribing pharmacist hereunder.

(d) For the purposes of this section, extremely hazardous excretions shall mean any excretion from a patient on a regimen of chemotherapy agents that are antineoplastic or cytotoxic, and which may be excreted during the period of administration or the time period referenced in subsection (c)(2) of this section, including, but not limited to, drugs listed in the NIOSH list of antineoplastic and other hazardous drugs, as the same may be updated or amended from time to time.

SECTION 5. Chapter 27-20 of the General Laws entitled "Health Maintenance Organizations" is hereby amended by adding thereto the following section:

27-20-73. Cancer patient safety and environmental protection.

(a) Chemotherapy precautions following treatment. All physicians, pharmacists, or other health care professionals licensed in the state of Rhode Island authorized to prescribe and/or administer chemotherapy treatment shall:

(1) Provide written notice from the prescribing pharmacist to each patient undergoing such treatment as to the hazards posed to patients and their families of extremely hazardous excretions, including, but not limited to, urine, vomit, and feces, for a period following treatment as generally determined by the food and drug administration label accompanying said chemotherapy drug or drugs. To the extent such notices are generally consistent with those now provided for patients undergoing treatment with radioactive drugs, or consistent with the recommendations of the World Health Organization with regard to cytotoxic drugs, or otherwise consistent with similar standards

that may be approved by the department of environmental management in the context of a product stewardship plan adopted pursuant to chapter 19.16 of title 23, then the prescribing pharmacist will not be held liable for the form of such notice;

(2) Participate in an approved product stewardship program for the collection, safe and proper disposal of extremely hazardous wastes, including cytotoxic drugs and related byproducts and wastes adopted pursuant to chapter 19.16 of title 23 in order that providers and patients can safely collect and contain extremely hazardous excretions for a period of time as determined by the United States Food and Drug Administration ("FDA") and referenced on the relevant FDA prescription insert(s).

(b) Cytotoxic drug producers shall provide for the costs of managing and safely disposing of the health care waste identified in this section in accordance with chapter 19.16 of title 23.

(c) Receipt of notice from the party administering chemotherapy drugs or their agent responsible for proper disposal of the hazardous wastes by the prescribing pharmacist or chief pharmacist that the wastes have been disposed of in accordance with a product stewardship plan shall satisfy the responsibility of the prescribing pharmacist hereunder.

(d) For the purposes of this section, extremely hazardous excretions shall mean any excretion from a patient on a regimen of chemotherapy agents that are antineoplastic or cytotoxic, and which may be excreted during the period of administration or the time period referenced in subsection (c)(2) of this section, including, but not limited to, drugs listed in the NIOSH list of antineoplastic and other hazardous drugs, as the same may be updated or amended from time to time.

SECTION 6. Chapter 27-41 of the General Laws entitled "Health Maintenance Organizations" is hereby amended by adding thereto the following section:

27-41-90. Cancer patient safety and environmental protection.

(a) Chemotherapy precautions following treatment. All physicians, pharmacists, or other health care professionals licensed in the state of Rhode Island authorized to prescribe and/or administer chemotherapy treatment shall:

(1) Provide written notice from the prescribing pharmacist to each patient undergoing such treatment as to the hazards posed to patients and their families of extremely hazardous excretions, including, but not limited to, urine, vomit, and feces, for a period following treatment as generally determined by the food and drug administration label accompanying said chemotherapy drug or drugs. To the extent such notices are generally consistent with those now provided for patients undergoing treatment with radioactive drugs, or consistent with the recommendations of the World Health Organization with regard to cytotoxic drugs, or otherwise consistent with similar standards

that may be approved by the department of environmental management in the context of a product stewardship plan adopted pursuant to chapter 19.16 of title 23, then the prescribing pharmacist will not be held liable for the form of such notice;

(2) Participate in an approved product stewardship program for the collection, safe and proper disposal of extremely hazardous wastes, including cytotoxic drugs and related byproducts and wastes adopted pursuant to chapter 19.16 of title 23 in order that providers and patients can safely collect and contain extremely hazardous excretions for a period of time as determined by the United States Food and Drug Administration ("FDA") and referenced on the relevant FDA prescription insert(s).

