Region 1 of the United States Environmental Protection Agency (EPA), the region that includes Connecticut, will soon launch a program for encouraging "voluntary compliance" with environmental laws and regulations by hospitals and other health care institutions in its geographical domain.

Several years ago Region 1 set the stage by instituting a voluntary self-audit program for colleges and universities. More recently EPA’s Region 2, the region that includes New York and New Jersey, undertook a similar program, the "Health Care Institutions Compliance Initiative," which has received much attention in the environmental and health-care press. Although Region 2’s program was limited to hospitals, and Region 1 has not announced the full extent of its anticipated program, the use of the words "health care institutions" clearly suggests that other entities that share environmental issues with hospitals, such as nursing homes, may be targeted and therefore should be alert to these developments.

Part of a National Program to Encourage Voluntary Compliance

These programs result from EPA’s national voluntary disclosure program under which entities report their compliance problems to the agency before EPA compels them to do so. By signing an agreement to enter the program, the health care facility commits both to identify and to correct compliance violations before those violations otherwise come to EPA’s attention. The "carrot" EPA holds out for such disclosure is the opportunity for the health care institution to reduce or altogether avoid penalties EPA would impose if the agency discovers the violations before the voluntary disclosure. Failure by a health care facility to enter the voluntary audit and disclosure program could draw EPA attention to the facility, resulting in EPA’s inspection of the facility and its issuance of notices of violation and requests for civil penalties.

EPA has expressed concern about health care institution attention to mercury, dioxin, and other persistent, bioaccumulative toxics (PBTs) in the environment. Hospitals constitute the fourth largest source of mercury discharged into the environment. Hospitals also generate a wide variety of hazardous waste, such as chemotherapy and antineoplastic chemicals, solvents, formaldehyde, photographic chemicals, radionuclides, and waste anesthetic gases. In addition, hospitals produce 2 million tons of solid waste, which comprises 1% of the total municipal solid waste in the United States. The laws and regulations covered by the voluntary disclosure program comprehend all the "media" governed by EPA: i.e., emissions to air, water and land. These include EPA requirements with regard to wastewater discharges, oil spill prevention, hazardous waste management, underground storage tanks, pesticides, polychlorinated biphenyls (PCBs), asbestos, lead-based paint, biomedical waste, and chemical reporting and community "right-to-know."

The Region 2 Experience

Recognizing that since 1995 it had issued over one million dollars in penalties to hospitals for air, toxic substances, and
EPA's Health Care Institutions Compliance Initiative

A message to Hospitals: “Report on Compliance or Face Inspections and Potential Fines”

water violations, EPA Region 2 began its program with a December 27, 2002 letter to more than 400 hospital presidents and CEOs. As of the end of January, 2003, more than a dozen hospitals in New York and New Jersey had signed Voluntary Audit Agreements with EPA Region 2. In April 2003, EPA started to inspect hospitals that had not yet signed voluntary audit agreements. Region 2 appears to have inspected about ten hospitals in the New York metropolitan area, with others currently scheduled for inspection. On November 25, 2003, Region 2 announced a $64,349 penalty against Atlantic Health System, Inc, owner and operator of Mountainside Hospital in Montclair, New Jersey, citing the hospital for numerous violations of hazardous waste management requirements. Similarly, on January 27, 2004, EPA issued a press release announcing a $214,000 penalty against New York City’s Sloan-Kettering Cancer Center for violations of numerous hazardous waste management requirements. Region 2 issued its largest fine arising out of the program so far, $279,000, to Nassau Healthcare in Long Island in October, 2003, following the discovery of alleged violations of both federal and state hazardous waste regulations during a facility inspection earlier that year.

The Region 1 Approach

Rather than utilizing Region 2’s broadside approach with notice to the hundreds of hospitals under its jurisdiction, Region 1 may adopt a more deliberate approach, picking and choosing the health care facilities it will solicit to enter the program. Nonetheless, EPA Region 1’s voluntary compliance program will have significant implications for health care facilities in Connecticut and elsewhere in New England. Connecticut facilities that have taken advantage of financing from the Connecticut Health Education Facilities Authority (CHEFA) will have particularly noticeable vulnerability. CHEFA financing policies have required these hospitals to conduct environmental compliance audits and Phase I environmental site assessments. Reports from these audits and assessments may already disclose existing violations of environmental laws and contain recommendations for bringing the institution into compliance. These reports may provide fodder to aggressive EPA enforcement personnel who could interpret an institution’s failure to take remedial action to correct known violations as new “knowing violations” which subject the violator to more serious penalties.

Hospitals and other health care institutions that already have corporate compliance programs in place or have made voluntary disclosure s to the Medicare/Medicaid program about billing issues will find the concept of EPA’s voluntary disclosure program familiar. They may view the new EPA program as a logical extension of these existing compliance efforts.

Wiggin and Dana as a Resource

The environmental lawyers in the Real Estate, Environmental, and Land Use practice group at Wiggin and Dana are familiar with the significant issues driving EPA’s Health Care Institutions Compliance Initiative. They have extensive environmental compliance audit experience, including helping clients meet CHEFA’s compliance audit requirements mentioned above. Typically, we retain environmental consulting firms to conduct the actual audit with our oversight and review. We also have conducted environmental and structural diligence in transactions involving medical/hospital and pharmaceutical properties and are familiar with the EPA academic institution audit program undertaken by EPA Region 3 (Pennsylvania and the mid-Atlantic region). Our “hands-on” audit experience includes advising industrial clients on multi-media compliance issues, structuring and implementing responses to complex and invasive EPA multi-media audits, drafting guidance documents for clients to use in developing internal audit programs, and working on the substantive elements of environmental compliance software. Our experience in regulatory compliance and permitting for air emissions, waste water discharges, and solid waste treatment, storage, and disposal provides an important complement to our background in the audit arena.

Our extensive audit experience with commercial and industrial operations, combined with our in-depth knowledge of health care institutions drawn from years in the field will enable us to provide broad-based counseling to clients in the context of a Health Care Institution Compliance Initiative Audit.

If you have any questions about this message, please contact Bruce McDermott in our New Haven office at 203.498.4340, bmcdermott@wiggin.com, or Barry Trilling in our Stamford office at 203.363.7670, btrilling@wiggin.com.