U.S. ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF INSPECTOR GENERAL

Pollution Prevention

Follow-Up Report: EPA Proposes to Streamline the Review, Management and Disposal of Hazardous Waste Pharmaceuticals

Report No. 15-P-0260 **August 19, 2015**

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Abbreviations

EPA	U.S. Environmental Protection Agency
OIG	Office of Inspector General
OMB	Office of Management and Budget
OSWER	Office of Solid Waste Emergency Response
RCRA	Resource Conservation and Recovery Act

Cover photo: Disposable pharmaceutical waste item. (EPA photo)

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U.S. Environmental Protection Agency
Office of Inspector General

15-P-0260
August 19, 2015

At a Glance

Why We Did This Review

We assessed the U.S. Environmental Protection Agency's (EPA's) actions to address Recommendations 1 and 2 in Office of Inspector General (OIG) Report No. 12-P-0508, *EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal,* issued May 25, 2012. The Assistant Administrator for the Office of Solid Waste and Emergency Response (OSWER) was the action official responsible for ensuring the completion of corrective actions. EPA's information systems reported that OSWER completed corrective actions for the two recommendations.

This report addresses the following EPA goals or cross-agency strategies:

- *Ensuring the safety of chemicals and preventing pollution.*
- *Protecting America's waters.*

Send all inquiries to our public affairs office at (202) 566-2391 or visit www.epa.gov/oig.

The full report is at: www.epa.gov/oig/reports/2015/20150819-15-P-0260.pdf

Follow-Up Report: EPA Proposes to Streamline the Review, Management and Disposal of Hazardous Waste Pharmaceuticals

What We Found

OSWER corrective actions meet the intent of OIG recommendations to review new and existing pharmaceuticals that may qualify as hazardous waste. In our prior report:

- Recommendation 1 required OSWER to identify and review existing pharmaceuticals to determine whether they qualify for regulation as hazardous waste.
- Recommendation 2 required OSWER to establish a process to review new pharmaceuticals to determine whether they qualify for regulation as hazardous waste.

EPA states that it intends to issue a proposed rule, *Management Standards for Hazardous Waste*, which will attempt to streamline the approach to managing and disposing of hazardous and nonhazardous pharmaceutical waste.

A third recommendation required OSWER to develop a nationally consistent outreach and compliance assistance plan to help states address challenges that health care facilities, and others as needed, have in complying with Resource Conservation and Recovery Act regulations for managing hazardous waste pharmaceuticals. This recommendation is open with corrective action pending.

In March 2015, OSWER submitted a proposed rule to the Office of Management and Budget that requests comments on the approaches to review new and existing pharmaceuticals as well as the management and disposal of hazardous waste pharmaceuticals. Therefore, we make no recommendations, and this report is closed upon issuance.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

THE INSPECTOR GENERAL

August 19, 2015

MEMORANDUM

SUBJECT: Follow-Up Report: EPA Proposes to Streamline the Review, Management and Disposal of Hazardous Waste Pharmaceuticals
Report No. 15-P-0260

FROM: Arthur A. Elkins Jr.

TO: Mathy Stanislaus, Assistant Administrator
Office of Solid Waste and Emergency Response

This is our report on the subject review conducted by the Office of Inspector General (OIG) of the U.S. Environmental Protection Agency (EPA). EPA officials reviewed a draft of this report and informed the OIG that they agreed with the OIG's findings in this follow-up audit. However, technical comments were provided to ensure the language in this final report would accurately reflect actions contained in the *Management Standards for Hazardous Waste Pharmaceuticals* proposed rule that is currently under review by the Office of Management and Budget.

Because this report contains no recommendations, you are not required to respond to this report and it will be closed upon issuance. However, if you submit a response, it will be posted on the OIG's public website, along with our memorandum commenting on your response. Your response should be provided as an Adobe PDF file that complies with the accessibility requirements of Section 508 of the Rehabilitation Act of 1973, as amended. The final response should not contain data that you do not want to be released to the public; if your response contains such data, you should identify the data for redaction or removal along with corresponding justification.

We will post this report to our website at http://www.epa.gov/oig.

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Purpose

We reviewed corrective actions taken by the U.S. Environmental Protection Agency (EPA) to address two recommendations in Office of Inspector General (OIG) Report No. 12-P-0508, *EPA Inaction in Identifying Hazardous Waste Pharmaceuticals May Result in Unsafe Disposal*, issued May 25, 2012. The Assistant Administrator for the Office of Solid Waste and Emergency Response (OSWER) was the action official responsible for ensuring the completion of corrective actions in response to our recommendations. EPA's information systems reported that OSWER completed corrective actions for the following two recommendations raised by the OIG's 2012 audit report:

1. Identify and review existing pharmaceuticals to determine whether they qualify for regulation as hazardous waste.

2. Establish a process to review new pharmaceuticals to determine whether they qualify for regulation as hazardous waste.