(b) Cytotoxic drug producers shall provide for the costs of managing and safely disposing of the health care waste identified in this section in accordance with chapter 19.16 of title 23.

(c) Receipt of notice from the party administering chemotherapy drugs or their agent responsible for proper disposal of the hazardous wastes by the prescribing pharmacist or chief pharmacist that the wastes have been disposed of in accordance with a product stewardship plan shall satisfy the responsibility of the prescribing pharmacist hereunder.

(d) For the purposes of this section, extremely hazardous excretions shall mean any excretion from a patient on a regimen of chemotherapy agents that are antineoplastic or cytotoxic, and which may be excreted during the period of administration or the time period referenced in subsection (c)(2) of this section, including, but not limited to, drugs listed in the NIOSH list of antineoplastic and other hazardous drugs, as the same may be updated or amended from time to time.

SECTION 7. Title 23 of the General Laws entitled "HEALTH AND SAFETY" is hereby amended by adding thereto the following chapter:

Declaration of findings.

(1) It is acknowledged by medical experts that bodily wastes of patients undergoing chemotherapy treatment may contain levels of chemicals that are toxic, carcinogenic, mutagenic or teratogenic for a certain period of time, to such an extent that The World Health Organization defines genotoxic waste as chemotherapy drug waste including urine, feces and vomit from patients, which may contain potentially hazardous amounts of the administered cytostatic drugs or of their metabolites, and which should be considered genotoxic for at least forty-eight (48) hours and sometimes up to one week after drug administration. According to the World Health Organization ten percent (10 %) of known carcinogens are chemicals used to cure cancer.

(2) While, according to the American Society of Clinical Oncology, the cost of one additional cancer patient resulting from the exposure to these harmful chemicals is approximately

one hundred seventy thousand dollars ($170,000) per treatment year, the cost of the implementation of cytotoxic chemical safety protocols is estimated to be less than two percent (2%) of that cost.

(3) The World Health Organization further states that any discharge of genotoxic waste into the environment could have disastrous ecological consequences. The World Health Organization places the responsibility for genotoxic waste on the chief pharmacist and further states that the chief pharmacist also has the special responsibility of ensuring that genotoxic products are used safely, and that genotoxic waste is managed safely.

(4) The European Commission, Executive Agency for Health and Consumers undertook a comprehensive "Study on the environmental risks of medicinal products" which was released in June of 2014, drafted by BIO Intelligence Service, a division of Deloitte Consulting LLP, reviewing the prevalence of contaminants in drinking water and noting the extreme dangers arising from improper disposal of cytotoxic chemotherapy drugs.

(5) Dr. Christian G. Daughton, former chief of environmental chemistry for the United States Environmental Protection Agency, notes in a paper entitled "Eco-directed sustainable prescribing: feasibility for reducing water contamination by drugs" published in the journal "Science of the Total Environment" on June 3, 2014, that generally, the best practice for lowering the level of drugs in our environment is reduction of dosages, but that "[c]ertain drug classes (especially cytotoxic chemotherapeutics) may not be amenable to this approach; the best control measure for such highly toxic drugs may simply be the prevention of urine and feces from entering sewers."

(6) The federal Occupational Safety and Health Administration ("OSHA") is the main federal agency charged with the enforcement of safety and health legislation. OSHA, in concert with the National Institute for Occupational Safety and Health ("NIOSH") and the Joint Commission on Healthcare, an independent, not-for-profit organization that accredits and certifies more than twenty thousand (20,000) health care organizations and programs in the United States, stated in a 2011 letter to every hospital in the country that "[e]very day in healthcare settings across America, workers are exposed to hundreds of powerful drugs used for cancer chemotherapy, antiviral treatments, hormone regimens and other therapies. While these drugs are used to relieve and heal patients, many of them present serious hazards to the health and safety of your workers. Some of these drugs have been known to cause cancer, reproductive and developmental problems, allergic reactions, and other adverse effects that can be irreversible even after low-level exposures."

(7) Further, because of the risk of ongoing exposure to these extremely hazardous excreted drugs, the American Cancer Society has published a comprehensive list of safety precautions regarding the in-home personal hygiene for individuals undergoing chemotherapy and their

families.

