NACWA
A Clear Commitment to America's Waters

November 10, 2008

Attn: Docket ID EPA-HQ-OW-2008-0517
Water Docket
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001
Submitted via: www.regulations.gov

Dear Sir or Madam:

These comments are submitted on behalf of the National Association of Clean Water Agencies (NACWA) regarding the proposed Information Collection Request (ICR) for the Study of Unused Pharmaceuticals from Medical and Veterinary Facilities ("Study"). NACWA represents the interests of nearly 300 publicly owned wastewater treatment works (POTWs) nationwide. NACWA's members serve the majority of the sewered population in the United States, and collectively treat and reclaim more than 18 billion gallons of wastewater each day. NACWA members are engaged in the issue of pharmaceutical disposal practices through collection and take-back programs, as well as through a NACWA-led effort to develop an action plan for the water sector to deal with issues associated with pharmaceuticals in the environment.

NACWA supports the ICR and EPA's work to collect data on pharmaceutical disposal practices in health care facilities. NACWA members are concerned about pharmaceuticals that are discharged to the sewer system and end up at wastewater treatment plants. Evidence indicates that endocrine-disrupting compounds in pharmaceuticals and other sources can affect aquatic life. NACWA believes that pollution prevention efforts and source control can most effectively and reliably reduce the amount of pharmaceuticals entering the sewer system, and believes this ICR and subsequent study will shed light on such opportunities, as well as potentially new strategies, for reducing the discharge of pharmaceuticals from these facilities.

The information that EPA collects through its Study should shed light on how unused pharmaceuticals are currently disposed of by health care facilities. Although EPA is collecting this information as part of its detailed study of the Health Services Industry for the Effluent Guidelines Program, NACWA believes that health care facilities currently receive conflicting guidance on how to handle unused pharmaceuticals, and establishing effluent guidelines is not the most

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effective way to reduce the amount of unused pharmaceuticals entering the wastewater stream. Instead, the federal government should provide consistent guidance on proper pharmaceutical handling and break down existing regulatory barriers to pharmaceutical collection and take-back programs.

Flushing unused pharmaceuticals down the toilet was long a recommended practice, and is still recommended for certain drugs in federal guidelines issued by the White House Office of National Drug Control Policy (ONDCP) in February 2007. While the guidelines were developed by ONDCP in partnership with EPA, the recommendation to flush certain drugs is inconsistent with EPA's goals of reducing pharmaceuticals in the environment. This is just one example of how the information collected with this Study could be used to work with other federal agencies in developing clear, consistent guidelines or best management practices for disposal of unused pharmaceuticals. These guidelines should also extend to domestic use of pharmaceuticals, which may be another major source of pharmaceuticals that end up in the sewer.

The comments below are NACWA's suggestions for improving the questionnaires that EPA will distribute to health care facilities for this Study. Also, suggested wording and formatting changes for the questionnaires are attached.

Facilities Surveyed

EPA is considering distribution of questionnaires to hospitals, long-term care facilities, medical and dental offices, university and prison health clinics, and veterinary hospitals. NACWA recommends that all of these types of facilities be included in the survey, to develop a broad understanding of drug disposal practices. Although some types of facilities may handle only small quantities of pharmaceuticals, proper disposal practices are still important. As part of this survey or in the future, EPA should also include entities that are not considered health care facilities but may still handle pharmaceuticals, such as police and law enforcement centers with confiscated drugs, coroner and medical examiner offices, and research and development laboratories.

Completion Time for Questionnaire

The questionnaire is lengthy and requests information that a facility may not have available (e.g., annual data for 2007). If a facility does not already have annual data, time will be needed to put mechanisms in place for gathering and recording the data. Therefore, EPA should consider giving facilities up to 90 days, instead of 60 days, to complete the questionnaire.

NACWA appreciates the opportunity to comment on this ICR. If you have any questions, please contact me at 202/296-9836 or *cfinley@nacwa.org*.

Sincerely,

Cynthia A. Finley
Director, Regulatory Affairs

Attachment

Suggestions for Survey Format and Questions

The suggestions below are changes to the wording or formatting of the questionnaire for facilities that treat people. The same suggestions generally apply to the questionnaire for facilities that treat animals, although the question and table numbers may be different. These suggested changes are minor, but should be considered in order to make the questionnaire as clear and consistent as possible.

- The page numbers of the questionnaire should be changed to 1 of X, 2 of X, etc., with no pages i, ii, etc. and no letters associated with the attachment page numbers. The questionnaire may be divided and completed by different people, as suggested on page ii, and the current numbering system is confusing. A table of contents should be included show the various sections and attachments of the questionnaire.
- In the third paragraph of page ii, "e.g., Director of Nursing or Medical Director" should be changed to "e.g., Head Pharmacist, Director of Nursing or a Medical Director" to match Question A-4.
- Question A-6: Revise the wording of the options under "Hospital" to "General Medical and/or Surgical" and "Psychiatric and/or Substance Abuse."
- Question A-11: Add the option, "With patient/resident."
- Questions A-12 and A-13: Clarify the word "dose," since some medications may have multiple active ingredients.
- Questions A-15 through A-17: Provide examples of "special disposal" in addition to "hazardous waste." Facilities may be able to answer these questions more accurately if the term "special disposal" is better defined.
- Question A-18: This question does not ask for an annual quantity, only percentages, while Questions A-12 and A-13 ask for annual quantities. Question A-18 should also ask for annual quantities, or at least an estimate of quantities, to provide the most useful information to EPA.
- Table A-2, Question A-18, and Table A-3, Question A-20: Consider eliminating the management practice, "Returned directly to onsite *facility* pharmacy." Pharmaceuticals returned to the onsite pharmacy are still at the facility, and EPA should be interested in the ultimate disposal method that takes the pharmaceuticals outside of the facility. In addition, percentage symbols should be provided in each box of Table A-2, as is done in Table A-3.
- Question A-21: Table 1 in Attachment A is mentioned in this question as an alternative for a facility that does not have records available, and the question seems to indicate that Table 1 is different than the example Table A-4. However, the information in these two Tables is identical. The wording of the question should be clarified.
- Table A-4, Question A-21: Provide a note in the "Pharmaceutical Classification" column heading about the AHFS Classification (as is done in Table 1, Attachment A), with an asterisk referring to the footnote at the end of the table.
- Question A-24: Eliminate "Unknown" as an option for this question. If the person completing the survey does not know, they should be able to find the answer without too much effort.
- Question A-27: Include an option for trash/landfill disposal, which may be the easiest option for facilities to choose.
- Question A-28: Add "Local requirements" as an option.
- Question B-1: Facilities may have different definitions for full time and part time employees. A note should be added to this question if EPA wants the facility to use the 35-hours/week delineation currently given in the question, or if the facility should provide their own delineation.
- Table 1, Attachment B: Add the word "continued" in the table title, since this table is spread over multiple pages.