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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: Representative Joseph M. McNamara

Date Introduced: February 04, 2015

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
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 core principles require that all personnel associated with financing and supporting
10 healthcare activities should provide for the costs of managing healthcare waste. This is the duty of
11 care. The World Health Organization places the responsibility for genotoxic waste on the chief
12 pharmacist and further states that the chief pharmacist also has the special responsibility of
13 ensuring that genotoxic products are used safely, and that genotoxic waste is managed safely.

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

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

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

1 used to relieve and heal patients, many of them present serious hazards to the health and safety of
2 your workers. Some of these drugs have been known to cause cancer; reproductive and
3 developmental problems, allergic reactions, and other adverse effects that can be irreversible even
4 after low-level exposures."

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

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

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

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

24 (2) Provide a sufficient collection method so that providers and patients can safely collect
25 and contain extremely hazardous excretions for a period of time as determined by the United
26 States Food and Drug Administration ("FDA") and referenced on the relevant FDA prescription
27 insert(s); and

28 (3) Provide for safe and proper disposal of said collected extremely hazardous excretions.

29 (d) Consistent with the core principles of the World Health Organization for achieving
30 safe and sustainable management of healthcare waste, all personnel associated with financing and
31 supporting healthcare activities should provide for the costs of managing the healthcare waste
32 identified in this chapter.

33 (e) Receipt of notice from the party administering chemotherapy drugs or their agent
34 responsible for proper disposal of the hazardous wastes by the prescribing pharmacist or chief

1 pharmacist shall satisfy the responsibility of the prescribing pharmacist hereunder.

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

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

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

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

28 (2) While, according to the American Society of Clinical Oncology, the cost of one
29 additional cancer patient resulting from the exposure to these harmful chemicals is approximately
30 one hundred seventy thousand dollars (\$170,000) per treatment year, the cost of the
31 implementation of cytotoxic chemical safety protocols is estimated to be less than two percent
32 (2%) of that cost.

33 (3) The World Health Organization further states that any discharge of genotoxic waste
34 into the environment could have disastrous ecological consequences. The World Health

1 Organization core principles require that all personnel associated with financing and supporting
2 healthcare activities should provide for the costs of managing healthcare waste. This is the duty of
3 care. The World Health Organization places the responsibility for genotoxic waste on the chief
4 pharmacist and further states that the chief pharmacist also has the special responsibility of
5 ensuring that genotoxic products are used safely, and that genotoxic waste is managed safely.

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

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

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

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

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

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

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

16 (2) Provide a sufficient collection method so that providers and patients can safely collect
17 and contain extremely hazardous excretions for a period of time as determined by the United
18 States Food and Drug Administration ("FDA") and referenced on the relevant FDA prescription
19 insert(s); and

20 (3) Provide for safe and proper disposal of said collected extremely hazardous excretions.

21 (d) Consistent with the core principles of the World Health Organization for achieving
22 safe and sustainable management of health-care waste, all personnel associated with financing
23 and supporting healthcare activities should provide for the costs of managing the healthcare waste
24 identified in this chapter.

25 (e) Receipt of notice from the party administering chemotherapy drugs or their agent
26 responsible for proper disposal of the hazardous wastes by the prescribing pharmacist or chief
27 pharmacist shall satisfy the responsibility of the prescribing pharmacist hereunder.

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

34 SECTION 3. Chapter 27-19 of the General Laws entitled "Nonprofit Hospital Service

1 Corporations" is hereby amended by adding thereto the following section:

2 **27-19-73. Cancer patient safety and environmental protection.** -- (a) Purpose. It is the
3 policy of the state of Rhode Island not to permit introduction of pollutants into the ground waters
4 and water systems of the state or otherwise to be discharged in concentrations which are known to
5 be toxic, carcinogenic, mutagenic, or teratogenic as the same are defined in the Rhode Island
6 department of environmental management: groundwater quality rules and the rules and
7 regulations for hazardous waste management. More specifically, the Rhode Island department of
8 environmental management, in regulation #DEM OWM-HW 01-14, most recent revision dated
9 January 7, 2014, defines certain antineoplastic or cytotoxic chemotherapy agents and drugs as
10 "extremely hazardous waste."

