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In Good Health – January 2005

Business Journal of Central New York – December 10, 2004

EPA Health Care Enforcement Initiative A Word to the Wise

by Wendy Marsh, Esq.

The U.S. Environmental Protection Agency (USEPA) through its Region II office, which includes New York State, announced its Hospital Environmental Compliance Initiative nearly two years ago, in December 2002. Since targeting hospitals, over thirty hospitals have entered into Voluntary Self-Audit Agreements with USEPA, including two-thirds of the hospitals in the greater Rochester area. Additionally, USEPA has continued to aggressively enforce environmental laws, collecting penalties ranging from \$73,562 to \$214,420 for hazardous waste violations by New York hospitals in 2004.

Many hospitals have made the tactical decision to perform a self-audit without entering into an audit agreement with USEPA. There are risks involved with entering into the Audit with USEPA, as New York State Department of Environmental Conservation (NYSDEC) is not a party to the Agreement, although it is the agency responsible for implementing many of the environmental programs in the State. While the NYSDEC receives the results of such audit, it is not bound to waive any penalties for violations identified. Regardless of whether a hospital chooses to enter into an Agreement or perform a self-audit, such formal audits should be conducted, and it is very likely that some violations will be uncovered that must be addressed.

Environmental compliance is complex, but not unattainable. One problem is that hospitals use a large number of chemicals and typically have no gatekeeper to assess the waste disposal consequences of newly ordered chemicals. Because the applicability of hazardous waste regulations depends on the amount generated each month, these decisions can occasionally have a disproportionate effect on the facility's bottom line.

While most hospitals are familiar with the management and disposal of regulated medical waste and the red bag requirements, the identification and management of "hazardous waste" is an entirely different matter. Certain wastes, determined by either their characteristics or by specific definition, are considered "hazardous waste" and must be managed appropriately. A review of the Material Safety Data Sheets (MSDSs) for raw chemicals is insufficient to appropriately categorize a waste for disposal. Of USEPA penalties listed above, the most significant resulted from improper management of hazardous waste.

A potential area of concern is the disposal of liquid wastes in laboratory sinks. While it is common practice for many laboratories to dispose of wastes by diluting and pouring them down the drain, many of these materials may be classified as hazardous waste. Xylene, a common component of many laboratory solutions, is a hazardous material requiring special treatment. Similarly, many controlled substances are destroyed by sink disposal without any assessment as to whether or not such controlled substances are hazardous waste. Hospitals must identify all regulated hazardous wastes and manage them in accordance with applicable requirements.

Additionally, a common solution for handling expired or outdated pharmaceutical products is the so-called “reverse distribution” contract. Hospitals contract with an entity that collects pharmaceutical products, returns products to manufacturers for refund where possible, and disposes of the remainder, some of which is disposed as hazardous waste.

Hospitals participating in reverse distribution arrangements should carefully review their contracts to determine who is responsible for the management of the hazardous waste, and whether the hospital remains liable for any mismanagement by the reverse distributor. Additionally, USEPA has not yet formally clarified the regulatory liability between the hospital and the reverse distributor as to the responsibility for the hazardous waste.

In conclusion, environmental compliance is an important element in any hospital compliance program. Regulatory scrutiny is continuing. Self-audit agreements can be advantageous for some hospitals, while others may choose to review compliance without entering into an agreement with the government. Whichever path a facility chooses, this much is clear: the time to act is now, before USEPA and NYSDEC come knocking.

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