

OHIO E.P.A.

OCT 12 2010

BEFORE THE
OHIO ENVIRONMENTAL PROTECTION AGENCY

ENTERED DIRECTOR'S JOURNAL



In the Matter of:

Mercy Medical Center, Inc.
1320 Mercy Drive, NW
Canton, Ohio 44708

Director's Final
Findings and Orders

Respondent

PREAMBLE

It is agreed by the parties hereto as follows:

I. JURISDICTION

These Director's Final Findings and Orders (Orders) are issued to Mercy Medical Center, Inc., (Respondent) pursuant to the authority vested in the Director of the Ohio Environmental Protection Agency (Ohio EPA) under Ohio Revised Code (ORC) §§ 3734.13 and 3745.01.

II. PARTIES BOUND

These Orders shall apply to and be binding upon Respondent and successors in interest liable under Ohio law. No change in ownership of Respondent or of the Facility shall in any way alter Respondent's obligations under these Orders.

III. DEFINITIONS

Unless otherwise stated, all terms used in these Orders shall have the same meaning as defined in ORC Chapter 3734. and the rules promulgated there under.

IV. FINDINGS

The Director of Ohio EPA has determined the following findings:

I certify this to be a true and accurate copy of the official documents as filed in the records of the Ohio Environmental Protection Agency.

By: Jim Cassel Date: 10-12-10

1. Respondent is a "person" as defined in ORC § 3734.01(G) and Ohio Administrative Code (OAC) rule 3745-50-10(A).
2. Respondent operates a not-for-profit hospital located at 1320 Mercy Drive, NW, Canton, Stark County, Ohio, 44708 (Facility).
3. Respondent generates "hazardous waste" as that term is defined by ORC § 3734.01(J) and OAC rules 3745-50-10(A) and 3745-51-03. The hazardous waste generated by Respondent includes crushed spent fluorescent lamps (D009), lab wastes (F003, D001) and various other types of hazardous wastes referred to as "benchmark wastes" (F003, D001). Respondent generates hazardous waste in amounts classifying it as a small quantity generator. At the time of the investigation, Respondent was sending its crushed spent fluorescent lamps to an authorized facility located over two hundred (200) miles from the Facility.
4. On September 24, 2009, Ohio EPA conducted a complaint investigation at the Facility. The complaint was based upon an article that appeared in the Canton Repository Newspaper regarding Respondent's practice of crushing spent fluorescent lamps. The complaint investigation revealed that Respondent, *inter alia*:
 - a. Established and operated a hazardous waste storage facility without an installation and operation permit, in violation of ORC § 3734.02(E) and (F), by storing at least two (2) drums of hazardous waste crushed fluorescent lamps in excess of 270 days;
 - b. Failed to label and date forty (40) hazardous waste containers, in violation of OAC rules 3745-52-34(A)(2) and 3745-52-34(A)(3);
 - c. Failed to keep containers closed, in violation of OAC rule 3745-66-73(A);
 - d. Failed to conduct inspections of hazardous waste containers, in violation of OAC rule 3745-66-74;
 - e. Failed to maintain adequate aisle space to allow unobstructed movement of emergency equipment/personnel during an emergency event, in violation of OAC rule 3745-65-35;
 - f. Failed to test and maintain emergency equipment, in violation of OAC rule 3745-65-33; and

V. ORDERS

Respondent shall achieve compliance with Chapter 3734. of the ORC and the regulations promulgated there under according to the following compliance schedule:

1. Respondent shall pay Ohio EPA the amount of \$19,600.00 in settlement of Ohio EPA's claims for civil penalties, which may be assessed pursuant to ORC Chapter 3734. In lieu of payment to Ohio EPA of \$19,600.00, Respondent shall perform the Supplemental Environmental Projects (SEPs) set forth in these Orders, and more fully described in Attachment A, incorporated into these Orders and made a part of these Orders as if fully written herein, in accordance with the following provisions:
 - a. Within 30 days after the effective date of these Orders, Respondent shall submit to Ohio EPA a proposal for a pharmaceutical waste evaluation and disposal program at the Facility that uses industry best practices. Within 30 days after Ohio EPA approval of this proposal, Respondent shall implement the pharmaceutical waste evaluation and disposal program. Within 120 days after Ohio EPA approval of this proposal, Respondent shall submit documentation such as analytical results and/or manifests demonstrating the amount and types of hazardous waste pharmaceuticals identified as a result of this program, and invoices documenting implementation expenses and disposal costs.
 - b. Within 30 days after the effective date of these Orders, Respondent shall submit documentation to Ohio EPA demonstrating membership in *Operation: Medicine Cabinet*, including minutes from the August 10, 2010 meeting held by the Organization and attended by Respondent's representatives. As described in information provided by Respondent, *Operation: Medicine Cabinet* is a northeast Ohio educational and awareness group focused on collecting unused or expired medicines through community collection events.
 - c. On or before September 25, 2010, Respondent shall utilize the Facility for a drop-off collection point for pharmaceutically dispensed controlled substances and other medications that are wastes, as part of the Drug Enforcement Administration National Take Back Initiative. No later than November 1, 2010, Respondent