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

20 (2) 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 (3) 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 core principles require that all personnel associated with financing and supporting
28 healthcare activities should provide for the costs of managing healthcare waste. This is the duty of
29 care. The World Health Organization places the responsibility for genotoxic waste on the chief
30 pharmacist and further states that the chief pharmacist also has the special responsibility of
31 ensuring that genotoxic products are used safely, and that genotoxic waste is managed safely.

32 (4) The European Commission, Executive Agency for Health and Consumers undertook a
33 comprehensive "Study on the environmental risks of medicinal products" which was released in
34 June of 2014, drafted by BIO Intelligence Service, a division of Deloitte Consulting LLP,

1 reviewing the prevalence of contaminants in drinking water and noting the extreme dangers
2 arising from improper disposal of cytotoxic chemotherapy drugs.

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

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

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

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

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

33 (1) Provide written notice from the prescribing pharmacist to each patient undergoing
34 such treatment as to the hazards posed to patients and their families of extremely hazardous

1 excretions, including, but not limited to, urine, feces, and vomit, for a period following treatment
2 as generally determined by the food and drug administration label accompanying said
3 chemotherapy drug or drugs. To the extent such notices are generally consistent with those now
4 provided for patients undergoing treatment with radioactive drugs, or consistent with the
5 recommendations of the World Health Organization with regard to cytotoxic drugs, or otherwise
6 consistent with similar standards that may be adopted by the Rhode Island department of health,
7 then the prescribing pharmacist will not be held liable for the form of such notice;

8 (2) Provide a sufficient collection method so that providers and patients can safely collect
9 and contain extremely hazardous excretions for a period of time as determined by the United
10 States Food and Drug Administration ("FDA") and referenced on the relevant FDA prescription
11 insert(s); and

12 (3) Provide for safe and proper disposal of said collected extremely hazardous excretions.

13 (d) Consistent with the core principles of the World Health Organization for achieving
14 safe and sustainable management of healthcare waste, all personnel associated with financing and
15 supporting healthcare activities should provide for the costs of managing the healthcare waste
16 identified in this chapter.

17 (e) Receipt of notice from the party administering chemotherapy drugs or their agent
18 responsible for proper disposal of the hazardous wastes by the prescribing pharmacist or chief
19 pharmacist shall satisfy the responsibility of the prescribing pharmacist hereunder.

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

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

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

1 January 7, 2014, defines certain antineoplastic or cytotoxic chemotherapy agents and drugs as
2 "extremely hazardous waste."

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

12 (2) While, according to the American Society of Clinical Oncology, the cost of one
13 additional cancer patient resulting from the exposure to these harmful chemicals is approximately
14 one hundred seventy thousand dollars (\$170,000) per treatment year, the cost of the
15 implementation of cytotoxic chemical safety protocols is estimated to be less than two percent
16 (2%) of that cost.

17 (3) The World Health Organization further states that any discharge of genotoxic waste
18 into the environment could have disastrous ecological consequences. The World Health
19 Organization core principles require that all personnel associated with financing and supporting
20 healthcare activities should provide for the costs of managing healthcare waste. This is the duty of
21 care. The World Health Organization places the responsibility for genotoxic waste on the chief
22 pharmacist and further states that the chief pharmacist also has the special responsibility of
23 ensuring that genotoxic products are used safely, and that genotoxic waste is managed safely.

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

29 (5) Dr. Christan G. Daughton, former chief of environmental chemistry for the United
30 States Environmental Protection Agency, notes in a paper entitled "Eco-directed sustainable
31 prescribing: feasibility for reducing water contamination by drugs" published in the journal
32 "Science of the Total Environment" on June 3, 2014, that generally, the best practice for lowering
33 the level of drugs in our environment is reduction of dosages, but that "[c]ertain drug classes
34 (especially cytotoxic therapeutics) may not be amenable to this approach; the best control

1 measure for such highly toxic drugs may simply be the prevention of urine and feces from
2 entering sewers."

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

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

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

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

25 (1) Provide written notice from the prescribing pharmacist to each patient undergoing
26 such treatment as to the hazards posed to patients and their families of extremely hazardous
27 excretions, including, but not limited to, urine, feces, and vomit, for a period following treatment
28 as generally determined by the food and drug administration label accompanying said
29 chemotherapy drug or drugs. To the extent such notices are generally consistent with those now
30 provided for patients undergoing treatment with radioactive drugs, or consistent with the
31 recommendations of the World Health Organization with regard to cytotoxic drugs, or otherwise
32 consistent with similar standards that may be adopted by the Rhode Island department of health,
33 then the prescribing pharmacist will not be held liable for the form of such notice;

34 (2) Provide a sufficient collection method so that providers and patients can safely collect

1 and contain extremely hazardous excretions for a period of time as determined by the United
2 States Food and Drug Administration ("FDA") and referenced on the relevant FDA prescription
3 insert(s); and

4 (3) Provide for safe and proper disposal of said collected extremely hazardous excretions.

