
Disposing of Pharmaceutical Waste: Some Progress

By William J. Walsh / Jan 22, 2013

In 2008, the U.S. Environmental Protection Agency (EPA) seemed to be on the road to providing some much-needed clarity to the health care industry concerning the disposal of pharmaceuticals by proposing that hazardous waste pharmaceuticals be handled as Universal Wastes (a simpler regulatory regime that would improve proper disposal). Five years later, new waste management standards for hazardous waste pharmaceuticals (albeit only from health care facilities) are under development, with a proposal anticipated to be published for public comment in August 2013. Meanwhile, in the absence of clear federal guidance, states have adopted a variety of policies; for example, Kansas, Florida and Michigan require some form of best management practices for nonhazardous pharmaceuticals (through exemptions, policies or guidance and with differences in the details).

Part of the confusion about the proper disposal method for pharmaceutical waste is due to the fact that the U.S. Drug Enforcement Administration (DEA) regulates controlled substances (which have the added concern that these “drugs” may be diverted to illegal use). In late December 2012, DEA (after consultation with EPA) issued a proposed rule that allows ultimate users to deliver the controlled substances to a third party, expands the list of those who can collect unwanted controlled substances (beyond law enforcement officials), and allows the disposal of commingled pharmaceutical waste and controlled substances (a more cost-effective approach). This proposal will establish three voluntary options: (a) a take-back event; (b) mail-back programs; and (c) collection receptacles at law enforcement offices, retail pharmacies, and long-term health care facilities. Hospitals without retail pharmacies are not permitted to be “collectors” under the proposed rule, possibly leaving a void for community and critical access hospitals.

There is also some progress in determining the degree to which pharmaceutical chemicals have already been released in the environment (*e.g.*, approximately 81 pharmaceutical chemicals have been found in drinking water at miniscule concentrations (part-per-trillion levels). Disparate federal agencies (EPA, the U.S. Department of Agriculture, the U.S. Food and Drug Administration, and the United States Geological Survey) now are working together to improve the monitoring of pharmaceuticals in drinking water (in both ground and surface water). However, the toughest task is still ahead – deciding whether and at what concentration to regulate these chemicals. According to EPA’s Deputy Administrator Robert Perciasepe, action to limit discharges from sewage plants is likely years away and may involve actions that differ from the traditional regulatory command and control approach.

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This article was originally published as a Pepper Hamilton LLP client alert.