(8) Therefore, for the protection of both the public health and the environment, the general assembly shall require that standards are set forth pursuant to this section to address this serious health and safety issue.

CHAPTER 19.17

SAFE CYTOTOXIC WASTE DISPOSAL ACT

23-19.17-1. Short title.

This section shall be known and may be cited as the "Safe Cytotoxic Waste Disposal Act."

23-19.17-2. Definitions.

As used in this chapter:

(1) "Cytotoxic drugs" means any drug defined by the department as extremely hazardous waste or any waste byproduct or substance containing such a drug.

(2) "Department" means the Rhode Island department of environmental management.

(3) "Drug wholesaler" means a business that sells or distributes cytotoxic drugs for resale to an entity other than a consumer.

(4) "Entity" means a person other than an individual.

(5) "Mail-back program" means a system whereby residential generators of wastes from cytotoxic drugs obtain prepaid and pre-addressed shipping containers in which to place wastes for shipment to an entity that will dispose of them safely and legally.

(6) "Person" means an individual, firm, sole proprietorship, corporation, limited liability corporation, general partnership, limited partnership, limited liability partnership, association, cooperative, or other legal entity, however organized.

(7) "Plan" or "product stewardship plan" means a product stewardship plan required under this chapter that describes the manner in which a product stewardship program will be provided.

(8) "Producer" shall be determined, with regard to a cytotoxic drug that is sold, offered for sale, or distributed in Rhode Island as meaning one of the following:

(i) The person who manufactures a cytotoxic drug and who sells, offers for sale, or distributes that cytotoxic drug in Rhode Island under that person's own name or brand.

(ii) If there is no person who sells, offers for sale, or distributes the cytotoxic drug in Rhode Island under the person's own name or brand, the producer of the cytotoxic drug is the owner or licensee of a trademark or brand under which the cytotoxic drug is sold or distributed in Rhode Island, whether or not the trademark is registered.

(iii) If there is no person who is a producer of the cytotoxic drug pursuant to subsections (8)(i) and (8)(ii) of this section, the producer of that cytotoxic drug is the person who brings the

cytotoxic drug into Rhode Island for sale or distribution. "Producer" does not include:

(A) A retailer that puts its store label on a cytotoxic drug; or

(B) A pharmacist who dispenses prescription drugs to, or compounds a prescribed individual drug product for a consumer.

(9) "Product stewardship program" or "program" means a program financed and operated by producers to collect, transport, and dispose of cytotoxic drugs.

(10) "Residential generators" means residential or other locations outside a hospital facility where cytotoxic drugs are or may be excreted, unused, unwanted, disposed of, or abandoned.

(11) "Stewardship organization" means an organization designated by a producer or a group of producers to act as an agent on behalf of each producer to operate a product stewardship program.

23-19.17-3. Product stewardship program.

(a) Requirement for sale. This chapter shall apply only to a producer whose cytotoxic drug is sold or distributed in Rhode Island and shall be administered and implemented by the Rhode Island department of environmental management. Each producer must:

(1) Operate, individually or jointly with other producers, a product stewardship program approved by the department; or

(2) Enter into an agreement with a stewardship organization to operate, on the producer's behalf, a product stewardship program approved by the department.

(b) Product stewardship program costs.

(1) A producer, group of producers, or stewardship organization must pay all administrative and operational fees associated with their product stewardship program, including the cost of collecting, transporting, and disposing of cytotoxic drugs collected from residential generators and the proper disposal of packaging collected with the cytotoxic drugs.

(2) A producer, group of producers, or stewardship organization must pay for all fees associated with their specific product stewardship program and product stewardship plan.

(3) No person or producer may charge a specific point-of-sale fee to consumers to recoup the costs of their product stewardship program, nor may they charge a specific point-of-collection fee at the time the unwanted products are collected from residential generators or delivered for disposal.

(4) A producer, group of producers, or stewardship organization must pay all costs incurred by the state of Rhode Island, including, but not limited to, the department in the administration and enforcement of their product stewardship program. Exclusive of fines and penalties, the state shall only recover its actual costs of administration and enforcement under this chapter and shall not

charge any amounts under this chapter in excess of its actual administrative and enforcement costs.

23-19.17-4. Product stewardship plans.