5 (d) Consistent with the core principles of the World Health Organization for achieving
6 safe and sustainable management of healthcare waste, all personnel associated with financing and
7 supporting healthcare activities should provide for the costs of managing the healthcare waste
8 identified in this chapter.

9 (e) Receipt of notice from the party administering chemotherapy drugs or their agent
10 responsible for proper disposal of the hazardous wastes by the prescribing pharmacist or chief
11 pharmacist shall satisfy the responsibility of the prescribing pharmacist hereunder.

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

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

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

29 (b) Findings. (1) It is acknowledged by medical experts that bodily wastes of patients
30 undergoing chemotherapy treatment may contain levels of chemicals that are toxic, carcinogenic,
31 mutagenic or teratogenic for a certain period of time, to such an extent that the World Health
32 Organization defines genotoxic waste as chemotherapy drug waste including urine, feces and
33 vomit from patients, which may contain potentially hazardous amounts of the administered
34 cytostatic drugs or of their metabolites, and which should be considered genotoxic for at least

1 forty-eight (48) hours and sometimes up to one week after drug administration. According to the
2 World Health Organization, ten percent (10%) of known carcinogens are chemicals used to cure
3 cancer.

4 (2) While, according to the American Society of Clinical Oncology, the cost of one
5 additional cancer patient resulting from the exposure to these harmful chemicals is approximately
6 one hundred seventy thousand dollars (\$170,000) per treatment year, the cost of the
7 implementation of cytotoxic chemical safety protocols is estimated to be less than two percent
8 (2%) of that cost.

9 (3) The World Health Organization further states that any discharge of genotoxic waste
10 into the environment could have disastrous ecological consequences. The World Health
11 Organization core principles require that all personnel associated with financing and supporting
12 health-care activities should provide for the costs of managing healthcare waste. This is the duty
13 of care. The World Health Organization places the responsibility for genotoxic waste on the chief
14 pharmacist and further states that the chief pharmacist also has the special responsibility of
15 ensuring that genotoxic products are used safely, and that genotoxic waste is managed safely.

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

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

29 (6) The federal Occupational Safety and Health Administration ("OSHA") is the main
30 federal agency charged with the enforcement of safety and health legislation. OSHA, in concert
31 with the National Institute for Occupational Safety and Health ("NIOSH") and the Joint
32 Commission on Healthcare, an independent, not-for-profit organization that accredits and certifies
33 more than twenty thousand (20,000) health care organizations and programs in the United States,
34 stated in a 2011 letter to every hospital in the country that "[e]very day in healthcare settings

1 across America, workers are exposed to hundreds of powerful drugs used for cancer
2 chemotherapy, antiviral treatments, hormone regimens and other therapies. While these drugs are
3 used to relieve and heal patients, many of them present serious hazards to the health and safety of
4 your workers. Some of these drugs have been known to cause cancer; reproductive and
5 developmental problems, allergic reactions, and other adverse effects that can be irreversible even
6 after low-level exposures."

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

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

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

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

26 (2) Provide a sufficient collection method so that providers and patients can safely collect
27 and contain extremely hazardous excretions for a period of time as determined by the United
28 States Food and Drug Administration ("FDA") and referenced on the relevant FDA prescription
29 insert(s); and

30 (3) Provide for safe and proper disposal of said collected extremely hazardous excretions.

31 (d) Consistent with the core principles of the World Health Organization for achieving
32 safe and sustainable management of healthcare waste, all personnel associated with financing and
33 supporting healthcare activities should provide for the costs of managing the healthcare waste
34 identified in this chapter.

1 (e) Receipt of notice from the party administering chemotherapy drugs or their agent
2 responsible for proper disposal of the hazardous wastes by the prescribing pharmacist or chief
3 pharmacist shall satisfy the responsibility of the prescribing pharmacist hereunder.

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

10 SECTION 6. This act shall take effect on September 1, 2015.

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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 This act would take effect on September 1, 2015.

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