



STATE OF DELAWARE
DEPARTMENT OF NATURAL RESOURCES
AND ENVIRONMENTAL CONTROL

OFFICE OF THE
SECRETARY

89 KINGS HIGHWAY
DOVER, DELAWARE 19901

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**NOTICE OF ADMINISTRATIVE PENALTY ASSESSMENT
AND SECRETARY'S ORDER**

Pursuant to 7 *Del. C.* § 6005

Order No. 2015-WH-0018

*PERSONALLY SERVED BY AN ENVIRONMENTAL
PROTECTION OFFICER*

Issued To:

Mr. Terry M. Murphy, FACHE
President and CEO
Bayhealth Kent General Hospital
640 South State Street
Dover, DE 19901

Registered Agent:

Bayhealth, Inc.
640 S. State Street
Dover, DE 19901

Dear Mr. Murphy:

The Secretary of the Department of Natural Resources and Environmental Control ("Department") has found Bayhealth Medical Center's Kent General Hospital ("Respondent" or "Bayhealth's KGH") in violation of 7 *Del. C.* Chapters 60 and 63 and 7 DE Admin. Code 1302, Delaware's *Regulations Governing Hazardous Waste* ("DRGHW"). Accordingly, the Department is issuing this Notice of Administrative Penalty Assessment, pursuant to 7 *Del. C.* § 6005(b)(3).

BACKGROUND

Bayhealth Medical Center ("Bayhealth") is a full-service, non-profit healthcare system serving the central and southern portion of Delaware. Bayhealth operates two full-service hospitals; Kent General Hospital ("Bayhealth's KGH") in Dover and Milford Memorial Hospital ("Bayhealth's MMH") in Milford. In addition, Bayhealth also operates the Bayhealth Medical

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Center Emergency Center in Smyrna, Delaware, as well as numerous outpatient facilities across central and southern Delaware.

Respondent is a generator of hazardous waste and is, therefore, subject to compliance inspections, by the Solid and Hazardous Waste Management Section (SHWMS¹), pursuant to 7 DE Admin. Code 1302, Delaware's *Regulations Governing Hazardous Waste* ("DRGHW").

On July 31, 2014, the Department conducted a hazardous waste compliance assessment at Bayhealth's KGH. At the time of the assessment, it was determined that, due to the commingling of hazardous waste with infectious waste¹, by Respondent, Bayhealth's KGH was a large quantity generator ("LQG").² On the basis of the information gathered during the assessment, the Department found Respondent to be in violation of applicable state statutes and regulations governing the generation and management of hazardous waste.

The Department formally notified Respondent of its violations by issuing Notice of Violation ("NOV") No. 14-HW-19, dated August 18, 2014, to Respondent on August 22, 2014. The NOV identified twenty-two (22) violations of DRGHW and required Respondent to immediately comply with the NOV's requirements and additionally, to submit documentation demonstrating compliance within thirty (30) days of receipt of the NOV. Bayhealth's response was due on September 22, 2014.

It is relevant to note, that the Department also had conducted a hazardous waste compliance assessment at Bayhealth's MMH, on March 6, 2014, nearly five months prior to the compliance assessment at Bayhealth's KGH. During the compliance assessment at Bayhealth's MMH, eighteen (18) violations were identified, which prompted the Department to issue a NOV, formally notifying Bayhealth's MMH of the violations. The violations identified at Bayhealth's MMH were similar to those identified at Bayhealth's KGH. Bayhealth's MMH returned to compliance on May 27, 2014, after submitting required information to the Department.

Of further relevance, Bayhealth, in response to the violations discovered at Bayhealth's MMH, invited the Department to give a presentation on hazardous waste compliance to the Delaware Healthcare Quality Association. The presentation, conducted on April 22, 2014, was attended by Bayhealth's Safety Manager and Corporate Compliance/Risk Specialist. The presentation addressed regulatory compliance and its implementation and specifically addressed each compliance issue identified within this Order.

On September 23, 2014, one day after the response deadline, Bayhealth requested an extension to the deadline, as Respondent was having difficulty locating manifests referenced in Violation 13, below. As the deadline had already passed, no extension was granted; however, the

¹ "**Infectious Waste**" means those solid wastes which may cause human disease and may reasonably be suspected of harboring human pathogenic organisms, or may pose a substantial present or potential hazard to human health or the environment when improperly treated, stored, transported, disposed of or otherwise managed (Delaware's *Regulations Governing Solid Waste*, 2012).