shall submit to Ohio EPA a report summarizing the results of the Take Back Initiative, including the amount of waste pharmaceuticals collected and invoices documenting expenditures associated with sponsoring the Take Back Initiative and costs for disposal of the waste pharmaceuticals.

- d. Within 180 days after the effective date of these Orders, Respondent shall host a Healthcare Hazardous Waste Management Symposium at the Facility. At least 60 days prior to the date of the Symposium, Respondent shall submit to Ohio EPA for review and approval the informational materials to be presented at the Symposium and make arrangements to coordinate Ohio EPA participation in the Symposium. Within 30 days after Respondent hosts the Symposium, Respondent shall submit documentation summarizing the Symposium, including the number of attendees, the informational material presented, speakers, and invoices identifying the costs associated with hosting the Symposium.
 - e. Within 360 days after the effective date of these Orders, Respondent shall conduct a Community Pharmaceutical Collection Day at the Facility. Within 30 days after the Community Pharmaceutical Collection Day, Respondent shall submit a report to Ohio EPA documenting the results of the Community Pharmaceutical Collection Day, including the amount of pharmaceutical waste collected and invoices itemizing the costs to fund the event.
2. Should Respondent fail to conduct all of the SEPs within the required time frames set forth in these Orders, Respondent shall pay to Ohio EPA, within 7 days after failing to complete any or all of the required SEPs, the amount of \$19,600.00, which will be deposited into the hazardous waste cleanup fund established pursuant to ORC § 3734.28. Payment shall be made by an official check made payable to "Treasurer, State of Ohio" for \$19,600.00. The official check shall be submitted to Ohio EPA, Office of Fiscal Administration, Department L-2711, Columbus, Ohio 43260-2711, together with a letter identifying the Respondent and the Facility. A copy of this check shall be submitted in accordance with Section X. of these Orders.

VI. TERMINATION

Respondent's obligations under these Orders shall terminate when Respondent certifies in writing and demonstrates to the satisfaction of Ohio EPA that Respondent has performed all obligations under these Orders and Ohio EPA's Division of Hazardous Waste Management acknowledges, in writing, the termination of these Orders. If Ohio EPA does not agree that all obligations have been performed, then Ohio EPA will notify Respondent of the obligations that have not been performed, in which case Respondent shall have an opportunity to address any such deficiencies and seek termination as described above.

The certification shall contain the following attestation: "I certify that the information contained in or accompanying this certification is true, accurate and complete."

This certification shall be submitted by Respondent to Ohio EPA and shall be signed by a responsible official of Respondent. For purposes of these Orders, a responsible official is a [e.g., corporate officer] who is in charge of a principal business function of Respondent.

VII. OTHER CLAIMS

Nothing in these Orders shall constitute or be construed as a release from any claim, cause of action or demand in law or equity against any person, firm, partnership or corporation, not a party to these Orders, for any liability arising from, or related to, the operation of Respondent's Facility.

VIII. OTHER APPLICABLE LAWS

All actions required to be taken pursuant to these Orders shall be undertaken in accordance with the requirements of all applicable local, state and federal laws and regulations. These Orders do not waive or compromise the applicability and enforcement of any other statutes or regulations applicable to Respondent.

IX. MODIFICATIONS

These Orders may be modified by agreement of the parties hereto. Modifications shall be in writing and shall be effective on the date entered in the journal of the Director of Ohio EPA.

