

2016 -- H 7619

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STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2016

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A N A C T

RELATING TO INSURANCE -- ACCIDENT AND SICKNESS INSURANCE POLICIES

Introduced By: Representative Joseph M. McNamara

Date Introduced: February 12, 2016

Referred To: House Corporations

It is enacted by the General Assembly as follows:

1 SECTION 1. Chapter 27-18 of the General Laws entitled "Accident and Sickness  
2 Insurance Policies" is hereby amended by adding thereto the following section:

3 **27-18-82. Cancer patient safety and environmental protection. -- (a) Purpose. It is the**  
4 **policy of the state of Rhode Island not to permit introduction of pollutants into the ground waters**  
5 **and water systems of the state or otherwise to be discharged in concentrations which are known to**  
6 **be toxic, carcinogenic, mutagenic, or teratogenic as the same are defined in the Rhode Island**  
7 **department of environmental management groundwater quality rules and the rules and regulations**  
8 **for hazardous waste management. More specifically, the Rhode Island department of**  
9 **environmental management, in regulation #OEM OWM-HW 01-14, most recent revision dated**  
10 **January 7, 2014, defines certain antineoplastic or cytotoxic chemotherapy agents and drugs as**  
11 **"extremely hazardous waste."**

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

1 cancer.

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

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

12 (4) The European Commission, Executive Agency for Health and Consumers undertook a  
13 comprehensive "Study on the Environmental Risks of Medicinal Products" which was released in  
14 June of 2014, drafted by 810 Intelligence Service, a division of Deloitte Consulting LLP,  
15 reviewing the prevalence of contaminants in drinking water and noting the extreme dangers  
16 arising from improper disposal of cytotoxic chemotherapy drugs.

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

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

1 developmental problems, allergic reactions, and other adverse effects that can be irreversible even  
2 after low-level exposures."

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

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

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

13 (1) Provide written notice from the prescribing pharmacist to each patient undergoing  
14 such treatment as to the hazards posed to patients and their families of extremely hazardous  
15 excretions, including, but not limited to, urine, vomit, and feces, for a period following treatment  
16 as generally determined by the food and drug administration label accompanying said  
17 chemotherapy drug or drugs. To the extent such notices are generally consistent with those now  
18 provided for patients undergoing treatment with radioactive drugs, or consistent with the  
19 recommendations of the World Health Organization with regard to cytotoxic drugs, or otherwise  
20 consistent with similar standards that may be approved by the department of environmental  
21 management in the context of a product stewardship plan adopted under chapter 19.16 of title 23,  
22 then the prescribing pharmacist will not be held liable for the form of such notice;

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

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

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

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

7 SECTION 2. Chapter 27-18.5 of the General Laws entitled "Individual Health Insurance  
8 Coverage" is hereby amended by adding thereto the following section:

9 **27-18.5-11. Cancer patient safety and environmental protection.** -- (a) Purpose. It is  
10 the policy of the state of Rhode Island not to permit introduction of pollutants into the ground  
11 waters and water systems of the state or otherwise to be discharged in concentrations which are  
12 known to be toxic, carcinogenic, mutagenic, or teratogenic as the same are defined in the Rhode  
13 Island department of environmental management groundwater quality rules and the rules and  
14 regulations for hazardous waste management. More specifically, the Rhode Island department of  
15 environmental management, in regulation #OEM OWM-HW 01-14, most recent revision dated  
16 January 7, 2014, defines certain antineoplastic or cytotoxic chemotherapy agents and drugs as  
17 "extremely hazardous waste."

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

27 (2) While, according to the American Society of Clinical Oncology, the cost of one  
28 additional cancer patient resulting from the exposure to these harmful chemicals is approximately  
29 one hundred seventy thousand dollars (\$170,000) per treatment year, the cost of the  
30 implementation of cytotoxic chemical safety protocols is estimated to be less than two percent  
31 (2%) of that cost.

