



Dedicated to protecting and improving the health and environment of the people of Colorado

To: Members of the State Board of Health

From: Dr. Lisa Miller, Communicable Disease Branch Chief, Disease Control and Environmental Epidemiology (DCEED) ^{LM}

Through: Dr. Rachel Herlihy, DCEED Division Director ^{RH}

Date: December 2, 2015

Subject: **Request for Rulemaking Hearing**
Proposed Amendments to Rules and Regulations Pertaining to Epidemic and Communicable Disease Control, 6 CCR 1009-1 for the Board of Health rulemaking request occurring on December 16, 2015

On August, 19, 2015, the Board approved a number of updates, clarifications, and technical changes to the Rules and Regulations Pertaining to Epidemic and Communicable Disease Control. We were recently alerted by a stakeholder that one of the footnotes to the approved Reportable Diseases Table was incorrect and not consistent with our previous stakeholder communication. Through review, we also detected a second error within another footnote.

- 1) The Department communicated that we were changing the definition of carbapenem-resistant Enterobacteriaceae (CRE) to be consistent with a proposed national case definition. However, footnote #9 in the Reportable Diseases Table does not have the correct definition that was included in previous multiple communications with stakeholders, with the Board in the Statement of Basis and Purpose in the rulemaking document or as discussed in the Department's presentation to the Board. This was an oversight that was not detected in the multiple revisions to the rule.

The definition currently reads:

Escherichia coli, *Klebsiella* species, and *Enterobacter* species that are intermediate or resistant to at least one carbapenem (including imipenem, meropenem, doripenem, or ertapenem) AND resistant to all third-generation cephalosporins tested (ceftriaxone, cefotaxime, and ceftazidime); OR *Escherichia coli*, *Klebsiella* species, and *Enterobacter* species that test positive for carbapenemase production (by any method, including the Modified Hodge Test, disk diffusion, or PCR) production of a carbapenemase (i.e., KPC, NDM, VIM, IMP, OXA-48) demonstrated by a recognized test (e.g., polymerase chain reaction, metallo- β -lactamase test, modified-Hodge test, Carb-NP).

The definition should read:

Escherichia coli, *Klebsiella* species, and *Enterobacter* species that are resistant to at least one carbapenem (including imipenem, meropenem, doripenem, or ertapenem); OR *Escherichia coli*, *Klebsiella* species, and *Enterobacter* species that test positive for production of a carbapenemase (i.e., KPC, NDM, VIM, IMP, OXA-48)

demonstrated by a recognized test (e.g., polymerase chain reaction, metallo- β -lactamase test, modified-Hodge test, Carba-NP).

- 2) In response to stakeholder feedback received in September of 2015, the Department offered an amendment to the proposed rule during the rulemaking hearing on September 16, 2015. The amendment revised the Reportable Diseases Table pathogen/organism entry for *Pseudomonas*, carbapenem-resistant. The revision changed "Pseudomonas species" to "*Pseudomonas aeruginosa*." Though the table was revised to list *Pseudomonas aeruginosa* as a reportable organism, the Department did not revise the corresponding footnote (#14). The Department recommends that the footnote be revised to make this definition consistent with the table.

The definition currently reads:

Pseudomonas species that are resistant to at least one of the following carbapenems: imipenem, meropenem, or doripenem; OR *Pseudomonas* species that test positive for production of a carbapenemase (i.e., KPC, NDM, VIM, IMP, OXA).

The definition should read:

Pseudomonas aeruginosa resistant to at least one of the following carbapenems: imipenem, meropenem, or doripenem; OR *Pseudomonas aeruginosa* that tests positive for production of a carbapenemase (i.e., KPC, NDM, VIM, IMP, OXA).

No changes are proposed to the text of the rule or the Reportable Diseases Table, only footnote corrections. To provide context to the footnote entries the relevant excerpts from the Reportable Diseases Table have been provided; however, this is informational only.

**STATEMENT OF BASIS AND PURPOSE
AND SPECIFIC STATUTORY AUTHORITY**

for Amendments to
6 CCR 1009-1

Rules and Regulations Pertaining to Epidemic and Communicable Disease Control

Basis and Purpose.

