FACILITY DISPOSAL OF USED FENTANYL PATCHES

The drug fentanyl is a powerful, schedule II narcotic used to manage moderate to severe pain. Although available in oral (buccal) dosage forms, it is most commonly used in the form of an extended-release transdermal patch which confers pain relief to individuals over a 72-hour period. Customarily, the patch is applied externally to the individual, left intact for 72 hours, and then replaced with a new patch. The old patch is then disposed-of. Although a used patch may have been used for a 72-hour period, it will often still contain a significant amount of medication and thus present a risk of accidental exposure and opportunity for diversion, especially if disposed-of improperly. Janssen Pharmaceuticals is the manufacturer of Duragesic (brand of fentanyl), but there are several generic forms of fentanyl as well.

Over recent months, concerns have arisen concerning incidents of accidental exposure to discarded fentanyl patches. A number of the incidents resulted in the death of young children who were accompanying families visiting loved ones in nursing homes. Most of the incidents were directly related to staff having improperly disposed-of the used patches (e.g., throwing them in open trash cans, leaving them on bedside tables, leaving them stuck on bedside rails, etc.). There have likely been other occasions of disoriented residents inadvertently removing their patches and throwing them on the floor, etc. Thus, various groups (including FDA, DEA, ISMP, CMS and others) have expressed concerns over inappropriate disposal methods.

Traditionally, facilities have employed various methods for disposal of their used fentanyl patches. Some facilities have incorporated the used patches with their other unusable controlled substances, adding inert material such as sand, sawdust, or cat litter to render the mixture “unusable”, then disposing through their regular garbage. Other facilities have utilized a sharps container for disposal of the used patches. Most facilities have followed FDA and manufacturer recommendations (specifications) by flushing the used patches into the sewer system. However, it has been reported that a number of facilities have been told by EPA (The Environmental Protection Agency) to cease flushing the medications because of the potential negative effects to the water system and environment.

Neither CMS nor OIG may dictate what method a facility uses for disposal of its used fentanyl patches in particular, or for the disposal of its unusable controlled substances in general. OIG expects each LTCF to develop and implement its own policy regarding the disposition of discontinued, expired or unusable controlled substances. The policy must be compatible with any existing local, State, or Federal laws, regulations, or ordinances. Facilities should also consider the following points in deciding upon its policy:

- To be an effective policy, it must maximize safety, security and accountability, and thereby minimizing the risk for accidental exposure and opportunity for diversion.
- OIG has learned that there are currently no specific regulations (from EPA or others) that prohibit waste such as used fentanyl patches from disposal by flushing. However, flushing does
pose a potential risk to our environment and water system, and disposal via a contained landfill or incineration would probably be a better alternative.

- Both the FDA and the drug manufacturer recommend that used fentanyl patches should be immediately flushed following removal. Indeed, the EPA in its consumer document titled “How to Dispose of Medications Properly” instructs that consumers “Do not flush expired or unwanted prescription or over-the-counter drugs down the toilet or drain unless the label or accompanying patient information specifically instructs you to do so”.

- The EPA does approve of the “general” disposal of unwanted controlled substances by placing the drugs in a leak-proof receptacle, then rendering the resultant mixture “unusable” by adding a sufficient amount of inert substance (sand, cat litter, sawdust, etc.). The container could then be thrown out with the facility’s regular garbage.

- OIG agrees that the use of a designated sharps container would be an acceptable method for disposal of unused fentanyl patches. A leak-proof sharps container maintained under locked security located within a medication cart would be appropriate for that purpose. However, the use of sharps containers located within individual resident rooms or other common areas of the facility should not be used for that purpose. Once the sharps container is filled to capacity, it may be removed from the cart, but must continue to be securely stored until such time as all sharps containers and other bio-hazardous waste are picked-up for destruction.

- Regardless of the disposal method, it is suggested that two staff members be involved in the disposal and documentation of the used patches. Moreover, it would be a “best practice” check the patch placement for all applicable residents on a per-shift basis.

When surveying the nursing home environment, surveyors are encouraged to be especially vigilant to observe resident rooms (and other areas) for the inappropriate disposal of used fentanyl patches (e.g., disposal in trash cans, dropping them on the floor, leaving on bedside tables, or attached to bedside rails). Such observations may lead to a citation under F 323.