² Generators of more than 1,000 kilograms (2,200 pounds) of hazardous waste in any calendar month are large quantity generators (Delaware's *Regulations Governing Hazardous Waste*, 2013).

SHWMS did provide copies of the manifests that had been retained by the Department in order to expedite Kent General Hospital's response. On September 26, 2014, Kent General Hospital submitted its response to NOV 14-HW-19. Eighteen (18) of the 22 violations were corrected. Kent General Hospital submitted additional information on September 29, 2014 and October 9, 2014 correcting two additional violations. On May 1, 2015, Kent General Hospital submitted the remaining information correcting the two final violations.

FINDINGS OF FACT AND VIOLATION INCLUDING REGULATORY REQUIREMENTS

1. Section 262.11 of DRGHW states in part:

"A person who generates a solid waste, as defined in §261.2, must determine if that waste is a hazardous waste using the following method:

(a) He should first determine if the waste is excluded from regulation under § 261.4.

(b) He must then determine if the waste is listed as a hazardous waste in Subpart D of Part 261.

(c) For the purpose of compliance with Part 268, or if the waste is not listed in Subpart D of Part 261, the generator must then determine whether the waste is identified in Subpart C of Part 261 by either:

(1) Testing the waste according to the methods set forth in Subpart C of Part 261, or according to an equivalent method approved by the Secretary under Part 260, Subpart C, or;

(2) Applying knowledge of the hazard characteristic of the waste in light of the materials or the processes used.

(d) If the waste is determined to be hazardous, the generator must refer to Parts 261, 264, 265, 266, 268 and 273 of these regulations for possible exclusions or restrictions pertaining to management of the specific waste."

On July 31, 2014, Respondent had not identified those pharmaceuticals qualifying as hazardous waste when disposed. Rather, these waste pharmaceuticals were commingled with infectious waste or the packaging associated with P-listed waste thrown in the general trash. Failing to make a hazardous waste determination of the waste pharmaceuticals is a violation of § 262.11 of DRGHW.

2. Section 262.34(c)(1)(ii) of DRGHW states in part:

"(c)(1) A generator may accumulate as much as 55 gallons of hazardous waste or one quart of acutely hazardous waste... in containers at or near any point of generation where wastes initially accumulate... provided he:

(ii) Marks his containers either with the words 'Hazardous Waste' or with the word 'Waste' and a description to identify the contents of the container (e.g., Waste Acetone, Waste Solvent)."

On July 31, 2014, Department representatives observed that none of the containers utilized to accumulate infectious waste commingled with spent pharmaceuticals meeting the definition of hazardous waste, particularly those that carry the P- or U-listing³ in the pharmacy areas or nursing areas were labeled. Failure to properly label containers of hazardous waste is a violation of § 262.34(c)(1)(ii).

3. Section 262.34(c)(1) of DRGHW states in part:

“(c)(1) A generator may accumulate... one quart of acutely hazardous waste listed in §261.31 or §261.33(e) in containers at or near any point of generation where wastes initially accumulate, which is under the control of the operator of the process generating the waste...”

On July 31, 2014, Department representatives observed a 30 gallon gray poly container in the Packaging Room of the pharmacy to collect waste medication in the form of tablets and capsules. The container was labeled to indicate that warfarin tablets should be placed in the 55 gallon red poly container utilized for vials and syringes. While the 55 gallon red poly container is eligible to be managed under satellite accumulation rules, warfarin carries the hazardous waste code P001 and is therefore an acute hazardous waste. Acute hazardous waste is limited to a volume of 1 quart in a satellite accumulation area. Exceeding 1 quart of P-waste in a satellite accumulation area is a violation of § 262.34(c)(1).

4. Section 262.12(c) of DRGHW states:

“A generator must not offer his hazardous waste to transporters that have not received an EPA identification number and a Delaware hazardous waste transporter permit or to treatment, storage, or disposal facilities that have not received an EPA identification number.”

