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Biomedical Waste Regulation in Florida

The term "biomedical waste" conjures up images of needles washing up on the shores of New Jersey or Florida. But biomedical waste, referred to simply as "medical waste" in many other states, includes any potentially infectious waste generated by the medical industry, and its management, treatment, and disposal are increasingly important to Floridians. Florida generates approximately 50,000 tons of biomedical waste each year.¹ Ninety-two percent of that amount is generated by hospitals and physicians, and the remainder by nursing homes, veterinarians, laboratories, dentists, and others.² This waste must be treated to remove its infectious character before it can be disposed. Recently Florida has taken significant strides toward the safe regulation of biomedical waste.

Background

Biomedical waste is defined in Florida as "any solid or liquid waste which may present a threat of infection to humans."³ The term, formerly referred to as "biohazardous waste," includes human tissue and body parts, human blood and blood products, and human body fluids.⁴ The term also includes discarded disposable "sharps," such as needles, scalpels, and blades that are capable of breaking the skin when handled, and also includes laboratory waste and veterinary waste that contain human-disease-causing agents.⁵ The potential threat to human health from infection is the aspect of biomedical waste that is regulated. Otherwise, biomedical waste is merely solid waste and, unless mixed with hazardous materials, typically shares nothing in common with "hazardous waste," which is subject to more stringent regulation.

The legislature has developed a comprehensive regulation of biomedical waste to protect public health from the threat of infection via the management, treatment, and disposal of biomedical waste

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Because of the potential for the spread of infection, the management of biomedical waste is specifically regulated under Florida Statutes. Before 1988, the Department of Environmental Regulation (DER) minimally regulated such waste as "infectious waste." The Solid Waste Act of 1988 substantially revised the regulation of this waste.⁶ This revision was followed by incidents in New Jersey and northwest Florida where needles were observed washing up on the beaches. First, the legislature renamed the waste "biohazardous waste."⁷ Second, the Department of Health and Rehabilitative Services (HRS) was given joint regulatory authority with DER, which later was merged with the Department of Natural Resources, to form the current De-

partment of Environmental Protection (DEP). The legislature directed these two agencies to coordinate regulation and enforcement through an inter-agency agreement and to adopt rules regulating biomedical waste management.⁸

The Regulatory Framework

The 1988 Legislature divided the regulation of biomedical waste between DER and HRS based upon whether the regulated management was "onsite" or "offsite." "Onsite" activity takes place at the generating facility.⁹ As of 1996, HRS has authority to regulate onsite packaging, storage, treatment, and disposal of biomedical waste. DEP regulates the transport and all offsite management of the waste. DEP also has authority over both onsite and offsite biomedical waste incinerators. In 1989, DEP was directed to implement a system for tracking the amounts and disposition of biomedical waste.¹⁰ Both HRS and DEP have adopted rules to implement their statutory mandates.¹¹

All biomedical waste generators generating greater than 25 pounds per month must receive an annual permit from HRS.¹² Biomedical waste is typically treated to remove its infectious potential before it is disposed. There are several standard methods of treatment: Incineration, steam treatment, and chemical disinfection are most common. Treatment may take place either onsite or offsite. Many hospitals have their own onsite treatment facilities, but several, like smaller generators, contract with transporters to haul the waste to an offsite facility, typically an autoclave or incinerator. The generator is required to segregate sharps into impenetrable containers, and all biomedical waste must be placed in red bags which meet national American Society of Test-

ing and Materials standards.¹³ These bags must bear the international biohazard symbol and be prominently labelled as "biomedical waste."¹⁴ In order to track the waste, containers must be labelled to identify the generating facility, and quantities must be weighed at the generator and upon arrival at the treatment facility.¹⁵ Transporters must register annually with DEP.¹⁶ Storage is allowed onsite for a maximum of 30 days or at a permitted storage facility.¹⁷

Treatment facilities, whether onsite or offsite, must undergo testing upon startup and every 40 hours of operation in order to demonstrate effectiveness at disinfecting the waste.¹⁸ Standards for efficacy of treatment are set by HRS rules, which specify types and numbers of organisms which must be killed by the treatment process. A demonstration of efficacy is achieved by a Log 4 kill (99.99%) of the specified test organisms.¹⁹

Trade Secrets

Because Florida generates over 50,000 tons of potentially infectious biomedical waste each year, protection of trade secret information is important to companies who design and sell products to remove the threat of infection from that waste. Protection of these trade secrets encourages the development of new products which reduce the threat from this waste. Trade secret information is submitted to HRS and DEP, which review such information in the exercise of their respective regulatory authority.

Florida has a very broad public records law found in F.S. Ch. 119, which preserves the public's access to state records. F.S. §403.73 provides for protection from disclosure of trade secret information submitted to DEP with regard to solid waste disposal including biomedical waste. The person submitting trade secret information must request that DEP keep the information confidential and explain the basis for the claim of trade secret. DEP in turn, subject to notice and opportunity for hearing, must determine whether the information claimed to be a trade secret is or is not a trade secret.

When the Florida Legislature in 1988 delegated to HRS the regulation of biomedical waste at generating facilities, it did not expressly extend the trade secret provision in DEP's enabling statute to HRS. Thus, a "glitch" existed that

arguably would have permitted information submitted to the DEP and HRS to be protected by DEP but not HRS. DEP and HRS work closely together regarding the regulation of biomedical waste and through an interagency agreement ensure maximum efficiency in coordinating, administering, and regulating biomedical waste. In order to carry out their respective duties, the agencies must share trade secret information and retain the confidentiality of the information received. In recognition of this glitch, the 1995 Florida Legislature created F.S. §381.83, which provides an exemption from disclosure for records, reports, or information obtained by HRS related to biomedical waste. The legislature also conformed F.S. §403.73 to make it virtually identical to F.S. §381.83.

