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November 8, 2010

Ms. Megan Hessenauer
Engineering and Analyst Division (4303T)
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington D.C. 20460

Submitted electronically to unusedpharms@epa.gov

Re: Best Management Practices for Unused Pharmaceuticals at Health Care Facilities

Federal Register Docket Number 2010-22325

Dear Ms. Hessenauer:

The American Nurses Association (ANA) welcomes the opportunity to offer comments on the draft guidance document "Best Management Practices for Unused Pharmaceuticals at Health Care Facilities".

The ANA is the only full-service professional organization representing the interests of the nation's 3.1 million registered nurses, the single largest group of healthcare professionals in the United States. We represent registered nurses in all roles and practice settings, through our constituent member nurses associations and organizational affiliates. Nurses have an interest in the Best Management Practices for Unused Pharmaceuticals at Health Care Facilities since the goals, strategies and measurements it outlines will directly affect and improve human health. ANA is actively involved in forming public policy that affects human health and patient advocacy, and has long recognized that a clean, safe environment is a fundamental requirement for ensuring and maintaining the health of our patients, our families, and our communities.

ANA is actively working with federal agencies and local partners to understand the implications of emerging contaminants such as pharmaceuticals, endocrine-disrupting chemicals, and personal care products detected in drinking water, wastewater, surface water, and groundwater. These are fundamental requirements for ensuring and maintaining the health of our patients, our families, and our communities.

ANA applauds the EPA's efforts to increase its work to better understand pharmaceutical waste in the health care facilities. The "Guidance Document: Best Management Practices for Unused Pharmaceuticals at Health Care Facilities" is an excellent resource to help to clarify this complex issue and guide health care facilities to reduce the amount of pharmaceutical waste being discharged into bodies of water.

1.1 About this Best Management Practices (BMPs) Guidance Document

The reference to “doctor’s offices” should be changed to “office based settings”. For consistency, the abbreviation of “Best Management Practices (BMP)” should be (BMPs) as is referenced in other parts of the document.

The target audience for the document is not well defined. It would be helpful to define for whom the document is intended.

1.2 Background

The science behind the need to focus on the health risks and environmental damage created by improper disposal of unused pharmaceutical waste is only superficially mentioned in the background. Providing additional study findings will strengthen the case for the need of proper disposal of unused pharmaceuticals by health care facilities.

2. Conduct An Inventory of Pharmaceuticals and Unused Pharmaceuticals

This is an important section in understanding the origin of the unused pharmaceuticals. The timeframe for assessing in two weeks to one month appears to be a short timeframe. Consider a longer period of assessing the unused pharmaceuticals or a guideline linked to the size and/or type of facility. Depending on the size of the facility, a longer time frame would be needed to properly assess the inventory and the status of unused pharmaceuticals.

2.2 Identify the Unused Pharmaceuticals Generated and How They Are Currently Managed

It would be more helpful and complete if the wording is “identification of current disposal methods” rather than “where the waste goes”.

For many years, healthcare facilities have been disposing of unused pharmaceuticals by flushing them to sewers. Flushing unused drugs has been a primary means of disposal because it is easy and accessible if there is no access to a hazardous waste hauler. The practice of flushing or other practices which do not follow the best management practices (BMPs) have been used for a long time without technically violating the law; most patients consider this action normal and harmless. Incineration is another method that may be current practice in facilities as well. If the environmental impact is delineated, this can help to motivate the changes needed.

3. Reducing or Avoiding Unused Pharmaceuticals

ANA recommends listing “Eliminating” first in the title as it is preferable to eliminate unused pharmaceuticals from the waste stream. An example of the cost saving opportunity would be helpful in building a business case for pharmaceutical waste management.

4. Identifying & Managing Types of Unused Pharmaceutical and Applicable Disposal Regulations

This section provides an excellent overview of regulation and managing different types of pharmaceuticals. Figure 1 and Table 3 are particularly helpful as well as the listing of hazardous and non-hazardous waste.

