**FINAL AND PROPOSAL**

**FINAL AAP**

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**Title 10
MARYLAND DEPARTMENT OF HEALTH**

**Subtitle 10 LABORATORIES**

**10.10.11 Biological Agents Registry Program**

Authority: Health-General Article, §§17-601—17-605, Annotated Code of Maryland

**Notice of Final Action**

[20-017-F]

On April 28, 2020, the Secretary of Health adopted amendments to Regulations **.03**, **.04**, **.07**, **.09—.14**, **.21**, and **.22** under **COMAR 10.10.11 Biological Agents Registry Program**. This action, which was proposed for adoption in 47:2 Md. R. 96—99 (January 17, 2020), has been adopted as proposed.

**Effective Date: May 18, 2020.**

ROBERT R. NEALL
Secretary of Health

**PROPOSAL**

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**Issue Date: January 17, 2020**

**Volume 47 • Issue 2 • Page 96-99**

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Authority: Health-General Article, §§17-601—17-605, Annotated Code of Maryland

**Notice of Proposed Action**

[20-017-P]

     The Secretary of Health proposes to amend Regulations **.03**, **.04**, **.07**, **.09—.14**, **.21**, and **.22** under **COMAR 10.10.11 Biological Agents Registry Program**.

**Statement of Purpose**

The purpose of this action is to amend COMAR 10.10.11 to require persons to notify local health officers regarding incidents involving possible human exposure to biological agents (as set forth in CFR Title 42, Part 73; Title 7, Part 331; and Title 9, Part 121). The Department also proposes to revise and add definitions to COMAR 10.10.11 to clarify terms and procedures and update the methods and/or processes used to exchange BAR information with local jurisdictions, the Maryland Emergency Management Agency (MEMA), the BAR Program, the Department, the Maryland Institute for Emergency Medical Services Systems (MIEMSS), the Maryland Department of the Environment (MDE), and persons registered in the BAR program.

**Comparison to Federal Standards**

In compliance with Executive Order 01.01.1996.03, the proposed regulations are more restrictive or stringent than corresponding federal standards as follows:

(1) Regulation citation and manner in which it is more restrictive than the applicable federal standard:

     COMAR 10.10.11.09 — .13 provides that, in addition to the CDC and/or APHIS, incidents involving potential human exposure to biological agents must also be reported to the BAR Program, the Maryland Department of the Environment, Emergency Management Director(s) and health officer(s) of the affected jurisdiction(s).

(2) Benefit to the public health, safety or welfare, or the environment:

     Reporting to these State entities will ensure that individuals subject to potential exposure of a biological agent will be followed and/or monitored by health officers and their respective local health departments.

(3) Analysis of additional burden or cost on the regulated person:

     The effect of the proposed amendments on the BAR Program, Maryland Department of the Environment, State Emergency Management Directors, and health officers should be minimal since the amendments only provide additional reporting requirements.

(4) Justification for the need for more restrictive standards:

     Public safety is paramount in the event of possible human exposure to biological agents. Containment of the biological agent can only be achieved through a coordinated effort to disseminate information to State entities charged with managing emergency situations, and to local health departments who can follow and monitor persons potentially affected by exposure to biological agents.

**Estimate of Economic Impact**

The proposed action has no economic impact.

**Economic Impact on Small Businesses**

The proposed action has minimal or no economic impact on small businesses.

**Impact on Individuals with Disabilities**

The proposed action has no impact on individuals with disabilities.

**Opportunity for Public Comment**

Comments may be sent to Jake Whitaker, Acting Director, Office of Regulation and Policy Coordination, Maryland Department of Health, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499 (TTY 800-735-2258), or email to mdh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through February 18, 2020. A public hearing has not been scheduled.

**.03 Definitions.**

A. (text unchanged)

B. Terms Defined.

(1)—(5) (text unchanged)

(6) BAR Information Custodian.

(a) (text unchanged)

(b) “BAR information custodian” may include:

**(**i) A health officer *or designee*;

(ii)An Emergency Management Director or **[**equivalent**]***designee*; and

(iii) (text unchanged)

(7)—(23) (text unchanged)

*(24) “Exposure” means the condition of being subjected to a biological agent which may have a harmful effect.*

**[**(24)**]** *(25)*—**[**(30)**]** *(31)*(text unchanged)

**[**(31)**]***(32)*Nature of a Biological Agent.

(a) (text unchanged)

(b) “Nature of a biological agent” includes:

(i)—(vii) (text unchanged)

(viii) Any combination of **[**§B(30)(b)(i)**]***§B(32)(b)(i)*—(vii) of this regulation.