(a) Plan content. Each product stewardship program shall have a product stewardship plan that contains each of the following:

(1) Certification that the product stewardship program will accept all cytotoxic drugs regardless of who produced them, unless excused from this requirement by the department as part of the approval of the plan;

(2) Contact information for the individual and the entity submitting the plan and for each of the producers participating in the product stewardship program;

(3) A description of the methods by which cytotoxic drugs from residential generators will be collected in Rhode Island and an explanation of how the collection system will be convenient and adequate to serve the needs of Rhode Island residents;

(4) A description of how the product stewardship plan will provide collection services for cytotoxic drugs for all patients in Rhode Island that are convenient and adequate to meet the needs of patients and caregivers, including the option for all patients to utilize a mail-back program;

(5) The timing and method of delivery to patients of shipping containers for a mail-back program;

(6) A list containing the name, location, permit status, and record of any penalties, violations, or regulatory orders received in the previous five (5) years by each person that will be involved in transporting cytotoxic drugs and each disposal facility proposed to participate in the product stewardship program;

(7) A description of how the cytotoxic drugs will be safely and securely tracked and handled from collection through final disposal and the policies and procedures to be followed to ensure security;

(8) A description of the public education and outreach activities to patients, caregivers, and health care professionals, and how their effectiveness will be evaluated;

(9) A description of education and outreach efforts to law enforcement, public safety, transportation officials and other personnel regarding the findings and requirements of this chapter, and the process for safe handling and disposal of cytotoxic drugs and related wastes or byproducts they may encounter;

(10) A description of how the scope and extent of the product stewardship program can reasonably be expected to identify and address each instance in which a cytotoxic drug is prescribed in Rhode Island;

(11) A starting date when collection of cytotoxic drugs will begin and, in the case of a

program utilizing a stewardship organization, the contracted term of engagement of that stewardship organization; and

(12) If more than one producer will be involved in a proposed product stewardship program, then the product stewardship plan for that program must include a fair and reasonable manner for allocating the costs of the program among the participants in that program, in order that the portion of costs paid by each producer is reasonably related to the amount of cytotoxic drugs that producer sells in the state of Rhode Island.

(b) Department review, approval and updates:

(1) Nothing herein shall prevent an existing producer, group of producers, or stewardship organization from collecting cytotoxic drugs and related waste and byproducts prior to the effective date of this chapter.

(2) Product stewardship plans must be submitted to the department for approval. The initial plans must be submitted by December 1, 2020.

(3) Within sixty (60) days after receipt of a product stewardship plan, the department shall conduct a public hearing and determine whether the plan complies with the requirements of this chapter and of any regulations adopted pursuant to this chapter.

(i) The department may reject a plan within thirty (30) days of receipt without conducting a public hearing.

(ii) As part of its approval, the department may set reasonable performance goals for the program.

(iii) If the department approves a plan, it shall notify the applicant of its approval in writing.

(iv) If the department rejects a plan, it shall notify the applicant in writing of its reasons for rejecting the plan.

(4) An applicant whose plan has been rejected by the department must submit a revised plan to the department within sixty (60) days after receiving notice of the rejection.

(5) If the department rejects a revised product stewardship plan or any other subsequently revised plan, the producer(s) at issue shall be out of compliance with this chapter and are subject to the enforcement provisions contained in this chapter.

(c) At least every three (3) years, a producer, group of producers or stewardship organization operating a product stewardship program shall update its product stewardship plan and submit the updated plan to the department for review and approval.

(d) A producer who begins to offer a cytotoxic drug for sale in the state of Rhode Island after July 1, 2021, must submit a product stewardship plan to the department or provide evidence of having joined an existing approved product stewardship program prior to the producer's initial

offer for sale of a cytotoxic drug.

(e) Any proposed changes to a product stewardship plan must be submitted in writing to the department and approved by the department in writing prior to implementation of any change.

23-19.17-5. Disposal of cytotoxic wastes.

(a) Compliance with applicable law. Each product stewardship program must comply with all local, state, and federal laws and regulations applicable to its operations, including laws and regulations governing the disposal of extremely hazardous wastes and their byproducts.

