EXHIBIT H

DEPARTMENT OF HEALTH

SUBJECT: Rules and Regulations Pertaining to Reportable Disease

DESCRIPTION: The Outbreak Response Section proposes the following changes to the Rules and Regulations Pertaining to Reportable Diseases. The following proposed changes agree with recent modifications of the nationally notifiable disease list by the Council of State and Territorial Epidemiologists and practices among other state health departments:

Conditions newly made mandatorily reportable nationally:
Carbapenem-resistant Enterobacteriaciae (CRE):
These rare but highly drug-resistant infections are emerging nationally as an important clinical problem. They are highly fatal and often reflect major deviations in recommended antibiotic prescribing and thus are a focus of intensive infection containment and quality improvement efforts.

Conditions newly defined nationally:
Candida Auris (Candida haemulonii):
This non-albicans Candida species emerged internationally in the last 12 months and has been found to be resistant to all anti-fungal medicines. Infections are often fatal and risk factors are poorly defined. Identifying the organism is challenging and it is routinely mis-identified as *C. haemulonii*, so we propose to add both rare organisms to the list.

Conditions newly proposed to be added at the state level:
Bacillus cereus as well as Bacillus species that cannot be ruled out as *B. anthracis* or *B. cereus bv anthracis*, and *Yersinia enterocolitica:*
Both *B. cereus* and *Y. enterocolitica* are rarely diagnosed, but are thought to be an important cause of preventable foodborne disease outbreaks. If an Arkansan tests positive for these infections via a lab test, we would want to know of it.

Conditions proposed to be removed from the state's reportable disease list:
Non-fatal and non-hospitalized influenza infection:
Influenza remains a major public health and clinical priority, killing hundreds and sickening hundreds of thousands of Arkansans each year. The reporting of influenza has been recognized as a major burden for clinicians and the ADH for years and has been a target of ongoing surveillance improvement strategies. Several automated electronic data feeds from the majority of Arkansas hospitals, many clinics, a few large pharmacies, vital records, industry partners, and the state's largest insurer have been piloted for the last two years and are now considered mature enough to forgo the need for individual provider-based case reporting of routine influenza cases. We still intend to require that all influenza hospitalizations and deaths be reported as before.

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Conditions added to improve detection of potential terrorist events/radiation misadministration:
Suspected unintentional radiation exposure:
While it is unlikely that a provider would not recognize this as an example of potential terrorism, we wanted to assure that the ADH was notified early, along with law enforcement, in case it represented a failure to appropriately contain or handle medical supplies or medical waste.

Clinical radiation adverse event:
The ADH licenses and regulates providers who administer radiotherapy. Suspected equipment failure, radiation misdosing, or unusually severe reactions should initiate prompt investigation by the licensee and ADH.

Updates regarding isolates or specimens that must be submitted to the ADH public health laboratory:
Bacillus cereus bv anthracis or Bacillus species that cannot be ruled out as *B. anthracis* or *B. cereus bv anthracis,Candida Auris (Candida haemulonii),Vibrio Cholera, V. parahaemoliticus, V. vulnificus,* Brucellosis, Melioidosis (Burkholderia pseudomallei), Glanders (Burkholderia mallei),
During the last update to these rules and regulations, these rare species were inadvertently left off from being required to be submitted.

Clarifications:
All outbreaks of diseasès on the list (or other emerging diseases not specifically mentioned on the list) should be reported immediately (within 4 hours) via phone to the ADH.

All unusually drug resistant infections should be reported within 24 hours to the ADH.

PUBLIC COMMENT: A public hearing was held on November 1, 2018. The public comment period expired on November 1, 2018. The Department received no comments.

The proposed effective date is pending legislative review and approval.

FINANCIAL IMPACT: There is no financial impact.

LEGAL AUTHORIZATION: Arkansas Code Annotated §§ 20-7-109(a)(1)(A)&(C) authorize the State Board of Health to make all necessary and reasonable rules and regulations of a general nature for the protection of the public health and safety and for the suppression and prevention of infectious, contagious, and communicable diseases.

QUESTIONNAIRE FOR FILING PROPOSED RULES AND REGULATIONS WITH THE ARKANSAS LEGISLATIVE COUNCIL

DEPARTMENT/AGENCY Arkansas Department of Health

DIVISION Outbreak Response Section

DIVISION DIRECTOR Dirk Haselow MD, PhD, Outbreak Response Medical Director

CONTACT PERSON Catherine Waters RN, Outbreak Response Section Chief

ADDRESS 4815 West Markham, Little Rock, AR 72205

PHONE NO. 501-661-2318 **FAX NO.** 501-661-2300 **E-MAIL** catherine.waters@arkansas.gov

NAME OF PRESENTER AT COMMITTEE MEETING Laura Shue

PRESENTER E-MAIL laura.shue@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

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1. What is the short title of this rule? Rules and Regulations Pertaining to Reportable Disease

2. What is the subject of the proposed rule? Proposed updates alter the current Communicable Disease list to agree with federal guidance and clarify bacterial isolate submission requirements.

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 Ark. Code Ann. §§ 20-7-101 et seq.

7. What is the purpose of this proposed rule? Why is it necessary? To agree with federal guidance regarding communicable disease reporting and to clarify bacterial isolate submission requirements.

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/rules-and-regulations

9. Will a public hearing be held on this proposed rule? Yes ☒ No ☐
If yes, please complete the following:

Date: November 1, 2018
Time: 10:00 a.m.
Place: Room # 2508 of the Department of Health building at 4815 West Markham Street, Little Rock, Arkansas

10. When does the public comment period expire for permanent promulgation? (Must provide a date.)
4:30 p.m. on November 1, 2018

11. What is the proposed effective date of this proposed rule? (Must provide a date.)
_____

12. Please provide a copy of the notice required under Ark. Code Ann. § 25-15-204(a), and proof of the publication of said notice. _____

13. Please provide proof of filing the rule with the Secretary of State and the Arkansas State Library

as required pursuant to Ark. Code Ann. § 25-15-204(e). _____

14. 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. Association for Professionals in Infection Control and Epidemiology (APIC)- for, American Society of Clinical Laboratory Services (ASCLS) and Clinical Laboratory Management Association (CLMA)-for

FINANCIAL IMPACT STATEMENT

PLEASE ANSWER ALL QUESTIONS COMPLETELY

DEPARTMENT Arkansas Department of Health

DIVISION Outbreak Response Section

PERSON COMPLETING THIS STATEMENT Catherine Waters RN

TELEPHONE 501-661-2318 **FAX** 501-661-2300 **EMAIL:** catherine.waters@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 Proposed Changes to Rules and Regulations Pertaining to Reportable Disease

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		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		Other (Identify)	
Total	0	Total	0

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

Current Fiscal Year		Next Fiscal Year	
General Revenue		General Revenue	
Federal Funds		Federal Funds	
Cash Funds		Cash Funds	
Special Revenue		Special Revenue	
Other (Identify)		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
$ _____

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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
$ 0

Next Fiscal Year
$ 0

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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.

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