

DRUGS AND THE DEA

How New Regulations May Impact Your Hospital

By Charlotte A. Smith, RPh, MS



The abuse of prescription drugs, particularly controlled substances regulated by the Drug Enforcement Administration (DEA) as “drugs of abuse,” has reached epidemic proportions, exceeding that of traditional illicit drugs in all cases except marijuana.¹ Many of these drugs are obtained not from shadowy drug dealers on street corners but from the medicine cabinets of parents and grandparents. Due to the “closed loop” nature of the current Controlled Substances Act, these drugs cannot be returned to a pharmacy or other healthcare provider but must be delivered directly to law enforcement. Community take-back programs must have a law enforcement officer present to receive the controlled substances, making these events more costly and difficult to organize. For the short term, DEA has responded to the need to remove these drugs from the market by establishing bi-annual “take back days,” usually in the fall and spring.² Seeking a long-term solution, Congress passed the Safe and Responsible Drug Disposal Act of 2010³ that amends the Controlled Substances Act to enable additional methods for the management and disposal of unwanted consumer-controlled substances. DEA was charged with writing the specific

regulations under the Act and published its “notice of proposed rulemaking” on December 21, 2012. Interested parties were asked to comment by February 19, 2013. According to the DEA Diversion website,⁴ “The proposed regulations contain specific provisions that:

- Continue to allow law enforcement agencies to voluntarily conduct take-back events, administer mail-back programs, and maintain collection boxes;
- Allow authorized manufacturers, distributors, reverse distributors, and retail pharmacies to voluntarily administer mail-back programs and maintain collection boxes; and
- Allow authorized retail pharmacies to voluntarily maintain collection boxes at long-term care facilities.”

So how does this proposed regulation impact your hospital environment? Interestingly enough, DEA chose this opportunity to clarify, and in some cases tighten, rules for disposal of controlled substances within healthcare settings, including hospitals and long-term care facilities (LTCFs). While these proposed regulations are not yet finalized, it’s important to understand what has been proposed. The challenge in the hospital setting is to balance concerns about diversion by staff and visitors with DEA, EPA, and other regulatory requirements.

With respect to community take-back events, it’s not clear whether a hospital may offer a public take-back event, as some

have in the past. What is clear is that a retail pharmacy located within a hospital may have a kiosk located within the pharmacy itself, but a hospital may not offer a kiosk in any other area. DEA’s reasoning is that the pharmacy is a more controlled environment under the close supervision of pharmacists and staff. DEA anticipates the retail pharmacy will ship the controlled substances to a reverse distributor for eventual destruction.

Of special interest to hospitals will be the proposed regulations regarding the destruction of unused controlled substances generated during patient care. For example, DEA proposes that the destruction of a controlled substance, such as occurs routinely by nurses, be documented on a DEA Form 41. This form, even if modified, is a paper document and would require the signatures of two nurses or other healthcare professionals. Currently, such “double witness” documentation is performed electronically through the automated dispensing machine, such as Pyxis, Omnicell, etc. Requiring a paper format would be incredibly cumbersome and would eliminate the automated checks and balances in the current system. In addition, the proposed regulations require such witnesses of destruction to be “authorized employees” who are working as full-time employees. In today’s healthcare environment, both pharmacists and nurses are often part-time or working from a professional pool.

Of even more concern is DEA’s proposed standard of destruction—non-retrievable—which reads as follows: “‘non-retrievable’ means to permanently

¹www.deadiversion.usdoj.gov/fed_regs/rules/2012/fr1221_8.htm

²The next DEA Take-Back Day will be held October 26th, 2013, from 10 am to 2 pm. www.deadiversion.usdoj.gov/drug_disposal/takeback/

³www.gpo.gov/fdsys/pkg/PLAW-111publ273/pdf/PLAW-111publ273.pdf

⁴www.justice.gov/dea/divisions/hq/2012/hq122612.shtml

Of special interest to hospitals will be the proposed regulations regarding the destruction of unused controlled substances generated during patient care.

alter any controlled substance's physical and/or chemical state through irreversible means in order to render that controlled substance unavailable and unusable for all practical purposes." Incineration and chemical digestion are cited as examples of qualifying technologies. While DEA is well-intentioned by not requiring a particular method of destruction, by not defining more specific parameters, inventors and entrepreneurs who DEA expects to create alternatives will be left in limbo as to what constitutes non-retrievable. Likewise, hospitals and other healthcare facilities will be unsure what current and future systems should be used to comply with the regulations. This ambiguous situation is made even more urgent by an earlier statement in the proposed regulations that "Flushing and mixing controlled substances with coffee grounds or cat litter are examples of existing methods of destruction that do not meet the non-retrievable standard." While we can all appreciate that flushing is the least desirable method from an environmental perspective, it would certainly render the drugs non-retrievable "for all practical purposes" as required by the proposed regulations.

