

## Environment Alert

September 23, 2016

### **EPA IG's Concerns About Oversight of Hospital Disinfectants Reinforces Need for Robust Infection Control Programs**

On September 19, 2016, the Inspector General (IG) for the Environmental Protection Agency (EPA) issued the latest in a long line of reports identifying flaws in EPA's process for ensuring the efficacy of hospital-grade, hard-surface disinfectants. The IG concluded that EPA's Antimicrobial Testing Program (ATP) "does not assure that hospital disinfectant products continue to be effective after they are registered" and that some products listed as effective on EPA's ATP website "could now be ineffective" due to inconsistencies in distributor products, product degradation or improper quality assurance. EPA IG, *EPA Needs a Risk-Based Strategy to Assure Continued Effectiveness of Hospital-Level Disinfectants*, Report No. 16-P-0316 (Sept. 19, 2016) ("[2016 IG Report](#)"). These products are critical components of hospitals' infection control programs, which are designed to prevent hospital-acquired infections (HAIs) among patients and staff. The report's findings suggest that hospitals and other health care facilities should use diligence in selecting cleaning products, avoid overreliance on chemical disinfectants and tuberculocides alone, and develop robust infection control protocols in order to minimize the risk of increased HAI rates among patients and staff, and the concomitant legal exposure and reimbursement consequences.

The 2016 IG Report focuses on hospital-grade disinfectants and tuberculocides used for hard-surface disinfection, and does not apply to chemical sterilants used on critical and semicritical devices, which are regulated by the Food and Drug Administration (FDA) under a separate regime. Under federal pesticide law, companies must conduct extensive premarket testing to ensure that hard-surface disinfectants and tuberculocides comply with federal safety standards and demonstrate efficacy against all pathogens identified on the label. EPA reviews this health and efficacy data, along with other supporting documentation and labeling, and limits market entry to only those products and uses that meet federal standards. Approved products are granted "registrations" that stipulate allowed uses, conditions for use, and required labeling.

EPA initiated the ATP in 1991, following an August 1990 General Accounting Office (GAO) report concluding that up to 20 percent of disinfectants on the market were ineffective and that EPA lacked a system to ensure the efficacy of these products. GAO, *Disinfectants: EPA Lacks Assurance They Work*, GAO/RCED-90-139 (Aug. 1990). The ATP was to serve as a complement to the premarket registration process, determining, through independent laboratory evaluations, whether hospital disinfectants and tuberculocides were formulated correctly and continued to meet applicable efficacy standards once on the market. Significantly, however, the program has struggled over time. A 2010 EPA IG report concluded that, "after nearly 19 years, over 40 percent of registered products have not been tested . . . [and] those that have been tested have experienced a consistently high failure rate." *EPA IG, Evaluation Report: EPA*

*Needs to Assure Effectiveness of Antimicrobial Pesticide Products, Report No. 11-P-0029* (Dec. 15, 2010).

Now, the 2016 IG Report comes just months after EPA announced that it had completed its review of the majority of registered hospital disinfectants and tuberculocidal products, and had prepared a list of products for use by users in making informed choices regarding infection control in their facilities. EPA, *The Antimicrobial Testing Program: Hospital Disinfectant and Tuberculocidal Products Tested or Pending Testing* (July 1, 2016). The 2016 IG Report raises new questions about the reliability of this list, however, noting that, “[s]ince the EPA only tests products once, there could be products listed as effective on the agency’s website that were tested several years ago but could now be ineffective.”

For hospitals and other health care facilities, the key takeaway of the 2016 IG Report is that they should exercise and document independent diligence in selecting and using chemical disinfectants and tuberculocides for hard-surface disinfection and that effective disinfection control regimes may benefit from the use of multiple products, as well as nonchemical disinfection protocols. Having an active infection prevention and control program is a key Condition of Participation (CoP) under Medicare. Although, in general, the CoP rules allow hospitals flexibility in aligning their programs with nationally recognized practices and guidelines, hospitals are expected to use EPA-registered disinfectants. Moreover, federal regulators are proposing to strengthen the infection control CoP and heighten the role and accountability of a hospital’s governing body in program implementation and oversight. As hospitals assess the effectiveness of their infection control programs, the 2016 IG Report suggests that hospitals may not necessarily want to rely on EPA registration alone.

Ensuring the effectiveness of a disinfection control regime is also particularly important, given the high cost, in terms of staff and patient safety, institutional legal liability and reduced reimbursement, of HAIs. In that regard, a 2009 report by the Centers for Disease Control estimated the overall annual direct medical cost of HAIs to U.S. hospitals to be between \$28.4 billion and \$33.8 billion in 2007 dollars, or between \$16,359 and \$19,430 per case. R. Douglas Scott II, CDC, *The Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention* (Mar. 2009). Tort or malpractice litigation can increase these costs significantly. Furthermore, federal health care programs like Medicare are penalizing hospitals with high rates of HAIs through various incentive programs designed to improve quality and cut down on waste. For instance, hospitals with high HAI rates in a given year could see a 1 percent reduction in Medicare inpatient rates under the Hospital Acquired Conditions program, which includes a number of infection-related measures. High HAI rates could also materially impact a hospital’s performance score under the Medicare Hospital Value-Based Purchasing program, which now carries penalties of up to 2 percent. Finally, even if the financial consequences of HAIs do not materially impact a hospital’s bottom line, there are certainly reputational consequences for institutions with high HAI rates, since federal and nonfederal transparency initiatives are publishing more data that differentiate between “high-quality” and “low-quality” providers.

If you have any questions about the 2016 IG Report or infection control programs, or about assessing the overall effectiveness of your EPA compliance program and training, please let us know.

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