On July 31, 2014, Department representatives discovered that Respondent was commingling its hazardous waste pharmaceuticals with infectious waste, which renders the entire mixture hazardous waste. The waste was transported by either Culver Enterprises or Curtis Bay Energy to Curtis Bay’s Baltimore, Maryland facility for disposal. Additionally, packaging waste generated from P-listed pharmaceuticals was placed in the site’s general trash, which is disposed of at DSWA’s Central Solid Waste Management Center. It was also discovered that hazardous waste pharmaceuticals were returned to Guaranteed Returns via FedEx for reverse distribution. Offering hazardous waste to Culver Enterprises, Curtis Bay Energy, the Delaware Solid Waste Authority, FedEx, and Guaranteed Returns (who do not have EPA ID numbers, Delaware hazardous waste transporter permits, or hazardous waste treatment, storage, or disposal facility permits, as applicable) is a violation of § 262.12(c) of DRGHW.

³ As identified in § 261.33 of DRGHW.

5. Section 262.20(a)(1) of DRGHW states:

“A generator who transports, or offers for transportation, hazardous waste for offsite treatment, storage, or disposal, or a treatment, storage, and disposal facility who offers for transport a rejected hazardous waste load, must prepare a Manifest (U.S. OMB Control Number 2050 0039) on EPA Form 8700 22 and, if necessary EPA Form 8700 22A, according to the instructions included in the appendix to this part.”

On July 31, 2014, Department representatives discovered that Respondent had not utilized hazardous waste manifests for the shipments described in Violation #4, above. Failure to prepare a manifest for transporting hazardous waste is a violation of § 262.20(a)(1).

6. Section 265.173(a) of DRGHW states:

“(a) A container holding hazardous waste must always be closed during storage, except when it is necessary to add or remove waste.”

On July 31, 2014, Department representatives observed a solvent recovery system in the histology lab. The container, used to accumulate the sludge (xylene, alcohol, and paraffin waste) generated from the solvent recovery system, was open at the time of the assessment. Additionally, Department representatives observed a box of spent lamps in the hazardous waste accumulation shed. The box was labeled “Hazardous Waste – Broken Lamps,” but was open at the time of the assessment. Failing to close hazardous waste containers is a violation of §265.173(a).

7. Section 273.13(d)(1) of DRGHW states:

“(d) Lamps. A small quantity handler of universal waste must manage lamps in a way that prevents releases of any universal waste or component of a universal waste to the environment, as follows:

(1) A small quantity handler of universal waste must contain any lamp in containers or packages that are structurally sound, adequate to prevent breakage and compatible with the contents of the lamps. Such containers and packages must remain closed and must lack evidence of leakage, spillage or damage that could cause leakage under reasonably foreseeable conditions.”

On July 31, 2014, Department representatives observed nine (9) boxes of spent lamps, including both traditional and low-mercury lamps in the Plant Operations area. Each box was labeled “Universal Waste – Used Lamps.” Four (4) of the boxes were open at the time of the assessment. This is a violation of § 273.13(d)(1).

8. Section 273.14(a) of DRGHW states:

“A small quantity handler of universal waste must label or mark the universal waste to identify the type of universal waste as specified below:

(a) Universal waste batteries (i.e., each battery), or a container in which the batteries are contained, must be labeled or marked clearly with any one of the following phrases: ‘Universal Waste Battery(ies),’ or ‘Waste Battery(ies),’ or ‘Used Battery(ies);’

On July 31, 2014, Department representatives observed one (1) -- 15 gallon poly drum containing used batteries in the CSB – 2nd Floor area. Neither the drum, nor each of the individual batteries, was labeled. This is a violation of § 273.14(a).

9. Section 262.34(a)(3) of DRGHW states in part:

“(a) ... a generator may accumulate hazardous waste on site for 90 days or less without a permit or without having interim status, provided that: ...

(3) While being accumulated on site, each container and tank is labeled or marked clearly with the words ‘Hazardous Waste’;”

On July 31, 2014, Department representatives observed two (2) -- 55 gallon drums of waste xylene in the hazardous waste accumulation shed. Neither drum was labeled with the words “Hazardous Waste;” a violation of § 262.34(a)(3).

