EMERGENCY RULE

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APPENDIX II-K

COVER SHEET FOR EMERGENCY RULE

Document Number 13388 Rule Number **Ph 404.08**

1. Agency Name & Address:

N.H. Board of Pharmacy
c/o Office of Professional
Licensure & Certification
7 Eagle Square
Concord, NH 03301

5. Date of Filing: **May 25, 2022**

2. RSA Authority: **RSA 318:5-a, XII & XIII**
3. Federal Authority: **n/a**
4. Type of Action:
   - Adoption
   - Amendment **X**
   - Repeal

6. Short Title: **Compounding Procedures**

7. Contact person for copies and questions:

Name: **Tina M. Kelley** Title: **Program Specialist IV**
Address: **7 Eagle Square** Phone #: **(603) 271-5247**
Concord, NH 03301

**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: 5-25-2022

Signature: John Genovese

Name: John Genovese

Title: President

*("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.

Globally hospitals and providers are experiencing a severe shortage of contrast media for CT imaging. As of yesterday, the FDA continues to report shortages of GE Healthcare's iohexol and iodixanol intravenous contrast media products. Hospitals in New Hampshire are actively implementing conservation strategies to prioritize emergent and urgent patient cases and are evaluating all options available to them to use all resources appropriately. To that end, there is an opportunity to maximize single dose vials for more than one patient and these rules are intended to allow for that maximization.

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

If these emergency rules are not put in place at this time those individuals who require CT imaging could be placed in jeopardy either through prioritization of care or in cases that the contrast media for the CT scan is unavailable.

10. A description of those affected.

Those affected by this emergency are those individuals who seek treatment either in a hospital or one of New Hampshire's many providers for an injury or illness.

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Readopt with amendments Ph 404.08, effective 4-18-2015 (Document #10812), to read as follows:

Ph 404.08 Compounding Procedures.

(a) Each compounder shall ensure that all personnel adhere to the following when they are in the LAFW or buffer areas:

(1) No smoking, food, drink, or chewing gum shall be allowed in the buffer area at any time;

(2) No jewelry shall be worn on the hands or wrists and there shall be no visible piercings;

(3) No make-up shall be worn in the buffer area as it can shed particles;

(4) Before putting on gloves, the nails shall be cleaned, and the hands, wrists, and forearms shall be washed thoroughly for at least 30 seconds with warm water and antimicrobial skin cleanser;

(5) Personnel shall appropriately utilize gowns, masks, gloves, hair covers, and shoe covers;

(6) No paper, pens, labels, or trays shall be placed in the workbench; and

(7) No objects that shed particles shall be brought into the buffer area such as cardboard cartons, paper towels, and cotton items.

(b) Each compounder shall ensure when cleaning and disinfecting the interior work surfaces of the LAFW it is done from top to bottom, back to front, away for the HEPA filter.

(c) Each compounder shall ensure personnel check the quality, purity, amount, and identity of all ingredients.

(d) Each compounder shall ensure all personnel use the correct compounding procedures when compounding sterile products, and periodically disinfect gloves with sterile 70% isopropyl alcohol and allow them to dry thoroughly before continuing.

(e) Each compounder shall ensure that open and partially used containers are properly labeled and stored.

(f) Each compounder shall ensure the following:

(1) CSP has an appropriate BUD that is identified on all product labels;

(2) When the BUD exceeds USP standards, it is based on scientific criteria;

(3) Packaging is appropriate for sterility and stability;

(4) Product labels are appropriate and complete for safe use; and

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(5) Products are visually inspected for physical integrity during and after compounding, and a final check of the CSP is performed.

(g) Each compounder shall ensure any deficiencies in compounding procedures can be rapidly identified and corrected.

(h) Each compounder shall ensure that finished compounded products are maintained in a separate area away from the active compounding area, and that no more than 2 entries into any one sterile container or sterile administration device.

(i) Each compounder shall ensure all compounding activity only involves closed or sealed packaging systems.

(j) In the absence of stability and sterility testing of any CSP the compounder shall use BUD based on USP standards as defined for the following CSPs:

(1) Low risk compounded product storage shall not exceed 48 hours at room temperature, 14 days at cold temperature or 45 days in a frozen state if the stability of the product allows;

(2) Medium risk compounded product storage shall not exceed 30 hours at controlled room temperature, 9 days at cold temperature or 45 days in a frozen state;

(3) High risk compounded product storage shall not exceed 24 hours at room temperature**,** 3 days at cold temperature or 45 days in a frozen state.

(k) In response to the global shortage of iohexol and iodixanol intravenous contrast media products for CT imaging due to the ongoing COVID-19 pandemic and the immediate impact on access to critical care the NH Board of Pharmacy grants an extension of beyond-use-dates for single use vials of 4-days for medium-risk preparations stored at room temperature or 10 days refrigerated. In the event a bulk package or multidose bulk package are used, doses may be drawn up in a pharmacy clean room following USP guidelines with beyond-use-dating the same as for single dose containers. This beyond use dating is 4 days at room temperature or 10 days refrigerated. In the event the contents from a single does or single-use vile are used for more than one patient, adherence and compliance with the current edition of USP 797 as well as the manufacturer's recommendations pertaining to self-storage of that medication outside of its original container shall be followed.

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Rule	Specific State Statute the Rule Implements
Ph 404.08	RSA 318:5-a, II, IV-a