32 (3) The World Health Organization further states that any discharge of genotoxic waste  
33 into the environment could have disastrous ecological consequences. The World Health  
34 Organization places the responsibility for genotoxic waste on the chief pharmacist and further

1 states that the chief pharmacist also has the special responsibility of ensuring that genotoxic  
2 products are used safely, and that genotoxic waste is managed safely.

3 (4) The European Commission, Executive Agency for Health and Consumers undertook a  
4 comprehensive "Study on the Environmental Risks of Medicinal Products" which was released in  
5 June of 2014, drafted by 810 Intelligence Service, a division of Deloitte Consulting LLP,  
6 reviewing the prevalence of contaminants in drinking water and noting the extreme dangers  
7 arising from improper disposal of cytotoxic chemotherapy drugs.

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

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

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

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

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

4 (1) Provide written notice from the prescribing pharmacist to each patient undergoing  
5 such treatment as to the hazards posed to patients and their families of extremely hazardous  
6 excretions, including, but not limited to, urine, vomit, and feces, for a period following treatment  
7 as generally determined by the food and drug administration label accompanying said  
8 chemotherapy drug or drugs. To the extent such notices are generally consistent with those now  
9 provided for patients undergoing treatment with radioactive drugs, or consistent with the  
10 recommendations of the World Health Organization with regard to cytotoxic drugs, or otherwise  
11 consistent with similar standards that may be approved by the department of environmental  
12 management in the context of a product stewardship plan adopted under chapter 19.16 of title 23,  
13 then the prescribing pharmacist will not be held liable for the form of such notice;

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

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

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

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

32 SECTION 3. Chapter 27-19 of the General Laws entitled "Nonprofit Hospital Service  
33 Corporations" is hereby amended by adding thereto the following section:

34 **27-19-73. Cancer patient safety and environmental protection. -- (a) Purpose. It is the**

1 policy of the state of Rhode Island not to permit introduction of pollutants into the ground waters  
2 and water systems of the state or otherwise to be discharged in concentrations which are known to  
3 be toxic, carcinogenic, mutagenic, or teratogenic as the same are defined in the Rhode Island  
4 department of environmental management groundwater quality rules and the rules and regulations  
5 for hazardous waste management. More specifically, the Rhode Island department of  
6 environmental management, in regulation #OEM OWM-HW 01-14, most recent revision dated  
7 January 7, 2014, defines certain antineoplastic or cytotoxic chemotherapy agents and drugs as  
8 "extremely hazardous waste."

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

18 (2) While, according to the American Society of Clinical Oncology, the cost of one  
19 additional cancer patient resulting from the exposure to these harmful chemicals is approximately  
20 one hundred seventy thousand dollars (\$170,000) per treatment year, the cost of the  
21 implementation of cytotoxic chemical safety protocols is estimated to be less than two percent  
22 (2%) of that cost.

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

28 (4) The European Commission, Executive Agency for Health and Consumers undertook a  
29 comprehensive "Study on the Environmental Risks of Medicinal Products" which was released in  
30 June of 2014, drafted by 810 Intelligence Service, a division of Deloitte Consulting LLP,  
31 reviewing the prevalence of contaminants in drinking water and noting the extreme dangers  
32 arising from improper disposal of cytotoxic chemotherapy drugs.

33 (5) Dr. Christian G. Daughton, former chief of environmental chemistry for the United  
34 States Environmental Protection Agency, notes in a paper entitled "Eco-directed Sustainable

1 Prescribing: Feasibility for Reducing Water Contamination by Drugs" published in the journal  
2 "Science of the Total Environment" on June 3, 2014, that generally, the best practice for lowering  
3 the level of drugs in our environment is reduction of dosages, but that "[c]ertain drug classes  
4 (especially cytotoxic chemotherapeutics) may not be amenable to this approach; the best control  
5 measure for such highly toxic drugs may simply be the prevention of urine and feces from  
6 entering sewers."