Background

In the 2012 report, we reported that:

- Since 1980, the EPA has not used its Resource Conservation and Recovery Act (RCRA) authority to determine whether certain pharmaceuticals may qualify as hazardous waste.

- The EPA has not established a process for the regular identification and review of pharmaceuticals that may qualify for regulation as hazardous waste.

- The challenge to ensure the safe disposal of potentially hazardous pharmaceuticals is compounded because some health care-related facilities may be unaware of federal hazardous waste regulations; some drugs may have been disposed of and managed in an unsafe manner; and the EPA believed there was widespread noncompliance in the health care industry with RCRA regulation.

Our 2012 report made three recommendations. This report reviews the two recommendations, noted above, that were designated as completed. A third recommendation required OSWER to develop a nationally consistent outreach and compliance assistance plan to help states address challenges that health care facilities, and others as needed, have in complying with RCRA regulations for managing hazardous waste pharmaceuticals. This recommendation is open with corrective action pending.

Responsible Office

OSWER was responsible for completing corrective actions in response to recommendations included in the OIG's 2012 report.

Scope and Methodology

We performed our review from April 2014 through June 2015. We relied on recorded information from the EPA's Management Audit Tracking System to determine the status of completed corrective actions in response to Recommendations 1 and 2 included our 2012 report.

We interviewed EPA staff in OSWER who were involved in implementing completed corrective actions for these two recommendations. We also obtained the supporting documentation for the completed corrective actions from OSWER. We reviewed federal regulations and EPA guidance documents to assist us with our analysis and conclusions.

We conducted this performance audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Results of Review

The EPA's information systems reported that OSWER completed corrective actions for Recommendations 1 and 2 from our 2012 report. The results of our review determined that the corrective actions taken by OSWER met the intent of both OIG recommendations. In March 2015, the EPA submitted a proposed new rule to the Office of Management and Budget (OMB)—*Management Standards for Hazardous Waste Pharmaceuticals*—that satisfies both recommendations regarding the management and disposal of new and existing pharmaceuticals as hazardous waste.

Reviewing New and Existing Pharmaceuticals. In the proposed rule, OSWER stated that it intends to get information about new and existing hazardous pharmaceuticals by requesting comments. Because there are challenges in addressing the large number of existing and new pharmaceuticals, OSWER anticipates requesting from the public and other stakeholders[1] data and other information that might help them address this issue. This includes ways to identify new sources of

[1] OSWER defines "stakeholders" as people and organizations interested in, or potentially affected by, the regulation and management of waste pharmaceuticals. This has typically included pharmacies, hospitals, reverse distributors, organizations representing pharmacies and hospitals, environmental groups, and individual states. We were told that the EPA communicates with these groups in a variety of ways (i.e., in-person meetings, public speaking engagements, site visits to hospitals and other pharmaceutical waste generators, and the public notice-and-comment rulemaking process).

information to identify hazardous waste pharmaceuticals, as well as alternative approaches for addressing pharmaceutical waste generally. The action satisfies Recommendations 1 and 2 by creating, on a recurring basis, a process to review all pharmaceuticals to determine whether they qualify for regulation as hazardous waste.

Completing the Rulemaking Process. OSWER sent the proposed rule to OMB in March 2015. OSWER states that the OMB review process has a 90-day completion requirement. According to OSWER, after the OMB approval is obtained, the proposed rule will be published in the Federal Register. Additionally, OSWER stated that after it reviews public comments, it could take an additional 18 months or longer to finalize rulemaking.

Conclusion

The proposed rule OSWER submitted to OMB provides the means to uniformly identify, manage and dispose of all pharmaceutical wastes. The rule can be protective of human health and the environment by preventing the release of unused pharmaceuticals into the environment. The rule satisfies the intent of the two OIG recommendations in our 2012 report. Since the OSWER completed corrective actions on the recommendations we reviewed, this final report is closed upon issuance.

Agency Response and OIG Evaluation

On June 26, 2015, OSWER provided technical comments on our draft report. OSWER stated that it agreed with the OIG's findings in our follow-up audit. OSWER provided technical comments to ensure the language in the report reflected the proposed rule, *Management Standards for Hazardous Waste Pharmaceuticals,* that is currently under OMB review. Appendix A contains OSWER's response and technical comments to our draft report, as well as the OIG evaluation.