(b) Protocols for packaging and transport of cytotoxic drugs and related wastes from residential generators must address the destruction of pathogens and cytotoxins and the conversion of wastes to a non-liquid form prior to shipping or transport.

(c) Cytotoxic drugs and related wastes shall not be incinerated.

(d) Prior to shipment or transport from the location of the residential generator, the cytotoxic drugs, related wastes (including, but not limited to, protective equipment, medical supplies, clothing, bedding) and other contaminated materials must be contained to prevent exposure by handlers of the waste during shipment or transport.

23-19.17-6. Reporting.

(a) On or before July 1, 2021, (or at a later date as adopted in writing by the department) and in each subsequent year, every producer, group of producers, or stewardship organization operating a product stewardship program must prepare and submit to the department an annual written report describing the program's activities during the previous reporting period. The report must include the following:

(1) A list of producers participating in the product stewardship program;

(2) The quantity of cytotoxic drugs collected from residential generators;

(3) The name and location of disposal facilities at which cytotoxic drugs were disposed of and the quantities disposed of at each facility;

(4) Whether policies and procedures for collecting, transporting, and disposing of cytotoxic drugs, as established in the plan, were followed during the reporting period and a description of any noncompliance;

(5) Whether any safety or security problems occurred during collection, transportation, or disposal of cytotoxic drugs during the reporting period and, if so, what changes have or will be made to policies, procedures, or tracking mechanisms to alleviate the problem and to improve safety and security;

(6) A description of public education and outreach activities implemented during the reporting period, including the methodology used to evaluate the outreach and program activities;

(7) How the product stewardship program complied with all other elements in the product stewardship plan approved by the department, including its degree of success in meeting any performance goals set by the department as part of its approval of the program; and

(8) Any other information that the department may reasonably require.

(b) For the purposes of this section, "reporting period" means the period beginning January 1 and ending December 31 of the same calendar year.

(c) The department shall provide on its website a list of all producers participating in product stewardship programs approved by the department and a list of all producers the department has identified as noncompliant with this chapter or any regulations adopted pursuant to this chapter.

23-19.17-7. Rules, regulations and fees.

The director of the department of environmental management may, after a noticed public hearing, promulgate rules and regulations as necessary to implement, administer, and enforce this chapter. The rules and regulations shall include a schedule of fees to be charged to the producers to cover all of the state of Rhode Island's costs of administering and enforcing this chapter.

23-19.17-8. Enforcement by the department.

(a) The department of environmental management shall administer the penalty provisions of this chapter.

(b) The department of environmental management may issue an administrative citation to a producer for violation of this chapter or any rule or regulation adopted pursuant to this chapter. The department shall first send a written warning to the producer as well as a copy of this chapter and any rules and regulations adopted pursuant to this chapter. The producer shall have thirty (30) days after receipt of the warning to comply and correct any violations.

(c) If the producer fails to comply and correct any violations, the department may impose administrative fines for violations of this chapter or of any rules or regulations adopted pursuant to this chapter. Each day shall constitute a separate violation for those purposes.

(d) Any person in violation of this chapter or any rule or regulation adopted pursuant to this chapter shall be liable to the state of Rhode Island for a civil penalty in an amount not to exceed one thousand dollars ($1,000) per day, per violation. Each day in which the violation continues shall constitute a separate and distinct violation.

(e) In determining the appropriate penalties, the department of environmental management shall consider the extent of harm caused by the violation, the nature and persistence of the violation, the frequency of past violations, any action taken to mitigate the violation, and the financial burden to the violator.

(f) Any producer receiving an administrative citation under this chapter or any rule or regulation adopted pursuant to this chapter may file an appeal within twenty-one (21) calendar days from the date the administrative citation was issued. The administrative citation is deemed issued on the day it is sent by first class mail or personal service. The administrative citation shall state the date of issuance. If the deadline falls on a weekend or state holiday, then the deadline shall be extended until the next regular business day. The request to appeal must:

(1) Be in writing;

(2) Be accompanied by a deposit of the total fine and any fees noted on the administrative citation;

(3) Specify the basis for the appeal in detail;

(4) Be postmarked within twenty-one (21) days from the date the administrative citation was issued; and

(5) Be sent to the address as set forth on the administrative citation.