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

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

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

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

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



1 recommendations of the World Health Organization with regard to cytotoxic drugs, or otherwise  
2 consistent with similar standards that may be approved by the department of environmental  
3 management in the context of a product stewardship plan adopted under chapter 19.16 of title 23,  
4 then the prescribing pharmacist will not be held liable for the form of such notice;

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

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

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

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

23 SECTION 4. Chapter 27-20 of the General Laws entitled "Nonprofit Medical Service  
24 Corporations" is hereby amended by adding thereto the following section:

25 **27-20-69. Cancer patient safety and environmental protection.** -- (a) Purpose. It is the  
26 policy of the state of Rhode Island not to permit introduction of pollutants into the ground waters  
27 and water systems of the state or otherwise to be discharged in concentrations which are known to  
28 be toxic, carcinogenic, mutagenic, or teratogenic as the same are defined in the Rhode Island  
29 department of environmental management groundwater quality rules and the rules and regulations  
30 for hazardous waste management. More specifically, the Rhode Island department of  
31 environmental management, in regulation #OEM OWM-HW 01-14, most recent revision dated  
32 January 7, 2014, defines certain antineoplastic or cytotoxic chemotherapy agents and drugs as  
33 "extremely hazardous waste."

34 (b) Findings. (1) It is acknowledged by medical experts that bodily wastes of patients

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

9 (2) While, according to the American Society of Clinical Oncology, the cost of one  
10 additional cancer patient resulting from the exposure to these harmful chemicals is approximately  
11 one hundred seventy thousand dollars (\$170,000) per treatment year, the cost of the  
12 implementation of cytotoxic chemical safety protocols is estimated to be less than two percent  
13 (2%) of that cost.

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

19 (4) The European Commission, Executive Agency for Health and Consumers undertook a  
20 comprehensive "Study on the Environmental Risks of Medicinal Products" which was released in  
21 June of 2014, drafted by 810 Intelligence Service, a division of Deloitte Consulting LLP,  
22 reviewing the prevalence of contaminants in drinking water and noting the extreme dangers  
23 arising from improper disposal of cytotoxic chemotherapy drugs.

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

32 (6) The federal Occupational Safety and Health Administration ("OSHA") is the main  
33 federal agency charged with the enforcement of safety and health legislation. OSHA, in concert  
34 with the National Institute for Occupational Safety and Health ("NIOSH") and the Joint

1 Commission on Healthcare, an independent, not-for-profit organization that accredits and certifies  
2 more than twenty thousand (20,000) health care organizations and programs in the United States,  
3 stated in a 2011 letter to every hospital in the country that "[e]very day in healthcare settings  
4 across America, workers are exposed to hundreds of powerful drugs used for cancer  
5 chemotherapy, antiviral treatments, hormone regimens and other therapies. While these drugs are  
6 used to relieve and heal patients, many of them present serious hazards to the health and safety of  
7 your workers. Some of these drugs have been known to cause cancer, reproductive and  
8 developmental problems, allergic reactions, and other adverse effects that can be irreversible even  
9 after low-level exposures."

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

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

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

20 (1) Provide written notice from the prescribing pharmacist to each patient undergoing  
21 such treatment as to the hazards posed to patients and their families of extremely hazardous  
22 excretions, including, but not limited to, urine, vomit, and feces, for a period following treatment  
23 as generally determined by the food and drug administration label accompanying said  
24 chemotherapy drug or drugs. To the extent such notices are generally consistent with those now  
25 provided for patients undergoing treatment with radioactive drugs, or consistent with the  
26 recommendations of the World Health Organization with regard to cytotoxic drugs, or otherwise  
27 consistent with similar standards that may be approved by the department of environmental  
28 management in the context of a product stewardship plan adopted under chapter 19.16 of title 23,  
29 then the prescribing pharmacist will not be held liable for the form of such notice;

30 (2) Participate in an approved product stewardship program for the collection safe and  
31 proper and disposal of Extremely Hazardous Wastes, including Cytotoxic Drugs and related  
32 byproducts and wastes adopted pursuant to chapter 19.16 of title 23 so that providers and patients  
33 can safely collect and contain extremely hazardous excretions for a period of time as determined  
34 by the United States Food and Drug Administration ("FDA") and referenced on the relevant FDA

1 prescription insert(s).