10. Section 262.34(a)(2) of DRGHW states in part:

“(a) ... a generator may accumulate hazardous waste on site for 90 days or less without a permit or without having interim status, provided that:

(2) The date upon which each period of accumulation begins is clearly marked and visible for inspection on each container;”

On July 31, 2014, Department representatives observed that neither of the drums referenced in Violation #9, above, were marked with an accumulation start date, which is a violation of § 262.34(a)(2).

11. Section 262.34(a) of DRGHW states in part:

“(a) ... a generator may accumulate hazardous waste on site for 90 days or less without a permit...”

Based on manifest records provided to Department representatives on July 31, 2014 and those submitted to the Department by the Treatment, Storage and Disposal Facility (“TSD”), the last shipment of waste xylene occurred on January 20, 2014. Based on this information and the fact that waste xylene is regularly generated at Kent General Hospital, at least one of the observed drums referenced in Violation #10, above, has been on-site for

approximately 193 days, which is significantly greater than the 90 day limit applicable to large quantity generators of hazardous waste [and greater than the 180 day limit for small quantity generators, which Kent General Hospital believed to be its generator category]. This is a violation of § 262.34(a).

12. Section 122.1(c) of the DRGHW states in part:

“(c) Scope of the hazardous waste permit requirement. DNREC requires a permit for the ‘treatment’, ‘storage’, and ‘disposal’ of any ‘hazardous waste’ as identified or listed in Part 261.”

By accumulating hazardous waste in excess of 90 days, Respondent operated a hazardous waste storage facility without having first obtained a permit. This is a violation of § 122.1(c).

13. Section 262.40(a) of DRGHW states:

“(a) A generator must keep a copy of each manifest signed in accordance with § 262.23(a) for three years or until he receives a signed copy from the designated facility which received the waste. This signed copy must be retained as a record for at least three years from the date the waste was accepted by the initial transporter.”

On July 31, 2014, Respondent was not able to provide original and/or TSD-signed manifest copies for the following shipments:

DATE	MANIFEST	MISSING
07/22/11	008557083JJK	No copy
10/11/11	001052786GBF	No TSD signed copy
10/25/11	008557019JJK	No copy
02/23/12	008556817JJK	No copy
10/18/12	008556674JJK	No copy
11/15/12	003517228SKS	No copy
01/16/13	008556623JJK	No copy
05/07/13	011019917JJK	No copy

Failure to retain copies of manifests is a violation of § 262.40(a).

14. Section 262.42(b) of DRGHW states in part:

“(b) A generator must submit an Exception Report to the DNREC within 5 calendar days if he has not received a copy of the manifest/shipping paper with the handwritten signature of the owner or operator of the designated facility within 45 days of the date the waste was accepted by the initial transporter.”

Failure to notify the Department after not receiving a TSD-signed manifest (referenced in Violation #13, above) is a violation of § 262.42(b).

15. Section 262.41(a) of the DRGHW states in part:

“(a) A generator must prepare and submit a single copy of an Annual Report to the State of Delaware, Department of Natural Resources and Environmental Control by no later than March 1 for the preceding calendar year. The annual report ... must cover generator activities during the previous year.”

On July 31, 2014, the Department determined that due to the commingling of hazardous waste with infectious waste, Respondent was a LQG for calendar years 2011, 2012, and 2013, however Respondent did not submit an annual report for those calendar years. This is a violation of § 262.41(a).

16. Section 265.16(d)(1) of DRGHW states:

“(d) The owner or operator must maintain the following documents and records at the facility:

(1) The job title for each position at the facility related to hazardous waste management, and the name of the employee filling each job;”

On July 31, 2014, Respondent was unable to provide a list of job titles for each position at the facility responsible for hazardous waste management, and the name of the employee filling each position. Failure to maintain accurate names and job titles for each position at the facility related to hazardous waste management is a violation of § 265.16(d)(1).

17. Section 265.16(d)(2) of DRGHW states:

“(d) The owner or operator must maintain the following documents and records at the facility:

(2) A written job description for each position listed under paragraph (d)(1) of this section. This description may be consistent in its degree of specificity with descriptions for other similar positions in the same company location or bargaining unit, but must include the requisite skill, education, or other qualification, and duties of facility personnel assigned to each position;”

On July 31, 2014, Respondent was unable to provide a job description, as it relates to hazardous waste duties, for each employee responsible for handling hazardous waste. Failure to maintain job descriptions for each position at the facility related to hazardous waste management is a violation of § 265.16(d)(2).