(c) (text unchanged)

**[**(32)**]***(33)*—**[**(33)**]** *(34)*(text unchanged)

**[**(34)**]***(35)***[**Personal Protective Equipment (PPE).

(a)**]** “Personal protective equipment (PPE)” means the type of physical barrier equipment necessary to:

**[**(i)**]** *(a)*—**[**(ii)**]** *(b)*(text unchanged)

**[**(b) “Personal protective equipment (PPE)” includes, but is not limited to:

(i) Face protection, such as a face shield or goggles;

(ii) Protective clothing, such as a laboratory coat or gloves; and

(iii) Respiratory protection, such as a surgical mask, respirator, or self-contained breathing apparatus.

(c) “Personal protective equipment (PPE)” includes:

(i) For BSL-2, laboratory coat, gloves, and face protection as needed;

(ii) For BSL-3, protective laboratory clothing, gloves, booties, hair covering, face protection, and respiratory protection as needed; and

(iii) For BSL-4, full body, air-supplied, positive pressure personnel suit.**]**

**[**(35)**]***(36)*—**[**(37)**]** *(38)*(text unchanged)

*(39) “Secretary” means the Secretary of Health.*

**[**(38)**]** *(40)*—**[**(46)**]** *(48)*(text unchanged)

**.04 Incorporation by Reference.**

A. (text unchanged)

B. Documents Incorporated.

(1)—(4) (text unchanged)

(5) CDC/NIH publication, “Biosafety in Microbiological and Biomedical Laboratories”, 5th Edition, December 2009*, as amended.*

**.07 Responsibilities of the Department.**

The Department shall:

A.—E. (text unchanged)

F. Release BAR information, as provided in this chapter, to:

(1) (text unchanged)

(2) CDC; **[**and**]**

(3) Trusted partners**[**.**]***; and*

*(4) The Secretary or designee.*

**.09 Reporting Requirements.**

A. (text unchanged)

B. When to Report. A person shall:

(1) Complete and submit a report within 30 days of receiving**[**:**]** *a request to report from the Department;*

**[**(a) An initial request to report from the Department; and

(b) A periodic request to report from the Department;**]**

(2)—(4) (text unchanged)

C.—D. (text unchanged)

**.10 Additional Requirements Covering Possession, Maintenance, Transfer, or Receipt of a Biological Agent.**

A person possessing, maintaining, transferring, or receiving a biological agent at a facility located in the State shall:

A.—D. (text unchanged)

E. Inform the Emergency Management Director *or designee and health officer or designee* in the local jurisdiction where the biological agent is located of the nature and facility location of each reported biological agent that is located in that jurisdiction.

**.11 Reporting of Unauthorized Activities.**

On learning that there is an unauthorized activity involving a biological agent, including the unauthorized possession, unauthorized attempted possession, unauthorized maintenance, unauthorized transfer, or unauthorized receipt of a biological agent, a person shall immediately alert the Department by:

A. Telephoning the:

(1) Laboratories Administration at **[**410-767-6100**]***443-681-3787 or 410-925-3121*between 8 a.m. and 4:30 p.m. weekdays; or

(2) Department's emergency after-hours and weekend telephone line **[**at MIEMSS**]** at 410-795-7365 at other times;

B.—C. (text unchanged)

**.12 Biological Agent Incident Response Plan.**

A. (text unchanged)

B. A person required to submit a biological agent incident response plan shall:

(1)—(8) (text unchanged)

(9) Notify the **[**emergency management director**]***Emergency Management Director* in the local jurisdiction where the biological agent is located and the BAR Program**[**:**]** *before a drill or exercise is conducted;*

**[**(a) Before a drill or exercise is conducted; and

(b) When a biological agent incident has occurred;**]**

*(10) Notify the Emergency Management Director and the health officer in the local jurisdiction where the biological agent is located and the BAR Program immediately following a biological agent incident involving exposure or potential exposure as set forth in COMAR 10.06.01.03A;*

