



POSITION STATEMENT

Disposal of Pharmaceuticals in Long-Term Care Facilities (LTCF)

Position

Consultant Pharmacists should advise on and direct the management and disposal of pharmaceuticals in long-term care facilities.

Background

Disposal of pharmaceuticals poses a serious risk to public health. This risk is exacerbated in long-term care settings where large volumes of dispensed pharmaceuticals may be discontinued or abandoned as frequent medication changes and resident discharges are common. Pharmaceuticals to be disposed of pose a threat to the community through diversion and to the environment through improper disposal. Proper management and disposal of unused pharmaceuticals can help to prevent the illegal diversion of controlled substances, protect the water supply, and reduce costs.

Research by the Environmental Protection Agency (EPA) and Associated Press indicates that the amount of medical waste generated by health care facilities and the amounts of pharmaceutical ingredients appearing in US watersheds are increasing. In September 2008, the Associated Press estimated that U. S. hospitals and long-term care facilities annually generate at least 250 million pounds of waste that includes both pharmaceuticals and contaminated packaging.¹ Unused pharmaceuticals are handled by these facilities in a wide variety of ways, including reverse distribution, return to stock and reuse, flushing into the wastewater system, disposal in landfills, and incineration. This problem is compounded by a lack of coordination between federal, state and local agencies on how best to handle pharmaceuticals to be disposed resulting in a web of conflicting regulations and confusion for pharmacies and long-term care facilities. Consultant Pharmacists are uniquely positioned to provide the necessary support and guidance to facilities on how to handle unused pharmaceuticals.

Arguments and Research

At least four federal agencies have become involved in the management of pharmaceutical waste. The Drug Enforcement Administration (DEA), Centers for Medicare and Medicaid Services (CMS), EPA, and the Food and Drug Administration (FDA) all differ in their specifications for how unused pharmaceuticals should be handled.

Under DEA policies, The Secure and Responsible Drug Disposal Act of 2010 granted the Attorney General the authority to develop regulations outlining the disposal of controlled pharmaceutical waste.² On

September 8, 2014 the DEA made public The Disposal Act, the final rule regarding the disposal of controlled pharmaceutical substances. The Disposal Act amended the Controlled Substances Act (CSA) to give the DEA authority to promulgate new regulations within the framework of the CSA that will allow ultimate users to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion. The Disposal Act enabled the use of an “authorized collection receptacle” located at the facility, managed and maintained by an authorized retail pharmacy or on-site pharmacy at a LTCF. The additional costs, licensing, and complex rules included in providing authorized collection receptacles have been a hindrance to universal implementation of this alternative. Those LTCFs that do not have a collection receptacle may use any of the disposal options afforded to other ultimate users.³

Issued in 2011 and effective January 1, 2013, CMS has regulations for pharmacies who service Medicare beneficiaries residing in nursing facilities to reduce pharmaceutical waste by limiting dispensing of oral, solid, brand-name medications to 14-day supplies.⁴

On August 21, 2019, the EPA’s new regulations became effective under Part 266 Subpart P for the management of hazardous waste pharmaceuticals by healthcare facilities, which now encompasses certain long-term care facilities. The operating standards include a prohibition on sewerage hazardous waste pharmaceuticals.⁵ The rule establishes new regulations for the identification and management of hazardous waste pharmaceuticals.

The FDA’s guidance is solely consumer-focused and follows on the DEA’s recommendations for end users to dispose of controlled drugs through drug take-back sites or events, household trash, or to follow any guidance regarding flushing as stated on the manufacturers’ product information. This guidance is of limited effectiveness due to the sewer disposal prohibition and for the quantities of unused medications that long-term care facilities handle.⁶

Along with the aforementioned federal oversight, Consultant Pharmacists need to be cognizant of various state-specific regulations that have an effect on disposal of pharmaceuticals. In recognition of the benefit of reducing days-supply of dispensed medications in reducing pharmaceutical waste, some states have authorized the use of automated dispensing systems (ADS) located within the LTCF that allow for just-in-time medication dispensing and essentially reduces unused medications to zero. Pharmacies have also employed ADS technology at the pharmacy level to provide flexibility in dispensing shorter days-supply of medication. Additionally, various state EPA agencies maintain their own lists of regulated medical waste that need to be considered during disposal practices.

To meet these multiple regulatory requirements, nursing facilities must work with Consultant Pharmacists to develop and evaluate their pharmaceutical handling procedures, including packaging, delivery, storage, administration and disposal. Any approach to reducing pharmaceutical waste must consider the nursing facility’s regulatory obligations and the paramount need to safely and efficiently manage medications for its residents.

References

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