(g) The written request to appeal will be reviewed and, if found to be complete, a date, time and place shall be set for a hearing before a hearing officer designated by the director of the department of environmental management. Written notice of the time and place for the hearing will be served by first class mail or personal service at least twenty one (21) days prior to the date of the hearing to the producer appealing the citation. Service by first class mail, postage prepaid shall be effective on the date of mailing.

(h) Failure of any producer to file an appeal in accordance with the provisions of this section shall constitute waiver of that producer's rights to administrative determination of the merits of the administrative citation and the amount of the fine and any fees and shall constitute a failure by that producer to exhaust administrative remedies.

(i) The producer requesting the appeal may request the director of the department of environmental management to recuse a hearing officer for reasons of actual prejudice against the party's cause. The hearing officer shall conduct an orderly, fair hearing and accept evidence pursuant to chapter 32 of title 45 (the "administrative procedures act") as follows:

(1) A valid administrative citation shall be prima facie evidence of the violation;

(2) Testimony shall be by declaration under penalty of perjury except to the extent the hearing officer permits or requires live testimony concerning the violation.

(3) The hearing officer may reduce, waive or conditionally reduce the fines and any fees stated in the administrative citation. The hearing officer may impose deadlines or a schedule for payment of the fine and any fees due in excess of the deposit.

(4) The hearing officer shall make findings based on the record of the hearing and make a

written decision based on the findings entitled "hearing officer decision" (HOD). The HOD shall be served by first class mail on the producer appealing and the department. The HOD affirming or dismissing the administrative citation is final, unless a timely notice of appeal is filed for hearing by the superior court.

23-19.17-9. Appeal to superior court.

(a) An appeal may be filed with the superior court within ten (10) calendar days after the date of service of the hearing officer decision.

(b) The appeal may be taken by any producer or the department within said ten (10) day period, by filing with the clerk of the superior court a notice of appeal specifying the grounds for the appeal.

(c) Upon receiving an appeal, the department shall immediately arrange for an administrative record to be made available to the superior court of all of the documents constituting the record upon which the hearing officer's decision was based.

(d) The superior court may hear additional evidence in its sole discretion and may sustain, modify or overrule any order brought before it on appeal.

23-19.17-10. Enforcement by attorney general.

(a) Upon the failure of any producer to comply with any requirement of this chapter and any rule or regulation adopted pursuant to this chapter, the department of attorney general may petition any court having jurisdiction for injunctive relief, payment of civil penalties and any other appropriate remedy, including restraining such person from continuing any prohibited activity and compelling compliance with lawful requirements; provided, however, this subsection does not permit the department, the state of Rhode Island, or any court of competent jurisdiction to restrain the sale of any cytotoxic drug in Rhode Island.

(b) Any person who knowingly and willfully violates the requirements of this chapter or any rule or regulation adopted pursuant to this chapter is guilty of a misdemeanor and may be prosecuted by the department of attorney general. A conviction for a misdemeanor violation shall be punishable by a fine of not less than fifty dollars ($50.00) and not more than five hundred dollars ($500) per day, per violation, or by imprisonment for a period not to exceed six (6) months or both.

23-19.17-11. Construction and severability.

(a) Conflict with state or federal law. This chapter shall be construed in order to not conflict with applicable federal or state laws, rules or regulations.

(b) Severability. If any of the provisions of this chapter or the application thereof to any person or circumstance is held invalid, the remainder of those provisions, including the application of any part or provisions to persons or circumstances other than those to whom it is held invalid

shall not be affected thereby and shall continue in full force and effect.

SECTION 8. This act shall take effect upon passage.

========
LC004806
========

EXPLANATION

BY THE LEGISLATIVE COUNCIL

OF

A N A C T

RELATING TO INSURANCE -- ACCIDENT AND SICKNESS INSURANCE POLICIES

***

This act would establish a program related to the disposal of extremely hazardous wastes generated by the use of toxic, carcinogenic, mutagenic, or teratogenic chemotherapy drugs to be implemented by pharmacists, physicians, health care providers, and insurers in this state. Further this act would provide for a drug stewardship program to address procedures and industry financing of the proper disposal of these extremely hazardous wastes.

This act would take effect upon passage.

========
LC004806
========