X. NOTICE

All documents required to be submitted by Respondent pursuant to these Orders shall be addressed to:

Ohio Environmental Protection Agency
Northeast District Office
Division of Hazardous Waste Management
2110 East Aurora Road
Twinsburg, Ohio 44087
Attn: DHWM Manager

and Ohio EPA Central Office at the following address:

For mailings, use the post office box number:

Chris Korleski, Director
Ohio Environmental Protection Agency
Lazarus Government Center
Division of Hazardous Waste Management
P.O. Box 1049
Columbus, Ohio 43216-1049
Attn: Manager, Compliance Assurance Section

For deliveries to the building:

Chris Korleski, Director
Ohio Environmental Protection Agency
Lazarus Government Center
Division of Hazardous Waste Management
50 West Town Street
Columbus, Ohio 43215
Attn: Manager, Compliance Assurance Section

or to such persons and addresses as may hereafter be otherwise specified in writing by Ohio EPA.

XI. RESERVATION OF RIGHTS

Ohio EPA reserves its rights to exercise its lawful authority to require Respondent to perform closure and corrective action at the Facility at some time in the future, pursuant to ORC Chapter 3734, or any other applicable law. Respondent reserves its rights to raise any administrative, legal or equitable claim or defense with respect to any final action of the Director regarding such closure or corrective action. Ohio EPA and Respondent each reserve all other rights, privileges and causes of action, except as specifically waived in Section XII. of these Orders.

XII. WAIVER

In order to resolve disputed claims, without admission of fact, violation or liability, Respondent consents to the issuance of these Orders and agrees to comply with these Orders. Except for the rights to seek closure and corrective action at the Facility, which rights Ohio EPA does not waive, compliance with these Orders shall be a full accord and satisfaction for Respondent's liability for the violations specifically cited herein.

Respondent hereby waives the right to appeal the issuance, terms and conditions, and service of these Orders, and Respondent hereby waives any and all rights Respondent may have to seek administrative or judicial review of these Orders either in law or equity.

Notwithstanding the preceding, Ohio EPA and Respondent agree that if these Orders are appealed by any other party to the Environmental Review Appeals Commission, or any court, Respondent retains the right to intervene and participate in such appeal. In such an event, Respondent shall continue to comply with these Orders notwithstanding such appeal and intervention unless these Orders are stayed, vacated or modified.

XIII. EFFECTIVE DATE

The effective date of these Orders is the date these Orders are entered into the Ohio EPA Director's journal.


XIV. SIGNATORY AUTHORITY

Each undersigned representative of a party to these Orders certifies that he or she is fully authorized to enter into these Orders and to legally bind such party to these Orders.

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Mercy Medical Center, Inc.
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IT IS SO ORDERED AND AGREED:

Ohio Environmental Protection Agency

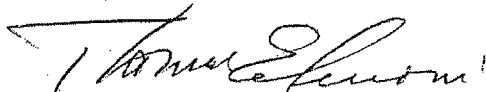


Chris Korleski
Director

October 12, 2010
Date

IT IS SO AGREED:

Mercy Medical Center, Inc.



Signature

9/29/2010
Date

Thomas E. Cecconi

Printed or Typed Name

President & Chief Executive Officer

Title

Attachment A



August 11, 2010

Harry E. Sarvis, Manager
Compliance Assurance Section
Ohio EPA
Division of Hazardous Waste Management
50 W. Town St., P.O. Box 1049
Columbus, Ohio 43216-1049

MERCY MEDICAL CENTER

RE: **Revised** Written Response to Proposed Director's Final Findings and Orders Dated May 11, 2010

Dear Mr. Sarvis,

This correspondence is being submitted on behalf of Mercy Medical Center in an effort to establish a strategic plan for the implementation of one or more supplemental environmental projects in lieu of paying a civil penalty settlement of \$ 19,600. Mercy Medical Center proposes to work in partnership with the Ohio EPA and the Office of Compliance Assistance and Pollution Prevention to establish the following programs:

- 1) Join Operation: Medicine Cabinet, a northeast Ohio educational and awareness group, focused on collecting unused or expired medicines through community collection events by working in partnership with local and regional law enforcement agencies. Operation: Medicine Cabinet is an outgrowth of the Drug Awareness and Prevention Inc. [www.DrugAwarenessAndPrevention.org], a group focused on preventing misuse and abuse of unwanted over-the-counter and prescription drugs. The group's mission is to educate families and communities about the safe disposal of pharmaceuticals, prevent unwanted medications from being abused, and protect the environment from the harms of improperly disposed of residential pharmaceutical chemicals. Richard Regula and Elaine Campbell attended a meeting of Operation: Medicine Cabinet at the Westlake Police Station on August 10, 2010. Continued participation with the group will enable educational and awareness opportunities. The September 25th Take Back Initiative will be advertised and promoted on the Operation: Medicine Cabinet website.