A facility must meet federal and state requirements for managing unused pharmaceutical waste. Among others, the statutes enforced by federal agencies affecting this area include the Controlled Substance Act (CSA); the Resource Conservation and Recovery Act (RCRA); and the Health Insurance Portability and Accountability Act (HIPAA). Healthcare facilities are required to follow implementing regulations under these laws, along with meeting other obligations mandated by state and local governments.

BMPs recommend the use of reverse distributors, private companies that provide a service to the health care industry by keeping the track of unused pharmaceuticals. The reverse distributor determines which medication may be returned to manufacturers or wholesalers and arranges for disposal of unused medication that are unused medication that constitutes waste. At the moment, some private hospitals, clinics, veterinary offices, are using reverse distributors to manage their disposal.

Regulations vary widely from one state to another; some waste regulations are more stringent than EPA's. For instance, under the Resource Conservation and Recovery Act (RCRA), some wastes are not regulated as hazards even though the same substances are identified as hazardous in the state of California. Also, many states allow reuse of uncontaminated pharmaceuticals (excluding controlled substances). California allows county health departments to collect unused pharmaceuticals from long-term facilities, wholesalers, and manufacturers to redistribute them to the uninsured poor. The wide range of levels of expertise, education, information and training at each facility is an issue; professional expertise in environmental health will require solving the puzzle at healthcare facilities on low budgets in order to implement BMP's successfully.

5.2 Training Staff in Proper Disposal Methods

Training of staff is critical to the success for a pharmaceutical waste management program. It would be helpful to provide a minimum time for training and suggested content for initial training. Although the draft document does include the

need for revised and updated training, no specific time frame is offered. Consider including a specific timeframe for refresher training.

Signage is a separate issue from training. Consider a separate category devoted to signage.

This section on training also includes periodic pharmaceutical stock inventory auditing. Auditing is important content but it is co-mingled with training. Consider a separate heading under program sustainability.

Additional Comments

EPA is currently gathering information on current practices at healthcare facilities where BMP's have been successfully implemented, with the goal of applying findings to other facilities in the future. If possible, facility type specific information such as long term care facilities, community practice sites, home health or other setting specific information would be helpful to the user of this guidance document.

When handling specific types of pharmaceuticals, it would be necessary to utilize proper personal protective equipment. ANA recommends the inclusion and reminder of the importance of proper protection when handling pharmaceuticals.

The document does not address any particular caution when disposing of unused pharmaceuticals that would include a sharp such as a prefilled syringe. The document should include recommendations for handling of such products to ensure safety of those disposing of the pharmaceutical and those handling the waste generated.

If possible, the inclusion of any tools to help to estimate cost savings would be helpful in determining the benefits of this program.

The inclusion of an index of terms used in the document would be helpful to those in the target audience that are unfamiliar with pharmaceutical waste terminology.

Conclusion

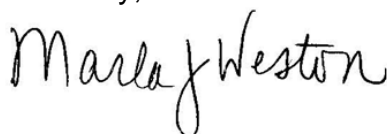
ANA recommends that EPA work closely with healthcare facilities and registered nurses in the United States to track, eliminate, reduce, manage and dispose of unused pharmaceutical waste in an environmentally safe manner.

It is important to ensure not only the safety of the patients and health care professionals working with pharmaceutical waste, but also of the environment and public health. Most healthcare facilities have increasing involvement and responsibility to ensure safety with hazardous and non-hazardous pharmaceuticals. ANA supports the implementation of BMPs in healthcare facilities.

ANA appreciates the opportunity to comment on the guidance document "Best Management Practices for Unused Pharmaceuticals at Health Care Facilities".

If you have any questions or comments, or if we can be of further assistance, please feel free to contact Jose Cardenas, Senior Policy Fellow, Center for Occupational and Environmental Health at jose.cardenas@ana.org or (301) 628-5138.

Sincerely,

A handwritten signature in black ink that reads "Marla J. Weston". The signature is written in a cursive, flowing style.

Marla J. Weston, PhD, RN
Chief Executive Officer

cc: Karen A. Daley, PhD, MPH, RN, FAAN