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

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

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

14 SECTION 5. Chapter 27-41 of the General Laws entitled "Health Maintenance  
15 Organizations" is hereby amended by adding thereto the following section:

16 **27-41-86. Cancer patient safety and environmental protection.** -- (a) Purpose. It is the  
17 policy of the state of Rhode Island not to permit introduction of pollutants into the ground waters  
18 and water systems of the state or otherwise to be discharged in concentrations which are known to  
19 be toxic, carcinogenic, mutagenic, or teratogenic as the same are defined in the Rhode Island  
20 department of environmental management groundwater quality rules and the rules and regulations  
21 for hazardous waste management. More specifically, the Rhode Island department of  
22 environmental management, in regulation #OEM OWM-HW 01-14, most recent revision dated  
23 January 7, 2014, defines certain antineoplastic or cytotoxic chemotherapy agents and drugs as  
24 "extremely hazardous waste."

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

34 (2) While, according to the American Society of Clinical Oncology, the cost of one

1 additional cancer patient resulting from the exposure to these harmful chemicals is approximately  
2 one hundred seventy thousand dollars (\$170,000) per treatment year, the cost of the  
3 implementation of cytotoxic chemical safety protocols is estimated to be less than two percent  
4 (2%) of that cost.

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

10 (4) The European Commission, Executive Agency for Health and Consumers undertook a  
11 comprehensive "Study on the Environmental Risks of Medicinal Products" which was released in  
12 June of 2014, drafted by 810 Intelligence Service, a division of Deloitte Consulting LLP,  
13 reviewing the prevalence of contaminants in drinking water and noting the extreme dangers  
14 arising from improper disposal of cytotoxic chemotherapy drugs.

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

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

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

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

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

11 (1) Provide written notice from the prescribing pharmacist to each patient undergoing  
12 such treatment as to the hazards posed to patients and their families of extremely hazardous  
13 excretions, including, but not limited to, urine, vomit, and feces, for a period following treatment  
14 as generally determined by the food and drug administration label accompanying said  
15 chemotherapy drug or drugs. To the extent such notices are generally consistent with those now  
16 provided for patients undergoing treatment with radioactive drugs, or consistent with the  
17 recommendations of the World Health Organization with regard to cytotoxic drugs, or otherwise  
18 consistent with similar standards that may be approved by the department of environmental  
19 management in the context of a product stewardship plan adopted under chapter 19.16 of title 23,  
20 then the prescribing pharmacist will not be held liable for the form of such notice;

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

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

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

33 (f) For the purposes of this section, extremely hazardous excretions shall mean any  
34 excretion from a patient on a regimen of chemotherapy agents that are antineoplastic or cytotoxic,

1 and which may be excreted during the period of administration or the time period referenced in  
2 subsection (c)(2) of this section, including but not limited to, drugs listed in the NIOSH list of  
3 Antineoplastic and Other Hazardous Drugs, as the same may be updated or amended from time to  
4 time.

5 SECTION 6. Title 23 of the General Laws entitled "HEALTH AND SAFETY" is hereby  
6 amended by adding thereto the following chapter:

7 CHAPTER 19.16

8 SAFE CYTOTOXIC WASTE DISPOSAL ACT

9 **23-19.16-1. Short title.** -- This section shall be known and may be cited as the "Safe  
10 Cytotoxic Waste Disposal Act".

