

EXHIBIT K

ARKANSAS DEPARTMENT OF HEALTH, CENTER FOR PUBLIC HEALTH PRACTICE

SUBJECT: Medical Waste Regulations Amendment

DESCRIPTION: The Medical Waste Program is making changes to the Rules and Regulations Pertaining to the Management of Medical Waste from Generators and Health Care Related Facilities; Section VII – Requirements for Transporters of Commercial Medical Waste (K.)

The proposed changes allow for variance in the manifest/tracking documentation that must be provided to the generators by the commercial medical waste transporters at the time of waste transfer.

PUBLIC COMMENT: A public hearing was held on September 20, 2016. The public comment period expired on September 20, 2016.

The Department received the following comment from Selin Hoboy and Al Burson from Stericycle, Inc:

COMMENT:

“Stericycle appreciates the opportunity to provide comments on these proposed regulations and respectfully request that the Arkansas Department of Health consider the use of volume (per DOT as stated) as an option instead of weight (only)” or the number of containers”, such that we can ensure compliance with the Department and DOT. Additionally, we request that VII. K. 4.b. be stricken from the proposed rules and not be adopted or amended to provide greater flexibility in time to return to generator (i.e. 45 days).”

RESPONSE:

The current proposed revision is as follows:

4. The weight (pounds) or the number of containers of commercial medical waste transported. (This will stay as is. The reporting of volume only is not descriptive enough for agency needs. ADH needs to ensure that each container of waste is accounted for by the transporter, while in transit. Volume may still be reported; however, either weight in pounds or the number of containers would be required by ADH. Further, changes to K. 4.b. as requested allows for the flexibility in reporting time (i.e. 45 days) to permit transporters with real-time tracking capability time to report the weight in pounds to the generators.)

a. The commercial medical waste transporter may provide at the time of pick-up the number of containers if the transporter can track real-time individual waste containers from the point of collection through the point of treatment.

If the weight (pounds) of each container is not provided at the time of transfer, the commercial medical waste transporter must report the weight (pounds) of each container to the generator within fourteen (14) days. (Our regulation states that this info is required

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to be included as part of the log/manifest to the generator. ADH will amend this to 45 days instead of 14).

The proposed effective date is tentatively set for February 15, 2017.

CONTROVERSY: This is not expected to be controversial.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: Arkansas Code Annotated § 20-7-109 (a)(1)(B) gives the Department of Health the authority to make all necessary rules and reasonable rules and regulations of a general nature regarding the sanitary and hygienic conditions within the state.

Specifically, Ark. Code Ann. § 20-32-106 (a) authorizes the Department of Health to regulate the segregation, packaging, storage, transportation, treatment and disposal of commercial medical waste.

**QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS
WITH THE ARKANSAS LEGISLATIVE COUNCIL AND JOINT INTERIM COMMITTEE**

DEPARTMENT/AGENCY Arkansas Department of Health
DIVISION Center for Public Health Practice
DIVISION DIRECTOR Shirley Louie
CONTACT PERSON Carrie Poston
ADDRESS ADH, 4815 West Markham, Slot 32, Little Rock, AR 72205
PHONE NO. 661-2621 FAX NO. 280-4090 E-MAIL carrie.poston@arkansas.gov
NAME OF PRESENTER AT COMMITTEE MEETING Robert Brech
PRESENTER E-MAIL robert.brech@arkansas.gov

INSTRUCTIONS

- A. Please make copies of this form for future use.
- B. Please answer each question **completely** using layman terms. You may use additional sheets, if necessary.
- C. If you have a method of indexing your rules, please give the proposed citation after "Short Title of this Rule" below.
- D. Submit two (2) copies of this questionnaire and financial impact statement attached to the front of two (2) copies of the proposed rule and required documents. Mail or deliver to:

**Donna K. Davis
Administrative Rules Review Section
Arkansas Legislative Council
Bureau of Legislative Research
One Capitol Mall, 5th Floor
Little Rock, AR 72201**

1. What is the short title of this rule? Medical Waste Regulations Amendment

2. What is the subject of the proposed rule? The proposed changes allow for variance in the manifest/tracking documentation that must be provided to the generators by the commercial medical waste transporters at the time of waste transfer.

3. Is this rule required to comply with a federal statute, rule, or regulation? Yes No
If yes, please provide the federal rule, regulation, and/or statute citation. _____

4. Was this rule filed under the emergency provisions of the Administrative Procedure Act? Yes No
If yes, what is the effective date of the emergency rule? _____

When does the emergency rule expire? _____

Will this emergency rule be promulgated under the permanent provisions of the Administrative Procedure Act? Yes No

5. Is this a new rule? Yes No
If yes, please provide a brief summary explaining the regulation. _____

Does this repeal an existing rule? Yes No
If yes, a copy of the repealed rule is to be included with your completed questionnaire. If it is being replaced with a new rule, please provide a summary of the rule giving an explanation of what the rule does. _____

Is this an amendment to an existing rule? Yes No
If yes, please attach a mark-up showing the changes in the existing rule and a summary of the substantive changes. **Note: The summary should explain what the amendment does, and the mark-up copy should be clearly labeled "mark-up."**

6. Cite the state law that grants the authority for this proposed rule? If codified, please give the Arkansas Code citation. Act 96 of 1913, as amended, the same being A.C.A. 20-7-109, Act 41 of 1992 and Acts 491 and 861 of 1993, the same being A.C.A. 20-32-101 through 112, and Act 150 of 1999, the same being A.C.A 20-32-108.

7. What is the purpose of this proposed rule? Why is it necessary? The proposed changes allow for variance in the manifest/tracking documentation that must be provided to the generators by the commercial medical waste transporters at the time of waste transfer.