Timeframe: Ongoing
Budget: -0-

- 2) Coordinate Mercy Medical Center's participation in the Drug Enforcement Administration First National Take Back Initiative on September 25, 2010 from 10:00 AM to 2:00 PM. The attached documents detail the National Take Back Initiative. Mercy Medical Center will be a drop-off collection site for pharmaceutically dispensed controlled substances and other medications in

accordance with the parameters of the national effort. The hospital will work in collaboration with the Stark County Sheriff's Department, the City of Canton's Police Department, and the DEA. Collection boxes, pick-up of the surrendered pharmaceuticals, and destruction of the surrendered materials will be provided by the DEA. Mercy's Green Team Coordinators, Richard Regula and Elaine Campbell, will coordinate the hospital's participation in this event. Mercy's security, pharmacy, and public relations department will be utilized to guarantee the optimum success of this event. This activity will build awareness and education in the community concerning the need to remove potentially dangerous controlled substances from the community's medicine cabinets. It will also provide Mercy with the experience of conducting a community drug collection program.

Timeframe: September 25, 2010 – 10:00 AM – 2:00 PM
Budget: \$ 1,000 [Publicity, Security, Supplies]

- 3) Launch an in-house, hospital wide pharmaceutical waste disposal program in compliance with Ohio EPA regulations and best practices for Hazardous Waste Management/RCRA and Non-RCRA Pharmaceuticals. The program will utilize Chemical Analytics, Inc. as a service provider for transport and disposal.

Timeframe: 4th Quarter 2010
Budget: \$ 26,500/Annual Fee -Transport /Disposal
\$ 2,500 Educational Materials

- 4) Host a Healthcare Hazardous Waste Management Symposium at Mercy Medical Center utilizing speakers and reference resources from the Ohio EPA and Office of Compliance Assistance and Pollution Prevention. Speaker topics will include pharmaceutical waste disposal, fluorescent bulb disposal, current hazardous waste regulation review, and other related topics. Invitees will include hospital personnel from the healthcare ministries of the Sisters of Charity Health System and hospitals in Medina, Portage, Stark, and Summit Counties that are members of the Akron Regional Hospital Association.

Timeframe: 1st Quarter 2011
Budget: \$ 3,500 [Refreshments, Speakers, Printing, Postage]

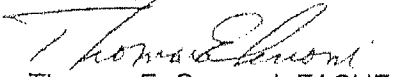
- 5) Offer a Community Pharmaceutical Collection Day at Mercy Medical Center. The hospital will follow the protocol established by the DEA pharmaceutical collection event in September, 2010. It will obtain permission from the DEA, utilize local law enforcement personnel, and fund the cost of the event.

Timeframe: 2nd Quarter 2011
Budget: \$ 10,000 – Pharmaceutical Disposal
\$ 2,000 – Local Law Enforcement
\$ 750 – Mercy Security & Supplies
\$ 500 – Publicity [Newspaper & Radio]

It is the intent of Mercy Medical Center that the proposed projects will be in compliance with the Ohio EPA. If you should have any additional questions regarding this effort, please feel free to ask.

Mercy Medical Center looks forward to continuing their environmental leadership in healthcare and working in cooperation with the Ohio EPA.

Sincerely,


Thomas E. Cecconi, FACHE
President and CEO

cc: Todd Anderson, Legal Office - Columbus
Kelly Smith, Environmental Specialist 2 – Columbus
Natalie Oryshkewych, Environmental Manager – Twinsburg
Suzanne Prusnek, Environmental Specialist – Twinsburg
Adrienne LaFavre, PhD, OCAPP – Environmental Specialist
Chris Cupples, Ohio Department of Development – Governor's Regional
Director



U. S. Department of Justice
Drug Enforcement Administration
Washington Division
800 K Street, NW, Suite 500
Washington, DC 20001

www.dea.gov

August 12, 2010

Dear Police Chief/Sheriff/Commissioner:

On September 25, 2010, the Drug Enforcement Administration (DEA) will coordinate and facilitate a one-day, collaborative effort with state and local law enforcement agencies to remove potentially dangerous controlled substances from our nation's homes. This national take-back initiative will provide a unified opportunity for the public to surrender pharmaceutically dispensed controlled substances and other medications to law enforcement officers for destruction. Prevention and treatment organizations may be contacting their local police departments to lend their support for this initiative.

