AP&S | ADLER POLLOCK & SHEEHAN P.C.

Memorandum

To: **Jim Mullowney**
From: **Kristen W. Sherman, Esq.**
Date: **November 17, 2011**
Re: **Rhode Island Regulation of Cytotoxic Drugs under the Rhode Island Groundwater Protection Act and Groundwater Quality Rules**[1]

You have asked us to examine whether the discharge of cytotoxic (chemotherapy) drugs into health care facility and provider wastewater streams is prohibited by the Rhode Island Groundwater Protection Act of 1985, R.I. Gen. L. § 46-13.1-1 et seq. ("Groundwater Act"), and/or the Rhode Island Department of Environmental Management's ("RIDEM") Groundwater Quality Rules (the "Groundwater Rules"). As detailed below, there is a strong argument that discharging wastewater containing cytotoxic chemicals is contrary to both the letter and spirit of the state's groundwater regulation scheme.[2] Indeed, the Groundwater Act and the Groundwater Rules can both be interpreted to impose an affirmative duty on hospitals and other providers to take steps to prevent any such potentially harmful discharges.

Overview of the Law

Both the Groundwater Protection Act and the Groundwater Rules recognize the need to protect groundwater as a "critical renewable resource" to insure "the availability of safe and potable drinking water for present and future needs"[3] To protect the drinking water supplies, it is imperative to protect the aquifers, recharge areas and watersheds.[4] Accordingly, the Legislature has made it an express state policy to "restore, enhance and maintain" the quality of state waters, including groundwater, in order to protect human health, fish and aquatic life, and scenic and ecological values of the water.[5] To this end, it is against public policy to introduce any "pollutants" into the groundwater in concentrations that are known to be toxic, carcinogenic, mutagenic or teratogenic.[6]

In addition to protecting the groundwater from further degradation, it is further the policy of the state to restore groundwater quality. Indeed, to the "maximum extent practicable" RIDEM

[1] To the extent that Pharma-Cycle, Inc. discloses the contents of this Memorandum, such disclosure shall not be deemed to waive the attorney-client privilege in any respect.
[2] For purposes of this memorandum, it is assumed that it can be shown that cytotoxic chemicals can and do pass through wastewater treatment systems into groundwater and then into the water supply.
[3] R.I. Gen. L. §46-13.1-2(2); Groundwater Rules at §6.1.2.
[4] R.I. Gen. L. §46-13.1-2(3); Groundwater Rules at §6.1.3.
[5] R.I. Gen. L. §46-13.1-2(1); Groundwater Rules at §6.1.1.
[6] R.I. Gen. L. §46-13.1-2(5); Groundwater Rules at §6.1.5.

directs that efforts must be made to remove pollutants from discharges that have already occurred.[7]

The Groundwater Rules implement the aforementioned policies by prohibiting any person from either causing or allowing the discharge of any "pollutant" to groundwater.[8] Similarly, it is a violation of the Groundwater Rules to operate or maintain a facility in a manner that "may result in a discharge of any pollutant to groundwater . . . ."[9] A "facility" is any parcel or contiguous parcels of real estate that constitutes a distinct geographic unit.[10] The definition of a "pollutant" is extremely broad and includes "*any* material or effluent which may alter the chemical, physical, biological, or radiological characteristics and/or integrity of water" and includes "chemical wastes."[11]

Under the Groundwater Rules, RIDEM can issue an immediate compliance order where a suspected violation has occurred.[12] Each day that the alleged violation continues is considered a separate violation.[13] In addition, there is the potential for civil penalties of up to $25,000 per day and/or imprisonment for violations.[14]

Analysis

Based on the aforementioned language, there is a strong argument that hospitals and other chemotherapy treatment providers should not be discharging waste containing chemotherapy chemicals where such chemicals have the potential to end up in the groundwater and, ultimately, the drinking water supply. There can be no serious dispute that these cytotoxic chemicals that pass through the body are regulated "pollutants" within the meaning of the Groundwater Rules because of their potential to alter the chemical and physical characteristics of water, as well as its integrity for drinking water purposes. These chemicals not only impair the integrity of the water, but also pose a significant threat to human health. Indeed, in an April 4, 2011 letter from The Joint Commission, NIOSH and OSHA recognized that some of these pharmaceuticals are "known to cause cancer, reproductive and developmental problems, allergic reactions, and other adverse effects that can be irreversible even after low-level exposures." These effects are particularly concerning for sensitive populations such as children and the unborn. Therefore, any conduct that causes the discharge of cytotoxic chemotherapy drugs into the groundwater is prohibited.

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[7] R.I. Gen.L. §46-13.1-2(5); Groundwater Rules at §6.1.5.
[8] Groundwater Rules at §8.2.
[9] Groundwater Rules at §8.3.
[10] Groundwater Rules at §7 (Definition of "facility").
[11] Groundwater Rules at §7 (Definition of "pollutant") (emphasis supplied).
[12] Groundwater Rules at § 20.1.
[13] Groundwater Rules at § 20.2.
[14] Although the Groundwater Act and Groundwater Rules do not expressly provide for penalties, the protections under the Water Pollution Act, R.I. Gen. L. §46-12-1 et seq,, extend to groundwater. See R.I. Gen. L. §46-12-28 (groundwater is considered among the waters of the state that are regulated under the Water Pollution Act). It is presumed that penalty provisions of the Water Pollution Act, R.I. Gen. L. §§ 46-12-13 to -14, would be extended to groundwater violations.

The Groundwater Rules not only prohibit health care facilities and other providers from affirmative conduct that causes a discharge of cytotoxins where they may enter groundwater, but also arguably imposes upon such facilities the duty to act to prevent such discharges.[15] Indeed, the Rhode Island courts have not hesitated to impose liability where a failure to act leads to actual or threatened environmental harm. See Power Test Realty Ltd. Partnership v. Sullivan, No. 10-0404, 2011 WL 3957619 (R.I. Super. September 1, 2011). Therefore, where one has knowledge that cytotoxic chemotherapy drugs are being discharged where into groundwater, there is arguably a duty to take action to prevent the discharge.

It is noteworthy that the prohibitions in the Groundwater Rules do not expressly require proof of harm or evidence of an exceedance of any threshold level of contaminants in groundwater to apply. Rather, the Groundwater Rules flatly prohibit operating a facility in a manner that "may" result in the discharge of pollutants to groundwater.[16] In short, it need only be shown that there is the potential for a discharge of pollutants to groundwater for the regulatory obligations to attach.

Conclusion

Based on the foregoing, hospitals and other health care providers that administer chemotherapy treatments should carefully examine their options for managing their wastewater where there is even the potential that cytotoxic chemical residues might enter the wastewater and ultimately end up in groundwater. Both the letter and the spirit of the law evince a strong public policy in favor of protecting and punishing both actual and threatened groundwater pollution by broadly regulating the discharge of "pollutants." In view of the significant penalties for non-compliance, let alone the potential health effects to our most vulnerable citizens, hospitals and other providers of chemotherapy should give serious consideration to implementing measures to prevent such discharges before they enter the wastewater stream.

[15] Groundwater Rules at §8.2 ("No person shall cause or allow a discharge of any pollutant to groundwater.") (emphasis supplied).
[16] Groundwater Rules at §8.3.