The proposed change in the definition of carbapenem-resistant Enterobacteriaceae (CRE) which was communicated in the original Basis and Purpose document, and communicated to stakeholders, was incorrect in footnote #9 to the Reportable Diseases Table.

Current footnote: *Escherichia coli*, *Klebsiella* species, and *Enterobacter* species that are intermediate or resistant to at least one carbapenem (including imipenem, meropenem, doripenem, or ertapenem) AND resistant to all third-generation cephalosporins tested (ceftriaxone, cefotaxime, and ceftazidime); OR *Escherichia coli*, *Klebsiella* species, and *Enterobacter* species that test positive for carbapenemase production (by any method, including the Modified Hodge Test, disk diffusion, or PCR) production of a carbapenemase (i.e., KPC, NDM, VIM, IMP, OXA-48) demonstrated by a recognized test (e.g., polymerase chain reaction, metallo- β -lactamase test, modified-Hodge test, Carb-NP).

Proposed footnote: *Escherichia coli*, *Klebsiella* species, and *Enterobacter* species that are resistant to at least one carbapenem (including imipenem, meropenem, doripenem, or ertapenem); OR *Escherichia coli*, *Klebsiella* species, and *Enterobacter* species that test positive for production of a carbapenemase (i.e., KPC, NDM, VIM, IMP, OXA-48) demonstrated by a recognized test (e.g., polymerase chain reaction, metallo- β -lactamase test, modified-Hodge test, Carba-NP).

In addition, the Reportable Diseases Table lists carbapenem-resistant *Pseudomonas aeruginosa* as a reportable organism, but the corresponding footnote (#14) refers to *Pseudomonas* species. The Department recommends that the footnote be revised to make this definition consistent with the table.

Current footnote: *Pseudomonas* species that are resistant to at least one of the following carbapenems: imipenem, meropenem, or doripenem; OR *Pseudomonas* species that test positive for production of a carbapenemase (i.e., KPC, NDM, VIM, IMP, OXA).

Proposed footnote: *Pseudomonas aeruginosa* resistant to at least one of the following carbapenems: imipenem, meropenem, or doripenem; OR *Pseudomonas aeruginosa* that tests positive for production of a carbapenemase (i.e., KPC, NDM, VIM, IMP, OXA).

Specific Statutory Authority.

The Board of Health rules are promulgated pursuant to the following statutes:

C.R.S. 25-1.5-102 Epidemic and communicable diseases - powers and duties of department.

C.R.S. 25-1-122 Named reporting of certain diseases and conditions - access to medical records - confidentiality of reports and records.

SUPPLEMENTAL QUESTIONS

Is this rulemaking due to a change in state statute?

_____ Yes, the bill number is _____; rules are ___ authorized ___ required.
___x___ No

Is this rulemaking due to a federal statutory or regulatory change?

_____ Yes
___x___ No

Does this rule incorporate materials by reference?

_____ Yes
___x___ No

Does this rule create or modify fines or fees?

_____ Yes
___x___ No

REGULATORY ANALYSIS

for Amendments to
6 CCR 1009-1

Rules and Regulations Pertaining to Epidemic and Communicable Disease Control

- 1. A description of the classes of persons who will be affected by the proposed rule, including classes that will bear the costs of the proposed rule and classes that will benefit from the proposed rule.**

Classes of persons affected by the proposed rule changes include 1) clinical laboratory personnel; 2) personnel at hospitals responsible for reporting, such as infection preventionists. Users will benefit from the alignment of previously communicated changes with the published rule. Most, if not all, users have already made changes to reporting processes based on the previous communications.

- 2. To the extent practicable, a description of the probable quantitative and qualitative impact of the proposed rule, economic or otherwise, upon affected classes of persons.**

For clinical laboratory personnel, the correction will positively impact the understanding of the rule.

- 3. The probable costs to the agency and to any other agency of the implementation and enforcement of the proposed rule and any anticipated effect on state revenues.**

Not applicable.

- 4. A comparison of the probable costs and benefits of the proposed rule to the probable costs and benefits of inaction.**

The benefit of these changes are clearer, updated rules that are more easily interpreted and therefore, followed.

