

JUN 17 2021

APPENDIX II-K
COVER SHEET FOR EMERGENCY RULE

ADOPTED RULE
DOCUMENT # <u>13214</u>
FILED <u>6-17-21 @ 2:16 PM</u>
EFFECTIVE <u>6-17-21 @ 2:16 PM</u>
EXPIRES <u>12-14-21</u>

Document Number 13214 Rule Number He-P 808.02 and He-P 817.02

<p>1. Agency Name & Address:</p> <p>Dept. of Health and Human Services Health Facilities Administration 129 Pleasant Street, Brown Building Concord, NH 03301</p> <p>5. Date of Filing: June 17, 2021</p>	<p>2. RSA Authority: RSA 151:2, I(a) and RSA 151:9, I(a) and (b)</p> <p>3. Federal Authority: _____</p> <p>4. Type of Action:</p> <p>Adoption _____</p> <p>Amendment _____</p> <p>Repeal _____</p> <p>Readoption _____</p> <p>Readopt with Amendment <u> X </u></p>
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6. Short Title: **Laboratory Rules/Collection Station Rules-Scope**

7. Contact person for copies and questions:

Name: Allyson Zinno	Title: Administrator- Administrative Rules Unit
Address: Dept. of Health & Human Services Administrative Rules Unit 129 Pleasant Street Concord, NH 03301	Phone #: 271-9604
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****PLEASE ATTACH THE FOLLOWING**, numbered to correspond to the numbers on this sheet (a separate sheet is not required for every item):

- 8. An explanation of the nature of (a) the imminent peril to public health or safety, demonstrating that the emergency rule is necessary to prevent the imminent peril, or (b) the substantial fiscal harm to the state or its citizens which could otherwise occur if the rule were not adopted as an emergency rule.
- 9. A summary of the effect if the rule were not adopted.
- 10. A description of those affected.

***PLEASE SUBMIT 2 COPIES OF THIS COVER SHEET** and all attachments along with 2 copies of the **emergency rule** to the Office of Legislative Services, Administrative Rules.

****PLEASE SIGN THE FOLLOWING:**
I, the adopting authority,* hereby certify that the attached is an accurate statement explaining why an emergency rule is necessary.

Date: 6/16/21

Signature: Lori Shibinette

Name: Lori A. Shibinette

Title: Commissioner

*("Adopting authority" is the official empowered by statute to adopt the rule, or a member of the group of individuals empowered by statute to adopt the rule.)

8. An explanation of the nature of (a) the imminent peril to public health or safety, demonstrating that the emergency rule is necessary to prevent the imminent peril, or (b) the substantial fiscal harm to the state or its citizens which could otherwise occur if the rule were not adopted as an emergency rule.

He-P 808 sets forth the licensing requirements for all laboratories, whether stationary or mobile, and laboratory services pursuant to RSA 151:2, I(c). He-P 817 sets forth the licensing requirements for all collection stations pursuant to RSA 151:2, I(c)

During the State of Emergency, the Department of Health and Human Services (Department), Bureau of Licensing and Certification was given the authority to waive various provisions of state statute to provide flexibility in order to facilitate the onsite point-of-care testing of all residents, staff, and visitors of residential facilities, to monitor and control the spread of COVID-19. On June 11, 2021 at 11:59pm, the State of Emergency concluded and this flexibility ended resulting in residential facilities being unable to continue the testing of residents, staff, and visitors for COVID-19.

The Department is proposing to readopt with amendment He-P 808.02 on the scope of the laboratories and laboratory service rules and He-P 817.02 on the scope of the collection station rules to allow for all residential facilities licensed pursuant to RSA 151 to conduct onsite point-of-care testing of residents, staff, and visitors for SARS-CoV-2, the novel coronavirus, also known as COVID-19. By entering into emergency rulemaking residential facilities would immediately continue to have the flexibility to conduct this testing which will prevent the imminent peril to the public health or safety by allowing residential facilities to quickly identify positive cases of COVID-19 and minimizing community transmission of COVID-19.