8. Please provide the address where this rule is publicly accessible in electronic form via the Internet as required by Arkansas Code § 25-19-108(b). www.healthy.arkansas.gov

9. Will a public hearing be held on this proposed rule? Yes No

If yes, please complete the following:

Date: September 20, 2016

Time: 3:30 p.m.

Place: ADH 5th Floor Briefing Room

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)
September 20, 2016

11. What is the proposed effective date of this proposed rule? (Must provide a date.)
Tentatively February 15, 2017

12. Do you expect this rule to be controversial? Yes No

If yes, please _____

explain.

13. Please give the names of persons, groups, or organizations that you expect to comment on these rules?
Please provide their position (for or against) if known.

unknown

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas Department of Health
DIVISION Center for Public Health Practice
PERSON COMPLETING THIS STATEMENT Carrie Poston
TELEPHONE NO. 661-2621 **FAX NO.** 280-4090 **EMAIL:** carrie.poston@arkansas.gov

To comply with Ark. Code Ann. § 25-15-204(e), please complete the following Financial Impact Statement and file two copies with the questionnaire and proposed rules.

SHORT TITLE OF THIS RULE Medical Waste Regulations Amendment

- 1. Does this proposed, amended, or repealed rule have a financial impact? Yes No

- 2. Is the rule based on the best reasonably obtainable scientific, technical, economic, or other evidence and information available concerning the need for, consequences of, and alternatives to the rule? Yes No

- 3. In consideration of the alternatives to this rule, was this rule determined by the agency to be the least costly rule considered? Yes No

If an agency is proposing a more costly rule, please state the following:

- (a) How the additional benefits of the more costly rule justify its additional cost;

- (b) The reason for adoption of the more costly rule;

- (c) Whether the more costly rule is based on the interests of public health, safety, or welfare, and if so, please explain; and;

- (d) Whether the reason is within the scope of the agency's statutory authority; and if so, please explain.

4. If the purpose of this rule is to implement a federal rule or regulation, please state the following:

- (a) What is the cost to implement the federal rule or regulation?

Current Fiscal Year

Next Fiscal Year

General Revenue _____
Federal Funds _____
Cash Funds _____
Special Revenue _____
Other (Identify) _____

General Revenue _____
Federal Funds _____
Cash Funds _____
Special Revenue _____
Other (Identify) _____

Total 0

Total 0

(b) What is the additional cost of the state rule?

Current Fiscal Year

Next Fiscal Year

General Revenue _____
Federal Funds _____
Cash Funds _____
Special Revenue _____
Other (Identify) _____

General Revenue _____
Federal Funds _____
Cash Funds _____
Special Revenue _____
Other (Identify) _____

Total 0

Total 0

5. What is the total estimated cost by fiscal year to any private individual, entity and business subject to the proposed, amended, or repealed rule? Identify the entity(ies) subject to the proposed rule and explain how they are affected.

Current Fiscal Year

Next Fiscal Year

\$ 0

\$ 0

6. What is the total estimated cost by fiscal year to state, county, and municipal government to implement this rule? Is this the cost of the program or grant? Please explain how the government is affected.

Current Fiscal Year

Next Fiscal Year

\$ 0

\$ 0

7. With respect to the agency's answers to Questions #5 and #6 above, is there a new or increased cost or obligation of at least one hundred thousand dollars (\$100,000) per year to a private individual, private entity, private business, state government, county government, municipal government, or to two (2) or more of those entities combined?

Yes No

If YES, the agency is required by Ark. Code Ann. § 25-15-204(e)(4) to file written findings at the time of filing the financial impact statement. The written findings shall be filed simultaneously with the financial impact statement and shall include, without limitation, the following:

(1) a statement of the rule's basis and purpose;

(2) the problem the agency seeks to address with the proposed rule, including a statement of whether a rule is required by statute;

(3) a description of the factual evidence that:

(a) justifies the agency's need for the proposed rule; and

- (b) describes how the benefits of the rule meet the relevant statutory objectives and justify the rule's costs;
- (4) a list of less costly alternatives to the proposed rule and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (5) a list of alternatives to the proposed rule that were suggested as a result of public comment and the reasons why the alternatives do not adequately address the problem to be solved by the proposed rule;
- (6) a statement of whether existing rules have created or contributed to the problem the agency seeks to address with the proposed rule and, if existing rules have created or contributed to the problem, an explanation of why amendment or repeal of the rule creating or contributing to the problem is not a sufficient response; and
- (7) an agency plan for review of the rule no less than every ten (10) years to determine whether, based upon the evidence, there remains a need for the rule including, without limitation, whether:
 - (a) the rule is achieving the statutory objectives;
 - (b) the benefits of the rule continue to justify its costs; and
 - (c) the rule can be amended or repealed to reduce costs while continuing to achieve the statutory objectives.



Arkansas Department of Health

4815 West Markham Street • Little Rock, Arkansas 72205-3867 • Telephone (501) 661-2000

Governor Asa Hutchinson

Nathaniel Smith, MD, MPH, Director and State Health Officer

SUMMARY OF RULE CHANGE

The Medical Waste Program is making the following changes to the *RULES AND REGULATIONS PERTAINING TO THE MANAGEMENT OF MEDICAL WASTE FROM GENERATORS AND HEALTH CARE RELATED FACILITIES; SECTION VII – Requirements for Transporters of Commercial Medical Waste (K.)*.

The proposed changes allow for variance in the manifest/tracking documentation that must be provided to the generators by the commercial medical waste transporters at the time of waste transfer. Attached for your review is a copy of the proposed changes.