- 5. A determination of whether there are less costly methods or less intrusive methods for achieving the purpose of the proposed rule.**

Conducting surveillance for communicable diseases of public health significance is a standard procedure of epidemic and communicable disease control. No alternative methods are available to achieve the purposes of the authorizing statutes.

- 6. Alternative Rules or Alternatives to Rulemaking Considered and Why Rejected.**

Without this rulemaking, stakeholders will be confused by the lack of alignment between previously communicated intent to change the rule and the published rule.

- 7. To the extent practicable, a quantification of the data used in the analysis; the analysis must take into account both short-term and long-term consequences.**

Not applicable.

STAKEHOLDER COMMENTS
for Amendments to
6 CCR 1009-1
Rules and Regulations Pertaining to Epidemic and Communicable Disease Control

The following individuals and/or entities were included in the development of these proposed rules:

A stakeholder notified CDPHE Communicable Disease staff on November 24, 2015 about a discrepancy between the carbapenem-resistant Enterobacteriaceae (CRE) definition listed in the rule's Reportable Diseases Table (footnote #9), and the CRE definition that was previously communicated to stakeholders throughout the process and in the Statement of Basis and Purpose in the rulemaking document. Upon further review of the Reportable Diseases Table, a second oversight was found involving the technical definition of carbapenem-resistant *Pseudomonas aeruginosa* (footnote #14).

The following individuals and/or entities were notified that this rule-making was proposed for consideration by the Board of Health:

All clinical hospital laboratories and infection preventionists will be notified of this proposed correction to the published rule.

Summarize Major Factual and Policy Issues Encountered and the Stakeholder Feedback Received. If there is a lack of consensus regarding the proposed rule, please also identify the Department's efforts to address stakeholder feedback or why the Department was unable to accommodate the request.

We anticipate that stakeholders will desire the published rule and the previously communicated changes to be consistent.

Please identify health equity and environmental justice (HEEJ) impacts. Does this proposal impact Coloradoans equally or equitably? Does this proposal provide an opportunity to advance HEEJ? Are there other factors that influenced these rules?

No HEEJ impacts were identified.

DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Disease Control and Environmental Epidemiology Division

RULES AND REGULATIONS PERTAINING TO EPIDEMIC AND COMMUNICABLE DISEASE CONTROL

6 CCR 1009-1

[Editor's Notes follow the text of the rules at the end of this CCR Document.]

1 *****

2 Appendix A. Reportable Diseases Table

Disease/Event	Pathogen/Organism	Time	Reporter ¹	Specimen Source(s) ²	Send Clinical Material ³	Limited Reporting area ⁴
3						
4	*****					
	Enterobacteriaceae, carbapenem-resistant (CRE) ⁹	Carbapenem-resistant <i>Escherichia coli</i> , <i>Klebsiella</i> species, <i>Enterobacter</i> species	7 days	L	All	Requested ⁸

5 *****

	Pseudomonas, carbapenem-resistant ¹⁴	<i>Pseudomonas aeruginosa</i>	7 days	L	All	Requested ⁸
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6 *****

7 9 *Escherichia coli*, *Klebsiella* species, and *Enterobacter* species that are ~~intermediate or~~ resistant to
 8 at least one carbapenem (including imipenem, meropenem, doripenem, or ertapenem) ~~AND~~
 9 ~~resistant to all third-generation cephalosporins tested (ceftriaxone, cefotaxime, and ceftazidime);~~
 10 OR *Escherichia coli*, *Klebsiella* species, and *Enterobacter* species that test positive for
 11 ~~carbapenemase production (by any method, including the Modified Hodge Test, disk diffusion, or~~
 12 ~~PCR)~~ production of a carbapenemase (i.e., KPC, NDM, VIM, IMP, OXA-48) demonstrated by a
 13 recognized test (e.g., polymerase chain reaction, metallo-β-lactamase test, modified-Hodge test,
 14 Carb_a-NP).

15 *****

16 14 *Pseudomonas* ~~species *aeruginosa* that are~~ resistant to at least one of the following carbapenems:
 17 imipenem, meropenem, or doripenem; OR *Pseudomonas* ~~species *aeruginosa* that tests~~ positive
 18 for production of a carbapenemase (i.e., KPC, NDM, VIM, IMP, OXA)

19 *****