18. Section 265.16(a)(1) of DRGHW states:

“(a)(1) Facility personnel must successfully complete a program of classroom instruction or on-the-job training that teaches them to perform their duties in a way that ensure that facility’s compliance with the requirements of this part. The owner or operator must ensure that this program includes all the elements described in the document required under paragraph (d)(3) of this section.”

On July 31, 2014, Respondent was unable to provide documentation demonstrating that employees handling hazardous waste had received training commensurate with their job duties. This is a violation of § 265.16(a)(1).

19. Section 265.174 of DRGHW states:

“The owner or operator must inspect areas where containers are stored at least weekly, looking for leaking containers and for deterioration of containers and the containment system caused by corrosion or other factors. A written record of the inspections must be maintained onsite for a minimum of 3 years.”

On July 31, 2014, the Department determined that Respondent had not conducted weekly inspections of the hazardous waste accumulation shed. This is a violation of § 265.174.

20. Section 265.51(a) of DRGHW states:

“(a) Each owner or operator must have a printed contingency plan for his facility. The contingency plan must be designed to minimize hazards to human health or the environment from fires, explosions, or any unplanned sudden or non-sudden release of hazardous waste or hazardous waste constituents to air, soil, or surface water.”

On July 31, 2014, Respondent had not developed a contingency plan to address emergencies related to hazardous waste; a violation of § 265.51(a).

21. Section 265.37(a) of DRGHW states:

*“(a) The owner or operator must attempt in writing, with documentation of receipt, to make the following arrangements, as appropriate for the type of waste handled at his facility and potential need for the services of these organizations:
(1) Arrangements to familiarize police, fire departments, and emergency response teams with the layout of the facility, properties of hazardous*

- waste handled at the facility and associated hazards, places where facility personnel would normally be working, entrances to roads inside the facility, and possible evacuation routes;*
- (2) Where more than one police and fire department might respond to an emergency, agreements designating primary emergency authority to specific police and a specific fire department, and agreements with any others to provide support to the primary emergency authority;*
 - (3) Agreements with State emergency response teams, emergency response contractors, and equipment suppliers; and*
 - (4) Arrangements to familiarize local hospitals with the properties of hazardous waste handled at the facility and the types of injuries or illnesses which could result from fires, explosions, or releases at the facility.”*

On July 31, 2014, Respondent was unable to provide documentation demonstrating that emergency response arrangements had been made with local emergency responders; a violation of § 265.37(a).

22. Section 268.7(a)(8) of DRGHW states in part:

“Generators must retain on-site a copy of all notices, certifications, waste analysis data, and other documentation produced pursuant to this section for at least three years from the date that the waste that is the subject of such documentation was last sent to on-site or off-site treatment, storage, or disposal.”

On July 31, 2014, Respondent was unable to provide the Land Disposal Restriction (“LDR”) notification associated with the waste shipped on Uniform Hazardous Waste Manifest Number 003517228SKS on November 15, 2012. Failure to maintain LDR notifications is a violation of § 268.7(a)(8).

CONCLUSIONS

Based on the foregoing, the Department has concluded that Bayhealth’s Kent General Hospital has violated the above cited regulatory provisions.

ASSESSMENT OF PENALTY AND COSTS

Pursuant to the provisions of 7 Del. C. § 6005(b)(3), this is written notice to Respondent that on the basis of its findings, the Department is assessing Respondent an administrative penalty of \$73,509.00 for the violations identified in this Assessment and Order.

In addition to the penalty assessment, Respondent is hereby assessed estimated costs in the amount of \$11,026.00, pursuant to 7 Del. C. § 6005(c), which were incurred by the Department in the investigation of the noted violations.

Respondent shall submit one check to the Department in the amount of \$73,509.00 to pay the penalty and one check to the Department in the amount of \$11,026.00 to pay the Department's costs within 30 days from the receipt of this Assessment and Order. The checks shall be made payable to the "State of Delaware" and shall be directed to: Devera B. Scott, Deputy Attorney General, Department of Justice, Environmental Unit, 102 W. Water Street-3rd Floor, Dover, Delaware 19904.