The trade secrets and confidentiality provision found at F.S. §381.83 provide that records or information obtained from any person is available to the public except upon a showing satisfactory to HRS by the person from whom the information is obtained that such

records or parts thereof contain trade secrets as defined in F.S. §812.081(1)(c).²⁰ Any such trade secrets are confidential and exempt from disclosure under art. I, §119.07(1) and §24(a) of the Florida Constitution. When submitting such information to the HRS, the person must request it be kept confidential and inform the HRS of the basis of the claim of trade secret. HRS then, subject to notice and opportunity for a hearing, must determine whether the information claimed to be a trade secret is or is not. The trade secret may be disclosed to authorized representatives of HRS or to other governmental entities for them to perform their duties, but such authorized representatives or other governmental entities must keep such information confidential. Anyone involved in a proceeding to determine the confidentiality, including the hearing officer, judge, or justice, must retain the confidentiality of any trade secret information revealed at the proceeding. F.S. §381.83.

In passing the trade secret amendment, the legislature determined that



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it was a public necessity that trade secret information obtained by HRS as well as DEP be held confidential and exempt. Otherwise, companies that produce waste treatment and disposal processes for biomedical waste might be hesitant to develop and market new products in Florida, to the detriment of the public. Such companies would have little incentive to invest and create new treatment formulas or processes if a competitor could gain access to the information and reap benefits from that company's trade secrets. The House of Representatives Committee on Governmental Operations found that, "[P]rotection of such trade secrets would encourage, for example, the creation of innovative, potentially more effective treatment processes and thereby promote the public health and safety."²¹ Conforming the trade secrets laws of HRS to those of DEP has benefited the public in the manner intended by the legislature and will enable further development and utilization of biomedical waste alternative treatment and disposal products in the State of Florida, thereby reducing the potential for infection and environmental problems.

Alternatives

Recent changes have occurred in the methods and technology of treatment of biomedical waste. The traditional method of dealing with biomedical waste has been incineration. Under that method, waste is packaged in red bags, marked "biomedical waste," and transported to an incineration facility, where it is burned to destroy any infectious agents which may be present. Tighter regulation of incinerators under the Clean Air Act Amendments of 1990 has made this method more expensive, contributing to increasing health care costs. Moreover, the packaging and transportation of the waste to the incineration facility increases the time during which a person may become exposed to the infectious agents, including hospital or other generator staff.²² Indeed, the Florida Legislature, responding to public concern over biomedical waste incineration, in 1992 enacted a moratorium on the construction of any new biomedical waste incinerators in the state.²³ The moratorium was set to expire in October 1994, but in 1994 the legislature extended the moratorium until October 1, 1996.²⁴ The

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moratorium was not extended by the 1996 Legislature and will expire on that date.

As an alternative to incineration, many new treatment methods and products have been developed that render biomedical waste noninfectious at or near the point of generation. The treatment technologies include micro-waving, chemical disinfection, and solidification. These technologies are typically designed to be used onsite at the generating facility. Some are designed to be mobile, enabling them to travel to several generating facilities to perform onsite treatment, avoiding the need to transport the waste to a treatment facility. New products such as disposable surgical clothing are designed to "dissolve" in water.²⁵ Increased use of these products should protect the health of all persons who may come into contact with the waste after it is generated, including waste handlers at the hospital or other generating facility, by reducing the amount of handling needed prior to treatment of the waste.

The 1996 Legislature recognized the shift in biomedical waste regulation toward a focus on protection of health with the passage of CS/HB 153. The legislature, along with HRS and DEP, saw an opportunity to streamline government and avoid duplicative regulation, through the combination of functions under one agency. CS/HB 153 consolidates most of the regulation of biomedical waste within HRS, without compromising the protection of the public health.

Overall, CS/HB 153 shifts the primary regulatory responsibility for bio-

medical waste from DEP to HRS,²⁶ and essentially eliminates the onsite versus offsite distinction present in the statutes since 1988. First, the legislation transfers the registration and regulation of transporters of biomedical waste from DEP to HRS. HRS is given permitting authority over all generators, storage facilities, and treatment facilities, except for incinerators. Permits for incinerators will continue to be issued by DEP, whether they are onsite or offsite. HRS permits are limited to five years in duration and a maximum fee of \$400. HRS is authorized to streamline permitting by combining permits for generating facilities which also treat or store biomedical waste. The legislation also engrafts the procedure for transfer of storage and treatment permits from the DEP statutes.²⁷ HRS may also develop a simplified permitting procedure for public sharps collection programs.

CS/HB 153 clarifies that HRS has the exclusive authority to establish efficacy standards for the treatment of biomedical waste. Because of the expertise of HRS in health-related regulation, DEP had in practice adopted the HRS standards into its rules, although it was not required to do so.²⁸ The legislation also transfers authority to HRS to implement a system of tracking biomedical waste from the generator to the treatment or incineration facility.²⁹

DEP retains authority to regulate environmental impacts of treatment or disposal, if any. CS/HB 153 also requires HRS and DEP to create an inter-agency agreement under which DEP may continue to issue permits for offsite treatment facilities. Under the agreement, HRS will review the permits to be issued by DEP for matters within its jurisdiction, such as treatment efficacy, the permits will be consolidated with other DEP-issued permits where possible for the purpose of streamlining, and the two agencies will consolidate inspections to avoid duplication. Finally, the legislation removes most references to biomedical waste in F.S. Ch. 403, except those dealing with incineration. A public notice provision upon application to construct or renovate a biomedical waste incinerator remains in the law.

Under CS/HB 153, HRS and DEP will engage in rulemaking to effect the transfer of the appropriate DEP rules to HRS. Rules of each department will

