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STATE OF RHODE ISLAND

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2015

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A N A C T

RELATING TO INSURANCE - ACCIDENT AND SICKNESS INSURANCE POLICIES

Introduced By: Senators Ottiano, and Archambault

Date Introduced: February 05, 2015

Referred To: Senate Health & Human Services

(by request)

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
8 regulations for hazardous waste management. More specifically, the Rhode Island department of
9 environmental management, in regulation #DEM 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 BIO 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. Christan 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) healthcare 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, feces, and vomit, 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 producer stewardship plan adopted under chapter 19.16 of title
22 23, then the prescribing pharmacist will not be held liable for the form of such notice;

23 (2) Participate in an approved producer stewardship program for the collection, safe and
24 proper disposal of extremely hazardous wastes, including cytotoxic drugs and related byproducts
25 and wastes adopted pursuant to chapter 19.16 of title 23 so that providers and patients can safely
26 collect and contain extremely hazardous excretions for a period of time as determined by the
27 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 producer stewardship plan
34 shall satisfy the responsibility of the prescribing pharmacist hereunder.

1 (f) For the purposes of this section, "extremely hazardous excretions" means 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 #DEM 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 BIO 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. Christan 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, feces, and vomit, 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 producer stewardship plan adopted under chapter 19.16 of title
13 23, then the prescribing pharmacist will not be held liable for the form of such notice;

14 (2) Participate in an approved producer stewardship program for the collection, safe and
15 proper disposal of extremely hazardous wastes, including cytotoxic drugs and related byproducts
16 and wastes adopted pursuant to chapter 19.16 of title 23 so that providers and patients can safely
17 collect and contain extremely hazardous excretions for a period of time as determined by the
18 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 producer 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
5 regulations for hazardous waste management. More specifically, the Rhode Island department of
6 environmental management, in regulation #DEM 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 BIO 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. Christan 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, feces, and vomit, 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 producer stewardship plan adopted under chapter 19.16 of title
4 23, then the prescribing pharmacist will not be held liable for the form of such notice;

5 (2) Participate in an approved producer stewardship program for the collection, safe and
6 proper disposal of extremely hazardous wastes, including cytotoxic drugs and related byproducts
7 and wastes adopted pursuant to chapter 19.16 of title 23 so that providers and patients can safely
8 collect and contain extremely hazardous excretions for a period of time as determined by the
9 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 producer 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**
30 **regulations for hazardous waste management. More specifically, the Rhode Island department of**
31 **environmental management, in regulation #DEM 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 BIO 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. Christan 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) healthcare 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, feces, and vomit, 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 producer stewardship plan adopted under chapter 19.16 of title
29 23, then the prescribing pharmacist will not be held liable for the form of such notice;

30 (2) Participate in an approved producer stewardship program for the collection, safe and
31 proper disposal of extremely hazardous wastes, including cytotoxic drugs and related byproducts
32 and wastes adopted pursuant to chapter 19.16 of title 23 so that providers and patients can safely
33 collect and contain extremely hazardous excretions for a period of time as determined by the
34 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 producer 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
21 regulations for hazardous waste management. More specifically, the Rhode Island department of
22 environmental management, in regulation #DEM 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 BIO 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. Christan 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, feces, and vomit, 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 producer stewardship plan adopted under chapter 19.16 of title
20 23, then the prescribing pharmacist will not be held liable for the form of such notice;

21 (2) Participate in an approved producer stewardship program for the collection, safe and
22 proper disposal of extremely hazardous wastes, including cytotoxic drugs and related byproducts
23 and wastes adopted pursuant to chapter 19.16 of title 23 so that providers and patients can safely
24 collect and contain extremely hazardous excretions for a period of time as determined by the
25 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 producer 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 chapter 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 BIO 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 chapter to
27 address this serious health and safety issue.

28 **23-19.16-3. Definitions.** -- (a) For the purposes of this chapter the following terms shall
29 mean:

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

32 (2) "Department" means the department of environmental management as established in
33 chapter 17.1 of title 42.

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 "producer stewardship plan" means a producer stewardship plan required
10 under this chapter that describes the manner in which a producer 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 (i) The person who manufactures a cytotoxic drug and who sells, offers for sale, or
15 distributes that 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 subparagraphs (i) and (ii) above, the producer of that cytotoxic drug is the person who brings the
22 cytotoxic drug into Rhode Island for sale or distribution.

23 (iv) Provided the term "producer" does not include: (A) A retailer that puts its store label
24 on cytotoxic drugs; or (B) A pharmacist who dispenses prescription drugs to, or compounds a
25 prescribed individual drug product for a consumer.

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

28 (10) "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 (11) "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 producer
33 stewardship program.

34 **23-19.16-4. Producer 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 department of environmental management.

3 Each producer must:

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

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

8 (b) Producer stewardship program costs.

9 (1) A producer, group of producers, or stewardship organization must pay all
10 administrative and operational fees associated with their producer 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 producer stewardship program and producer 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 producer stewardship program, nor may they charge a specific point-of-
17 collection fee at the time the unwanted products are collected from residential generators or
18 delivered for 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 producer 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. Producer stewardship plans.** -- (a) Plan content. Each producer stewardship
26 program shall have a producer stewardship plan that contains each of the following:

27 (1) Certification that the producer 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 producer 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 producer stewardship plan will provide collection services
2 for 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 producer 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 personnel 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 producer 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 producer stewardship
27 program, then the producer 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) Producer stewardship plans must be submitted to the department for approval. The
2 initial plans must be submitted by October 1, 2016.

3 (3) Within sixty (60) days after receipt of a producer 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 producer stewardship plan or any other
17 subsequently revised plan, the producer(s) at issue shall be out of compliance with this chapter
18 and will be subject 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 producer 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 December 1, 2015, must submit a producer stewardship plan to the department or provide
24 evidence of having joined an existing approved producer stewardship program prior to the
25 producer's initial offer for sale of a cytotoxic drug.

26 (8) Any proposed changes to a producer 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 producer 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. Protocols for packaging and transport of cytotoxic drugs and related wastes
33 from 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) Disposal of drugs. Cytotoxic drugs and related wastes shall not be incinerated.

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

6 **23-19.16-7. Reporting. --** (a) On or before July 1, 2016 (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 producer 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 producer 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 producer stewardship program complied with all other elements in the
25 producer stewardship plan approved by the department, including its degree of success in meeting
26 any 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 producer 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 chapter.

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 person or entity's cause. The hearing officer shall conduct an orderly, fair hearing and accept
15 evidence as 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's decision
24 shall be served by first class mail on the producer appealing and the department. The hearing
25 officer's decision affirming or dismissing the administrative citation is final, unless a timely
26 notice 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's 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 requirements 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) 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. Section 6 of this act shall take effect upon on July 1, 2016. The remaining
28 sections of this act shall take effect upon passage.

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LC000793/SUB A
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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 require 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, healthcare providers, and insurers in the state of
4 Rhode Island.

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

7 Section 6 of this act would take effect upon on July 1, 2016. The remaining sections of
8 this act would take effect upon passage.

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LC000793/SUB A
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