The Department reserves the right to take additional enforcement actions regarding these and other violations at Kent General Hospital, including but not limited to one or more of the following: an action under 7 *Del. C.* § 6005(b)(1) seeking penalties for past violations, an action under 7 *Del. C.* § 6005(b)(2) seeking penalties for continuing violations, an action in the Court of Chancery pursuant to 7 *Del. C.* § 6005(b)(2) seeking a temporary restraining order or an injunction, and the imposition of civil penalties and recovery of the Department's costs and attorney's fees pursuant to 7 *Del. C.* §§ 6005(b)(3) & (c)(1).

PUBLIC HEARING AND APPEAL RIGHTS

This Notice of Administrative Penalty Assessment and Order shall become effective and final unless the Department receives from Respondent, no later than 30 days from the receipt of this Notice, a written request for a public hearing on these matters as provided in 7 *Del. C.* § 6005(b)(3) and (c). The Department does not otherwise intend to convene a public hearing on these matters, but reserves the right to do so at its discretion. If no public hearing is requested within thirty days, this Order shall become final.

Any person whose interest is substantially affected by an action of the Secretary may appeal to the Environmental Appeals Board, pursuant to 7 *Del. C.* § 6008(a), within twenty (20) days of the receipt or publication of the Secretary's final order.

If no hearing is requested and no appeal is filed, the administrative penalty of \$73,509.00 and costs in the amount of \$11,026.00 shall be due and owing. In the alternative, Respondent may pay the penalty and costs within thirty (30) days of receipt of this Notice as delineated in the Assessment Section above by executing the attached waiver form and remitting two (2) checks payable to the State of Delaware in the amounts of \$73,509.00 and \$11,026.00, and mail to: Devera B. Scott, Deputy Attorney General, Department of Justice, 102 W. Water Street, Dover, Delaware 19904. By doing so, Respondent waives its right to a hearing and the opportunity to appeal or contest this Assessment and Order, which shall become a final Order.

To request a hearing, please submit your request, in writing, to:

Department of Natural Resources and Environmental Control
Office of the Secretary
89 Kings Highway
Dover, DE 19901
Ph: (302) 739-9000

To submit an appeal to the Environmental Appeals Board, there is a \$50.00 filing fee that should be made payable to the: "Environmental Appeals Board" and sent to:

Department of Natural Resources and Environmental Control
Office of the Secretary
Attn: Assistant to the Environmental Appeals Board
89 Kings Highway
Dover, DE 19901
Ph: (302) 739-9000

If you have any questions, please contact Karen J'Anthony at (302) 739-9403.

Date

9/24/15



David S. Small, Secretary

Enf/Bayhealth KGH Penalty Order

cc: Devera B. Scott, Deputy Attorney General
Marjorie A. Crofts, WHS Director
Nancy C. Marker, SHWMS Program Administrator
Karen G. J'Anthony, SHWMS Program Manager
Melissa A. Ferree, SHWMS Environmental Engineer
Jenny M. Bothell, Enforcement Coordinator
Susan S. Baker, Paralegal
SHWMS File

WAIVER OF STATUTORY RIGHT TO A HEARING

Bayhealth Kent General Hospital hereby waives its right to a hearing and its opportunity to appeal or contest this Assessment and Order and agrees to the following:

1. **Bayhealth Kent General Hospital** will pay the administrative penalty in the amount of \$73,509.00 by sending a check payable to the "State of Delaware" within 30 days of receipt of this Assessment and Order. The check shall be directed to Devera B. Scott, Deputy Attorney General, Department of Justice, 102 W. Water Street-3rd Floor, Dover, DE 19904; and
2. **Bayhealth Kent General Hospital** will reimburse the Department in the amount of \$11,026.00 which represents the Department's estimated costs. The reimbursement shall be paid within 30 days of receipt of this Assessment and Order. The check shall be made payable to the "State of Delaware" and be directed to Devera B. Scott, Deputy Attorney General, Department of Justice, 102 W. Water Street-3rd Floor, Dover, DE 19904.

Bayhealth Kent General Hospital

Date: _____

By: _____

Title: _____