11 **23-19.16-2. Declaration of findings.** -- (a) It is acknowledged by medical experts that  
12 bodily wastes of patients undergoing chemotherapy treatment may contain levels of chemicals  
13 that are toxic, carcinogenic, mutagenic or teratogenic for a certain period of time, to such an  
14 extent that the World Health Organization defines genotoxic waste as chemotherapy drug waste  
15 including urine, feces and vomit from patients, which may contain potentially hazardous amounts  
16 of the administered cytostatic drugs or of their metabolites, and which should be considered  
17 genotoxic for at least forty-eight (48) hours and sometimes up to one week after drug  
18 administration. According to the World Health Organization, ten percent (10%) of known  
19 carcinogens are chemicals used to cure cancer.

20 (b) While, according to the American Society of Clinical Oncology, the cost of one  
21 additional cancer patient resulting from the exposure to these harmful chemicals is approximately  
22 one hundred seventy thousand dollars (\$170,000) per treatment year, the cost of the  
23 implementation of cytotoxic chemical safety protocols is estimated to be less than two percent  
24 (2%) of that cost.

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

30 (d) The European Commission, Executive Agency for Health and Consumers undertook a  
31 comprehensive "Study on the Environmental Risks of Medicinal Products" which was released in  
32 June of 2014, drafted by 810 Intelligence Service, a division of Deloitte Consulting LLP,  
33 reviewing the prevalence of contaminants in drinking water and noting the extreme dangers  
34 arising from improper disposal of cytotoxic chemotherapy drugs.

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

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

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

25 (h) Therefore, for the protection of both the public health and the environment, the  
26 general assembly shall require that standards and rules be set forth pursuant to this section to  
27 address this serious health and safety issue.

28 **23-19.16-3. Definitions. --** For the purposes of this chapter, the following terms shall  
29 have the following meanings:

30 (1) "Cytotoxic drugs" means, for purposes of this chapter, any drug defined by the  
31 department as extremely hazardous waste or any waste byproduct or substance containing such a  
32 drug.

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

34 (3) "Drug wholesaler" means a business that sells or distributes cytotoxic drugs for resale



1 to an entity other than a consumer.

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

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

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

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

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

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

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

20 (iii) If there is no person who is a producer of the cytotoxic drug for purposes of  
21 subsection (8)(i) and (8)(ii), the producer of that cytotoxic drug is the person who brings the  
22 cytotoxic drug into Rhode Island for sale or distribution. "producer" does not include:

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

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

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

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

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

34 **23-19.16-4. Product stewardship program. -- (a) Requirement for sale. This chapter**

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

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

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

8 (b) Product stewardship program costs.

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

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

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

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

25 **23-19.16-5. Product stewardship plans. -- (a) Plan content. Each product stewardship**  
26 **program shall have a product stewardship plan that contains each of the following:**

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

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

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

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

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

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

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

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

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

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

23           (11) A starting date when collection of cytotoxic drugs will begin and, in the case of a  
24 program utilizing a stewardship organization, the contracted term of engagement of that  
25 stewardship organization;

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

31           (b) Department review and approval; updates.

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

1           (2) Product stewardship plans must be submitted to the department for approval. The  
2 initial plans must be submitted by December 1, 2016.

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

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

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

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

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

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

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

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

22          (7) A producer who begins to offer a cytotoxic drug for sale in the state of Rhode Island  
23 after July 1, 2017, must submit a product stewardship plan to the department or provide evidence  
24 of having joined an existing approved product stewardship program prior to the producer's initial  
25 offer for sale of a cytotoxic drug.

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

28          **23-19.16-6. Disposal of cytotoxic wastes. -** (a) Compliance with applicable law. Each  
29 product stewardship program must comply with all local, state, and federal laws and regulations  
30 applicable to its operations, including laws and regulations governing the disposal of extremely  
31 hazardous wastes and their byproducts.