The 2008 National Survey on Drug Use and Health (NSDUH) estimates there are currently 6.2 million non-medical users of psychotherapeutic drugs in the United States. The NSDUH survey further indicates there are more Americans abusing psychotherapeutics than the number of cocaine, heroin, and hallucinogen abusers combined. Expired, unused, or unwanted controlled substances in our homes are a potential source of supply that fuel this abuse and are an unacceptable risk to public health and safety.

We request your support and hope you will join us in this effort. Agencies wishing to participate are asked to plan for collections by your respective agency from 10:00 am through 2:00 pm at community sites of your choosing and should be staffed by law enforcement officers from your agency. Collection boxes and the pick-up of the surrendered pharmaceuticals will be provided by DEA. The destruction of the surrendered materials by DEA will be accomplished in accordance with all applicable federal and state laws and regulations. Since these pharmaceuticals will be incinerated, participating agencies must insure that no toxic or explosive materials are accepted at the time of surrender.

Attached to this letter is a document outlining the collection protocols for this event and a registration form. If interested in participating, please complete the attached registration form and return to the Washington Division Office [FAX: (202) 307-5823 / Attn: Jill Hicks] by COB, Friday, August 13, 2010. Once we receive your registration form, your designated agency representative (POC) will be contacted with additional information by local DEA representatives.

Thank you for your consideration of this important project. If you have questions concerning this matter, please contact Group Supervisor Karen Flowers at (202) 305-8112 or Assistant Special Agent in Charge Alan G. Santos at (202) 305-8182.

Sincerely,



Ava A. Cooper-Davis
Special Agent in Charge
Washington Field Division

Attachment: Registration Form
Collection Day Protocols

National Take Back Initiative

Introduction

On September 25, 2010, DEA will coordinate a collaborative effort with state and local law enforcement agencies focused on removing potentially dangerous controlled substances from our nation's medicine cabinets. A national take-back day will provide a unified opportunity for the public to surrender expired, unwanted, or unused pharmaceutical controlled substances and other medications to law enforcement officers for destruction. This one-day effort will bring national focus to the issue of pharmaceutical controlled substance abuse. The program provides an opportunity for law enforcement, prevention, treatment, and the business community to collaborate and establish a safe collection site for all Americans, regardless of where they reside.

Collection Day Protocols

- On Saturday, September 25, 2010, state and local law enforcement agencies will host one or more collection sites at locations of their choosing. Locations should be selected that provide easy access and available parking.
- Controlled, non-controlled, and over the counter substances may be collected. The general public is often unaware of the distinction in medication status.
- Collection efforts may be combined with community drug awareness activities and involve the distribution of brochures and other information.
- This program is anonymous and all efforts should be made to protect the anonymity of individuals disposing of medications. No questions or requests for identification should be made.
- Participants may dispose of medication in its original container or by removing the medication from its container and disposing of it directly into the disposal box. If an original container is submitted, the individual should be encouraged to remove any identifying information from the prescription label.
- No effort should be made by law enforcement personnel to count, inventory, or log medications.
- All solid dosage pharmaceutical product and liquids in consumer containers may be accepted. Liquid products, such as cough syrup, should remain sealed in their original container. The depositor should ensure that the cap is tightly sealed to prevent leakage.
- Intra-venous solutions, injectibles, and syringes will not be accepted due to potential hazard posed by blood-borne pathogens.

- Illicit substances such as marijuana or methamphetamine are not a part of this initiative and should not be placed in collection containers. If an individual attempts to surrender an illicit controlled substance, law enforcement personnel should handle such material as abandoned property in accordance with department policy.
- All participants must retain possession of their own medication during the surrender process. Law enforcement personnel should not handle the medications at any time.
- A law enforcement officer must remain with the drug disposal box at all times. Collected pharmaceutical products should be handled as drug evidence with law enforcement custody to safe-guard the surrendered material.
- If you need additional collection boxes, you are authorized to use a container approved by your department as part of its standard operating procedures.
- At the conclusion of the event, a law enforcement officer will seal the drug disposal boxes in accordance with your agency's policy and procedure. It is recommended that the box be sealed with tamper-evident tape or evidence sticker. Each box should be labeled as "Miscellaneous Pharmaceuticals to be turned over to DEA."
- The drug collection boxes should then be returned to your police department and stored per your department's standard operating procedures for safe keeping and temporary storage, until they are turned over to DEA.