**[**(10)**]** *(11)*—**[**(12)**]** *(13)*(text unchanged)

C. Monitoring Compliance. When a person submits a biological agent incident response plan to the BAR Program, the BAR Program shall**[**:**]***verify that the person submitting the plan has provided the information for planning and coordinating with local emergency responders to the Emergency Management Director in the local jurisdiction where the biological agent is located.*

**[**(1) Review the plan for compliance with this chapter; and

(2) Verify that the person submitting the plan has provided the information for planning and coordinating with local emergency responders to the emergency management director in the local jurisdiction where the biological agent is located.**]**

**.13 BAR Information Confidentiality and Release of BAR Information.**

A.—D. (text unchanged)

E. The BAR Program may release BAR information only to:

(1) (text unchanged)

(2) CDC; **[**and**]**

(3) BAR information custodians of trusted partners**[**.**]***;*

*(4) The Secretary or designee; and*

*(5) The health officer of any affected jurisdiction.*

F. Before the BAR Program releases BAR information to a person, except State and federal law enforcement agencies*,***[**and**]** the CDC, *and the Department,*the person shall:

(1)—(3) (text unchanged)

G. Mutual Aid Response. When multiple local jurisdictions respond to an emergency *or biological agent incident*, the **[**emergency management director] *Emergency Management Director* of one responding jurisdiction may share BAR information with an **[**emergency management director**]***Emergency Management Director* from another local jurisdiction*, and the health officer of one jurisdiction may share BAR information with the health officer of another jurisdiction* that is providing mutual aid by assisting with the emergency response.

H. (text unchanged)

I. 24/7 Access to BAR Information.

(1) MDE, MEMA, and MIEMSS may act as a back-up to the BAR Program by maintaining:

(a) (text unchanged)

(b) Access to BAR information when a trusted partner**[**:**]** *does not have access to BAR information.*

**[**(i) Experiences a BAR information computer information system malfunction; or

(ii) Otherwise does not have access to BAR information.**]**

(2) MDE, MEMA, or MIEMSS may release BAR information regarding the nature and location of a biological agent to each other or another BAR Program trusted partner if the trusted partner**[**:**]** *is unable to obtain access to BAR information.*

**[**(a) Has a computer information system failure or other incident that prevents access to BAR information; or

(b) Is unable to obtain access to BAR information.**]**

J. Emergency Release of Name or Identity of a Biological Agent. MDE, MEMA, or MIEMSS may release by any necessary means of communication the name or identity of the specific biological agent located at the site of an emergency response to protect the health and safety of the public and emergency response personnel if:

(1) There is:

*(a)***[**a**]** *A* breach in containment of a biological agent**[**or there is an**]***;*

*(b) An* imminent threat of a breach of containment*;**or*

*(c) An exposure or potential exposure*;

(2) The breach or imminent threat of a breach*, exposure, or potential exposure* is confirmed by the:

(a) (text unchanged)

(b) Emergency public safety personnel at the scene of the emergency response; **[**and**]**

*(c) Occupational Health; and*

(3) (text unchanged)

K. (text unchanged)

L. Notification Protocol.

(1) When there is a breach or imminent threat of a breach in containment of a biological agent*, exposure, or potential exposure* as described in §J of this regulation, the:

*(a) Responsible official or other designated person shall immediately notify the Emergency Management Director and health officer of any affected jurisdiction;*

**[**(a)**]***(b)* (text unchanged)

**[**(b)**]** *(c)*9-1-1 center personnel shall notify MIEMSS and each of the following individuals in the jurisdiction where the breach*, exposure, or potential exposure*occurred:

(i) The **[**emergency management director**]** *Emergency Management Director*; and

(ii) (text unchanged)

(2) When MIEMSS receives notice of a breach or an imminent threat of a breach of containment of a biological agent, *exposure, or potential exposure,* MIEMSS shall notify:

(a) (text unchanged)

(b) MDE; **[**and**]**

(c) MEMA**[**.**]***;and*

*(d) The health officer of any affected jurisdiction.*

(3) Immediately after the health officer is notified by 9-1-1 center personnel, the health officershall contact the Department’s physician on-call to:

(a)—(b) (text unchanged)

