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

IN GENERAL ASSEMBLY

JANUARY SESSION, A.D. 2015

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:

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

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

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

cancer.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

pharmacist shall satisfy the responsibility of the prescribing pharmacist hereunder.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

SECTION 6. 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

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

This act would take effect on September 1, 2015.

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