In the past, the director of pharmacy would request a blanket approval for destruction for controlled substances within the hospital. In the proposed regulation, the DEA Special Agent In Charge may authorize blanket approval for disposal but periodic reports would need to be filed and the controlled substances delivered to a reverse distributor. This process seems to contradict the concept of rendering the controlled substances non-retrievable at the facility.

There are two additional areas that have not been addressed in the new regulations that are important to hospitals. The first involves how to handle controlled substances brought in by patients if the drugs cannot be returned to the patient upon discharge. Currently, some hospitals send these drugs to a reverse distributor, although the drugs are technically already out of the closed loop, or the hospital may

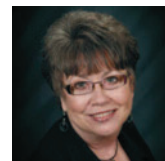
dispose of the drugs themselves with two witnesses, through either sewerage, solidification, or some other method. Hopefully DEA will provide a clear avenue for the management of these abandoned drugs in the final regulations.

The second area of great concern to hospitals is how to dispose of used fentanyl patches, which still contain enough drug to be attractive to those seeking such drugs and to be a poisoning risk to visitors, especially small children. Many hospitals currently have nurses fold the patches up and cut them into smaller pieces, then dispose the patches into a restricted entry red sharps or pharmaceutical waste container. Nurses should be trained never to dispose of the used patches in either the trash or the redbag waste for both diversion and safety reasons.

A number of healthcare organizations now include LTCF, assisted living, and independent living units as part of their overall corporate structure. Disposal of controlled substances in LTCFs is very specifically addressed in the proposed regulations. The new regulations enable LTCF provider pharmacies to place drug return kiosks at the LTCF for the collection of controlled substances and perhaps other drugs. Only pharmacy personnel may access and remove the inner containers. Two full-time pharmacy employees must be present to access and remove the collected drugs and return them to the pharmacy, where they will presumably be shipped to a reverse distributor for additional processing and eventual destruction. There is no requirement that provider pharmacies offer this service, however, and there are no other alternatives provided to LTCFs. Again, this well-intentioned plan may work at a majority of LTCFs, but alternatives should be available if needed. There is also no discussion of the cost of these programs and who will bear that cost. The proposed regulations are also silent with respect to disposal options for assisted living arrangements where caregivers manage medication administration and disposal. The assumption may be made

that those residing in independent living situations would be able to dispose of their own medications through community take-back events or the new retail options. We know this is not always the case, however.

Many organizations and associations, including the American Hospital Association, have offered their thoughts and suggestions during the 60-day response period. Hopefully DEA will take these ideas under consideration as the final rule is prepared. Regardless, it will be very important that the management teams at each hospital carefully review the final rule since it will most likely contain important changes for controlled substance management. From the viewpoint of environmental service professionals, you and your employees are the first line of defense if controlled substances are disposed of inappropriately in the trash or even as redbag waste. Ensure your employees are completely informed of your hospital's pharmaceutical waste management program and encourage them to be constantly aware of any inappropriate disposal practices. Only by constant vigilance will any program of this complexity and importance succeed. And stay tuned for the final regulations implementing the amended Controlled Substances Act. These regulations will impact us all! ●



Charlotte Smith is a consultant in the area of pharmaceutical waste management and Senior Regulatory Advisor, PharmEcology

Services, a business unit of Waste Management Healthcare Solutions, Inc. (WMHS), a Waste Management company. She founded PharmEcology Associates, LLC in 2000 and sold the company to WMHS in 2009. She co-founded Capital Returns, Inc., a nationally known pharmaceutical reverse distributor in 1991 and for 10 years served as president and chief regulatory advisor. She can be reached at 414-915-4026 or at charlottesmith12@gmail.com.

This paper is solely for educational purposes and provides only a general description of various regulatory requirements. For a complete description, please consult the relevant federal and state regulatory statutes. Nothing in this paper constitutes legal advice and you should not legally rely on any information provided in this presentation. We make no warranty, express or implied, with respect to such information and disclaim all liability resulting from any use or reliance of this information.