While there is no public hearing for emergency rulemaking, the Department will enter into regular rulemaking to permanently amend He-P 808.02 and He-P 817.02.

9. A summary of the effect if the rule were not adopted.

If the proposed He-P 808.02 and He-P 817.02 were not adopted then any residential facility licensed in the state of New Hampshire would be unable to continue conducting onsite point-of-care testing of their residents, staff, or visitors for COVID-19 without first obtaining licensure under He-P 808 and He-P 817. If onsite point-of-care was not allowed it could result in more harm in that residential facilities would not be able to identify positive cases of COVID-19 fast enough to reduce the spread.

10. A description of those affected.

The proposed He-P 808.02 and He-P 817.02 affect owners and operators of all residential facilities licensed pursuant to RSA 151 and their residents, staff, and visitors.

Doc. # 13214 (app. 6-17-21)
Emergency Rule Expires: 12-14-21

CHAPTER He-P 800 RESIDENTIAL CARE AND HEALTH FACILITY RULES

Statutory Authority: RSA 151:9

Readopt with amendment He-P 808.02, effective 2-2-13 (Document #10267), so that He-P 808.02 reads as follows:

PART He-P 808 LABORATORIES AND LABORATORY SERVICES RULES

He-P 808.02 Scope. This part shall apply to any individual, agency, partnership, corporation, government entity, association or other legal entity operating a laboratory, except:

- (a) The facilities listed in RSA 151:2, II (a)-(h);
- (b) All entities which are owned or operated by the state of New Hampshire, pursuant to RSA 151:2, II(i);
- (c) All laboratories which conduct testing solely for forensic purposes, pursuant to RSA 151:2, II(i);
- (d) All entities that are licensed in accordance with RSA 153-A by the department of safety as providers of transporting or non-transporting emergency medical care;
- (e) All entities that perform waived testing for the sole purpose of risk assessment and which test results are not used for the diagnosis or treatment of disease;
- (f) Laboratories that are duly licensed by the state of New Hampshire under this rule may perform the functions of a collection station without the additional requirement of an He-P 817 collection station license;
- (g) Laboratories that are owned, operated, and located on the licensed premises of a hospital licensed in accordance with RSA 151:2, I(a) and He-P 802; and
- (h) All residential facilities licensed pursuant to RSA 151, who are conducting onsite point-of-care testing of residents, staff, or visitors for SARS-CoV-2, the novel coronavirus, known as COVID-19.

Appendix

Rule	Specific State or Federal Statutes the Rule Implements
He-P 808.02	RSA 151:2,I(c); RSA 151:2,II; RSA 151:9,I(a)&(b)

PART He-P 817 COLLECTION STATION RULES

Readopt with amendment He-P 817.02, effective 11-20-15 (Document #10979), so that He-P 808.02 reads as follows:

He-P 817.02 Scope. This part shall apply to any individual, agency, partnership, corporation, government entity, association, or other legal entity operating a collection station, except:

- (a) All facilities listed in RSA 151:2, II(a)-(g);
- (b) All entities which are owned or operated by the state of New Hampshire, pursuant to RSA 151:2, II(h);
- (c) All collection stations that collect specimens from humans solely for forensic purposes, pursuant to RSA 151:2, II(h);
- (d) All entities which are licensed in accordance with RSA 153-A by the New Hampshire department of safety as providers of transporting or non-transporting emergency medical care;
- (e) Entities which are currently licensed under He-P 808 Laboratories and Laboratory Services Rules;
- (f) Entities which are currently licensed under He-P 806 Non-Emergency Walk-In Care Centers; and
- (g) All residential facilities licensed pursuant to RSA 151, who are conducting onsite point-of-care testing of residents, staff, or visitors for SARS-CoV-2, the novel coronavirus, known as COVID-19.

Appendix

Rule	Specific State or Federal Statutes the Rule Implements
He-P 817.02	RSA 151:9, I