

**Healthcare
Department
Partners**

For further information on the Healthcare group or this update, please contact one of our partners:

Thomas M. Fahey, Chair
312.977.4376
tmfahey@uhlaw.com

Steven F. Banghart, Partner
312.977.4880
sbanghart@uhlaw.com

James Broeking, Partner
312.977.4109
jbroeking@uhlaw.com

Edward Clancy, Partner
312.977.4487
eclancy@uhlaw.com

John J. Durso, Partner
312.977.4440
jdurso@uhlaw.com

Lynn Gordon, Partner
312.977.4134
lgordon@uhlaw.com

Joseph K. Hasson, Partner
312.977.4437
jkhasson@uhlaw.com

Floyd D. Perkins, Partner
312.977.4411
fdperkins@uhlaw.com

Julie K. Seymour, Partner
312.977.4353
jkseymour@uhlaw.com

Julie E. Treumann, Partner
312.977.4145
jtreumann@uhlaw.com

Sam Vinson, Partner
312.977.4388
svinson@uhlaw.com

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Healthcare Update

Environmental Law Developments Affecting the Healthcare Sector

This client alert is being sent to apprise you of some important developments in the area of environmental law relating to the healthcare sector. These developments include a new Illinois state law regulating the disposal of unused medications, a recent enforcement development in the healthcare sector, an upcoming pharmaceutical waste rule that is expected to be finalized this year, and a mandatory greenhouse gas reporting rule that took effect on January 1 of this year.

Illinois Safe Pharmaceutical Disposal Act

The Illinois Safe Pharmaceutical Disposal Act ("SPDA") took effect January 1, 2010. The legislation was passed in response to widespread concern about the presence of pharmaceutical substances in drinking water supplies. Under the SPDA, public and private healthcare institutions (such as hospitals, nursing homes and hospice programs) and their employees, staff and contractors are prohibited from disposing of unused medications into public sewer systems or septic tanks. "Unused medication" means any unopened, expired or excess medication that has been dispensed for patient or resident care and that is in a solid form (e.g., pills, tablets, capsules and caplets). There are two exceptions: healthcare institutions may still flush medications contained in IV fluids, syringes or transdermal patches, and long-term care facilities may flush Schedule II controlled substances. Each violation of the Act is subject to a \$500 fine. The SPDA also mandates that healthcare institutions modify written medication protocols to be consistent with the requirements of the Act.

When complying with the SPDA, facilities will need to take care that their actions do not violate other regulatory requirements. For instance, unused medications which are hazardous wastes under the Resource Conservation and Recovery Act and analogous state laws must be segregated and properly managed under the hazardous waste regulations. Also, the Drug Enforcement Administration ("DEA") rules under the Controlled Substances Act may affect how facilities treat medications covered under that Act. The DEA rules governing the handling and disposal of controlled substances are different for non-registrants (such as nursing homes) and registrants (such as hospitals). Other considerations may come into play as well. Healthcare institutions will need to keep this complex matrix of statutory and regulatory requirements in mind when modifying their medication protocols to be consistent with the Act.

Increased EPA Enforcement of Hazardous Waste Regulations at Healthcare Facilities

In August 2009, the United States Environmental Protection Agency (EPA) announced that it had entered into an agreement to settle violations of hazardous waste rules which it had noted during inspections of VA hospitals in Leavenworth and Topeka in January and April 2006. The settlement grew out of a complaint filed by the United States Department of Justice in federal district court against the United States Department of Veterans Affairs Eastern Kansas Health Care System alleging failure to perform hazardous waste determinations, operation of a hazardous waste treatment, storage, and disposal facility without a permit, offering hazardous waste for shipment to a transporter without a manifest, and offering hazardous waste for shipment to an unregistered transporter. As part of the settlement, the Eastern Kansas Health Care System agreed to pay fines totaling over \$51,000 and to spend over \$480,000 on a supplemental environmental project to develop and implement a program to properly identify and manage its pharmaceutical and chemical wastes at the two hospitals.

The violations that the VA hospitals were cited for are not uncommon for healthcare facilities. Just a few months earlier, a hospital in Merriam, Kansas paid over \$80,000 to settle similar waste

violations. The hazardous waste rules are targeted more toward industrial facilities with relatively few sources of waste arising from industrial processes. But the rules also apply to healthcare facilities, where any number of locations can be the source of hazardous wastes in the form of discarded pharmaceuticals or chemicals. A key factor in avoiding noncompliance is putting an effective system in place so that facility personnel know how to identify, segregate and manage these wastes. The management systems available can be cost effective to implement. In addition, if violations are identified through a voluntary program to audit current operations and develop management practices, then the healthcare facility may self-report those violations to EPA and obtain up to a 100% reduction in fines and penalties.

Proposed EPA Pharmaceutical Waste Rule

EPA recognizes that the healthcare sector has understandable difficulties in complying with the current waste rules. Accordingly, the Agency has been working for more than a year to finalize a new rule designed to facilitate the management of pharmaceutical wastes at healthcare facilities. For a more detailed discussion of the pharmaceutical waste rulemaking, please see our previously-published article at http://www.uhlaw.com/2010_pharma_waste_rule/. EPA is expected to finalize this rule in 2010. As the rule is currently drafted, if a healthcare facility has a hazardous waste management program in place, it will have the option to keep using its current system or adopt new practices to conform to the new rules. Facilities that do not have a current management system in place should take note of one of EPA's stated purposes for the rulemaking: to alert the healthcare sector to the need to properly manage wastes so that healthcare facilities are aware of the Agency's expectations that they will comply with the rules. It is anticipated that once the rule is finalized, enforcement actions at affected facilities may increase.

Greenhouse Gas Reporting Rule

Finally, large healthcare facilities should also be aware of a new mandatory greenhouse gas reporting rule that went into effect on January 1, 2010. This rule is largely targeted at the energy and heavy industrial sectors, but it includes a "catchall" provision. If the aggregate maximum rated heat input capacity of the stationary fuel combustion units (such as boilers) at the facility is 30 mmBtu/hour or greater, then the facility will need to calculate its emissions of carbon dioxide equivalent gases. If that calculation determines that the facility emits 25,000 metric tons of carbon dioxide equivalent gases per year, then the facility will be subject to the reporting rule and will have to report those emissions to EPA. It is possible that some large healthcare facilities may fall within the purview of this rule. For more information about this rule, see our Energy, Clean Technologies, and Climate Change Group's article posted online at http://www.uhlaw.com/epa_final_ghg_rule/.

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We would be pleased to assist you with any questions you may have regarding these or other environmental issues. If you would like to know more, contact **Stephen Armstrong** (312-977-4479) or **Timothy Ramsey** (312-977-4428) in our Environmental Practice Group.

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Ungaretti & Harris' Healthcare Department remains devoted to meeting the changing needs of the healthcare industry. Our firm of 100-plus lawyers devotes a substantial portion of its firm-wide practice to the legal needs of healthcare providers and other related clients.

CHICAGO
3500 Three First National Plaza
70 W. Madison Street
Chicago, IL 60602
312.977.4400
312.977.4405 fax

SPRINGFIELD
400 East Jefferson Street
Suite 1200
Springfield, IL 62701
217.544.7000
217.544.7950 fax

WASHINGTON
1500 K Street, NW
Suite 250
Washington, DC 20005
202.639.7500
202.639.7505 fax