Appendix A

Full Agency Response to Draft Report and OIG Evaluation

June 26, 2015

MEMORANDUM

SUBJECT: Response to Draft Follow-Up Report: EPA Proposes to Streamline the Review, Management and Disposal of Hazardous Waste Pharmaceuticals
Project No. OPE-FY14-0022

FROM: Mathy Stanislaus /s/
Assistant Administrator

TO: Carolyn Copper, Assistant Inspector General
Office of Program Evaluation

Thank you for the opportunity to review the Draft Follow-Up Report: EPA Proposes to Streamline the Review, Management and Disposal of Hazardous Waste Pharmaceuticals Project No. OPE-FY14-0022. OSWER agrees with the OIG's findings in this follow-up audit. We submit the following technical comments to ensure the language in the draft report accurately reflects the actions contained in the Management Standards for Hazardous Waste Pharmaceuticals proposed rule that is currently under review by the Office of Management and Budget (OMB).

If you have any questions regarding this response, please contact my office at 202-566-0200 or have a member of your staff contact Kecia Thornton at 202-566-1913.

Attachment

Technical Comments

1. Cover page – Recommend not using medical waste photos since they are not hazardous waste pharmaceuticals and may confuse readers.

OIG Evaluation 1 – The OSWER statement is reasonable concerning the broader issue of medical waste. In response, we have deleted two previous photos from our cover page. The cover now only includes a photo of a pill container.

2. On the "At a Glance" page there is a text box on the right side of the page which refers to the rule as having been proposed; but the rule is not proposed yet (but is close). OSWER recommends saying: "EPA intends to issue a proposed rule, Management Standards for Hazardous Waste, which will attempt to streamline the approach to managing and disposing of hazardous and non-hazardous pharmaceutical waste."

OIG Evaluation 2 – The OSWER statements are reasonable in regard to the nature of the rule (submitted to OMB rather than proposed). We have revised the text in our green box as follows:

> **"EPA states that it intends to issue a proposed rule, *Management Standards for Hazardous Waste,* which will attempt to streamline the approach to managing and disposing of hazardous and nonhazardous pharmaceutical waste."**

3. On the "At a Glance" page, last paragraph, second to last sentence, we recommend the sentence be revised to 1) reflect that OSWER has not proposed a rule yet, but submitted the rule to OMB in March 2015, and 2) the proposed rule does not "establish procedures to review new and old pharmaceuticals" but rather requests comment on the issue. The second to last sentence should read: "In March 2015, OSWER submitted a proposed rule to the Office of Management and Budget that requests comment on approaches to review new and old pharmaceuticals as well as the management and disposal of hazardous waste pharmaceuticals."

OIG Evaluation 3 – The OSWER statements are reasonable in regard to the nature of the rule (submitted to OMB rather than proposed). Therefore, we have revised the "At a Glance" to read as follows:

> **"In March 2015, OSWER submitted a proposed rule to the Office of Management and Budget that requests comments on the approaches to review new and existing pharmaceuticals as well as the management and disposal of hazardous waste pharmaceuticals."**

4. On page 4 of the memorandum, the section entitled, "OSWER Rationale for a New Rule" contains two paragraphs. In the second paragraph, first sentence, we recommend it be revised to read "OSWER stated that changes to the list of hazardous waste pharmaceuticals in the RCRA regulations required rulemaking." This edit adds the phrase "in the RCRA regulations" which is important to clarify as there are other lists of hazardous pharmaceuticals (e.g., NIOSH, some states) and we are talking specifically about the RCRA lists in this sentence. Also in this same paragraph, the two sentences that read: "In contrast, the proposed rule, when final, would potentially eliminate the need to change the list and establishes a review process for new and existing pharmaceuticals. The rule would offer a streamlined alternative system for managing hazardous waste pharmaceuticals that health care facilities could use to manage all pharmaceutical wastes." is not accurate because the proposed rule does not establish a review process for new and existing pharmaceuticals, but rather requests public comment on this. We suggest the following revised wording which combines both sentences into one: "In contrast, the proposed rule, when final, would potentially eliminate the need to change the list by offering a streamlined alternative system for managing hazardous waste pharmaceuticals that health care facilities could also use to manage *all* pharmaceutical wastes." OSWER also recommends then adding the following new sentence to the end of the same paragraph, to capture how the proposed rule will request comment on the review procedure: "In addition, consistent with the intent of Recommendation 2, EPA is requesting comment in the proposed rule on possible alternative processes to review and define new and existing pharmaceuticals as hazardous waste, that could be done more efficiently (i.e., consume less resources)."

OIG Evaluation 4 – The section referenced was removed from the final report.

5. In the next section entitled, "Completing the Rulemaking Process" OSWER recommends changing the third (last) sentence to two sentences that read: "After OMB approval is obtained, the proposed rule will be published in the federal register. After reviewing public comments, it could take an additional 18 months or longer to finalize the rulemaking." This new language more accurately reflects the process.

OIG Evaluation 5 – The OSWER statement provides clarity; therefore, we have included the following revisions to the last sentence:

> "**According to OSWER, after the OMB approval is obtained, the proposed rule will be published in the Federal Register. Additionally, OSWER stated that after it reviews public comments, it could take an additional 18 months or longer to finalize rulemaking**."

Appendix B

Distribution

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