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

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

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

6 **23-19.16-7. Reporting. --** (a) On or before July 1, 2017 (or at a later date as approved in  
7 writing by the department) and in each subsequent year, every producer, group of producers, or  
8 stewardship organization operating a product stewardship program must prepare and submit to  
9 the department an annual written report describing the program's activities during the previous  
10 reporting period. The report must include the following:

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

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

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

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

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

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

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

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

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

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

34 **23-19.16-8. Regulations and fees. --** The director of the department of environmental

1 management may, after a noticed public hearing, adopt such rules and regulations as necessary to  
2 implement, administer, and enforce this chapter. Said regulations shall include a schedule of fees  
3 to be charged to the producers to cover all of the state of Rhode Island's costs of administering  
4 and enforcing this ordinance.

5 **23-19.16-9. Enforcement. --** (a) The department of environmental management shall  
6 administer the penalty provisions of this chapter.

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

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

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

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

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

29 (1) Be in writing;

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

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

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

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

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

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

12 (i) The producer requesting the appeal may request the director of the department of  
13 environmental management to recuse a hearing officer for reasons of actual prejudice against the  
14 party's cause. The hearing officer shall conduct an orderly, fair hearing and accept evidence as  
15 follows:

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

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

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

22 (4) The hearing officer shall make findings based on the record of the hearing and make a  
23 written decision based on the findings ("hearing officer decision"). The hearing officer decision  
24 shall be served by first class mail on the producer appealing and the department. The hearing  
25 officer decision affirming or dismissing the administrative citation is final, unless a timely notice  
26 of appeal is filed for hearing by the superior court of the state of Rhode Island.

27 (j) A second appeal may be filed with the superior court within ten (10) calendar days  
28 after the date of service of the hearing officer decision.

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

32 (2) Upon receiving an appeal, the department shall immediately arrange for an  
33 administrative record to be made available to the superior court of all of the documents  
34 constituting the record upon which the action appealed was taken.

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

3           (k) The department of environmental management may establish appropriate  
4 administrative rules for implementing this chapter, conducting hearings, and rendering decisions  
5 pursuant to this section.

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

13           (m) Any person who knowingly and willfully violates the requirements of this chapter or  
14 any rule or regulation adopted pursuant to this chapter is guilty of a misdemeanor and may be  
15 prosecuted by the Rhode Island attorney general's office. A conviction for a misdemeanor  
16 violation under this chapter is punishable by a fine of not less than fifty dollars (\$50.00) and not  
17 more than five hundred (\$500) for each day per violation, or by imprisonment for a period not to  
18 exceed six (6) months, or by both such fine and imprisonment.

19           **23-19.16-10. Additional provisions.** -- (a) Conflict with state or federal law. This  
20 chapter shall be construed so as not to conflict with applicable federal or state laws, rules or  
21 regulations.

22           (b) Severability. If any of the provisions of this chapter or the application thereof to any  
23 person or circumstance is held invalid, the remainder of those provisions, including the  
24 application of such part or provisions to persons or circumstances other than those to which it is  
25 held invalid shall not be affected thereby and shall continue in full force and effect. To this end,  
26 the provisions of this chapter are severable.

27           SECTION 7. The educational and public awareness provisions of this act shall take effect  
28 upon passage. The requirements related to the implementation of product stewardship programs  
29 and the enforcement provisions related thereto, along with any other provisions not already in  
30 effect, shall take effect on July 1, 2017.

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EXPLANATION  
BY THE LEGISLATIVE COUNCIL  
OF  
A N A C T  
RELATING TO INSURANCE -- ACCIDENT AND SICKNESS INSURANCE POLICIES

\*\*\*

1           This act would provide that protections related to the disposal of extremely hazardous  
2 wastes generated by the use of toxic, carcinogenic, mutagenic, or teratogenic chemotherapy drugs  
3 be implemented by pharmacists, physicians, health care providers, and insurers in the state of  
4 Rhode Island.

5           The act would also provide for a drug stewardship program to address procedures and  
6 industry financing of the proper disposal of these extremely hazardous wastes.

7           The educational and public awareness provisions of this act would take effect upon  
8 passage. The requirements related to the implementation of product stewardship programs and the  
9 enforcement provisions related thereto, along with any other provisions not already in effect,  
10 would take effect on July 1, 2017.

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