M. (text unchanged)

**.14 Method of Non-Emergency Release of BAR Information.**

A. A person shall release and transfer BAR information to a trusted partner and a BAR information custodian in a secure manner, which includes the use of:

(1) (text unchanged)

(2) Encryption **[**and**]***,* decryption*, passwords, and firewalls*; **[**and**]**

(3) (text unchanged)

**[**B. Unless authorized or required by federal regulation as set forth in Regulation .04B(2)—(4) of this chapter and except as provided in Regulation .13G, H, J, and K of this chapter, a person other than the BAR Program may not release, transfer, or share BAR information using:**]**

**[**(1)**]** *(4)—***[**(2)**]** *(5)*(text unchanged)

**[**(3)**]** *(6)*An electronic or mechanical recording device; *and*

**[**(4)**]***(7)* (text unchanged)

**[**C.**]** *B.***[**Release of BAR Information to a Local Jurisdiction, MDE, MEMA, and MIEMSS.**]***The BAR Program shall release BAR information to a BAR information custodian of a local jurisdiction, MDE, MEMA, and MIEMSS:*

**[**(1) The BAR Program shall release BAR information to a BAR information custodian of a local jurisdiction, MDE, MEMA, and MIEMSS:**]**

**[**(a)**]** *(1)*When notified by the BAR Program that the BAR information is available for release;*and*

**[**(b) In person;

(c) At the BAR Program office; and**]**

**[**(d)**]***(2)* On weekdays between the hours of 8:30 a.m. and 3:30 p.m.

**[**(2) A designated representative of the BAR Program shall provide a CD-R containing BAR information to a BAR information custodian of a local jurisdiction, MDE, MEMA, and MIEMSS after the BAR information custodian presents:

(a) A government issued photo identification, such as:

(i) A valid Maryland driver's license; or

(ii) An employee identification badge; and

(b) A prior CD-R containing BAR information, if the BAR Program’s BAR information release log indicates a CD-R was provided at an earlier time.**]**

**[**D.**]***C.* BAR Program staff shall document the release of all BAR information to trusted partners in a permanent record that contains the:

(1)—(2) (text unchanged)

(3) **[**Coded identity of the CD-R containing BAR information**]***Means of release of BAR information, including but not limited to:*

*(a) Encrypted email; and*

*(b) CD-R*; and

(4) Date and time of the release or delivery of the **[**CD-R**]***BAR information*.

**.21 BAR Information Security — Physical Safeguards.**

A trusted partner shall establish physical safeguards to guard BAR information integrity, confidentiality, and availability, which include:

A. (text unchanged)

B. A secure work station location with physical safeguards to eliminate or minimize the possibility of unauthorized access to BAR information, including:

(1)—(2) (text unchanged)

(3) Placing the computer monitor in a way that screen contents are not viewable by an unauthorized person **[**from within or outside the room**]**;

(4)—(5) (text unchanged)

C. BAR information media control procedures that govern the receipt, removal, and disposal of BAR information CD-R discs *or thumb drives* into or out of the facility, which include:

(1)—(4) (text unchanged)

**[**D. Physical access controls that limit access of unauthorized personnel while ensuring that properly authorized access is allowed;**]**

**[**E.**]***D.*—**[**I.**]***H.*(text unchanged)

**.22 BAR Information Security — Technical Security Measures.**

A trusted partner shall establish a system of technical security measures to protect BAR information integrity, confidentiality, and availability, which include:

A.—B. (text unchanged)

**[**C. Making access to BAR information available only with a freestanding PC (personal computer) that has no:

(1) Connection to:

(a) The Internet;

(b) An intranet; or

(c) A network; and

(2) External devices connected such as a:

(a) Portable hard drive;

(b) Removable memory card; or

(c) Flash memory device;**]**

**[**D.**]***C.* (text unchanged)

**[**E.**]***D.* Establishing procedures and processes for computer system authorization control for an individual to obtain access for the use and disclosure of BAR information, which include:

(1)—(4) (text unchanged)

(5) A logon mechanism using a:

(a)—(c) (text unchanged)

(d) Any combination of **[**§E(5)(a)**]** *§D(5)(a)*—(c) of this regulation;

**[**F.**]***E.*—**[**H.**]***G.* (text unchanged)

ROBERT R. NEALL
Secretary of Health