State of New Hampshire

The Office of Professional Licensure and Certification

REQUEST FOR INFORMATION

RFI-2023-ADMIN-02-PHARM

FOR

Pharmacy Facility License Review

February 3, 2023

REQUEST FOR INFORMATION

1. Overview and Purpose

1.1. Overview

The Office of Professional Licensure and Certification (OPLC) is issuing this Request for Information (RFI) to solicit information regarding facility licensing application review for the Board of Pharmacy (Board), which includes but is not limited to:

- Sterile and Non-Sterile Compounding ("Outsourcing Pharmacy").
- Non-resident/Mail Order Pharmacies.
- Nuclear Pharmacies.
- Manufacturers, Wholesalers, and Distributers ("MWD").
- Limited Retail Drug Distributer ("LRDD").

1.2. Purpose

The primary objective of this RFI is to collect information to inform the OPLC of the capabilities of entities to review applications and provide recommendations to the Board regarding potential approval or denial of facility applicants for the State of New Hampshire.

The entities would be responsible for reviewing initial and renewal applications for minimum satisfactory qualifications of licensure and continued licensure.

2. Background Information

2.1. The OPLC is seeking to revise its current facility application review process to:

2.1.1. Increase the State's ability to adapt to changing policies, federal compliance requirements, program needs, and user needs.

2.1.2. Ensure the State follows industry best practices and approaches to facility pharmacy licensing.

2.1.3. Increase efficiencies and cost effectiveness.

2.2. The OPLC currently has the following number of licensees:

2.2.1.	Sterile and Non-Sterile Compounding	45
2.2.2.	Non-resident/Mail Order Pharmacies	754
2.2.3.	Nuclear Pharmacies	0
2.2.4.	MWD	1,874
2.2.5.	LRDD	380

2.3. The facility licensing renewal periods for non-resident/mail order and nuclear pharmacies occur in November and December every two (2) years. The facility licensing renewal periods for Outsourcing Pharmacies, MWDs, and LRDDs occur in May and June every two (2) years.

2.4. Currently initial and renewal applications that have been disciplined by the Federal Drug Administration (FDA) or other licensing jurisdictions are sent for Board review. These applications are reviewed by one (1) of two (2) board

members with expertise in the appropriate area of specialty to ensure the application meets the requirements of the board. These reviewers then submit recommendations to the board for final determination of licensure.

3. RFI Explanation and Questions

3.1. Notes to Respondents

3.1.1. The State is seeking a better understanding in the areas listed below and requests interested vendors provide responses to the following questions, as applicable.

3.1.2. Respondents may respond to some or all of the questions below. Responses to all questions are encouraged, but not required. Please label responses according to the question being addressed.

3.1.3. Respondents may look to NH RSA 318:51-a – 318:51-c, and the New Hampshire Board of Pharmacy Administrative Rules Parts Ph 601, Ph 900, Ph 1000, and Ph 2000, for reference

3.2. Factors to Consider When Evaluating Licenses (this information is intended to assist respondents to understand the work that evaluators will conduct).

3.2.1. Evaluator shall identify MWDs that have been disciplined by a state licensing agency within the last twenty-four (24) months.

3.2.2. Evaluator shall identify MWDs that have been inspected by the Food and Drug Administration (FDA) in the last twenty-four (24) months and were issued a 483 Observation or FDA Warning Letter or were required to withdraw a drug from the market because of safety reasons.

3.2.3. Evaluator shall identify Outsourcing Facilities (503-B) that have been disciplined by a state licensing agency within the last twenty-four (24) months.

3.2.4. Evaluator shall identify 503-Bs that have been inspected by the FDA within the last twenty-four (24) months and were issued a 483 Observation or FDA Warning Letter or were required to withdraw a drug from the market because of safety reasons.

3.2.5. Evaluator shall identify Non-Resident Mail order pharmacies that perform Non-Sterile or Sterile Compounding that have been disciplined by a state licensing agency.

3.2.6. Evaluator shall identify Non-Resident Mail order pharmacies that have been inspected by the FDA within the last twenty-four (24) months and were issued a 483 Observation or FDA Warning Letter or were required to withdraw a drug issued a drug recall of a Compound Sterile Product from the market because of safety reasons.

3.2.7. Evaluator shall identify Non-Resident Mail Order pharmacies that compound non-sterile and sterile compounds and have been disciplined by a state licensing agency within the last twenty-four (24) months.

3.2.8. Evaluator shall identify any MWD, Outsourcing Facility or Non-Resident pharmacy that compound or prepares pharmaceutical products that are identical or essentially a copy of an FDA approved product.

3.2.9. Evaluator shall identify any MWD, Outsourcing Facility or Non-Resident pharmacy that compound or prepares pharmaceutical products and ships into New Hampshire that ordered suspicious, inappropriate or unusual quantities.

3.2.10. Evaluator shall evaluate the compliance of current Good Manufacturing Practice (cGMP) for Outsourcing Facilities.

3.2.11. Evaluator shall evaluate the compliance or compounding state of control for Non-Resident Mail Order Pharmacies regarding documentation and implementation including but not limited to:

3.2.11.1. Air pressure in classified room (+ or -);

3.2.11.2. Air Exchanges per hour (in the classified room);

3.2.11.3. ISO Class certified upon inspection in PEC, SEC, and ante room;

3.2.11.4. Air sample reports; and

3.2.11.5. Surface sample reports.

3.2.12. Evaluator shall identify Non-Resident Mail Order Pharmacies and Outsourcing Facilities that have both permits at the **exact** same geographical address.

3.2.13. Evaluator shall evaluate nuclear pharmacies for compliance.

3.2.14. Evaluator shall prepare an executive summary of each renewal or new application reviewed with recommendations for the Board for consideration.

3.3. **Questions**

1. *Does the company conduct business in all fifty (50) states?*
2. *Does your firm review USP Chapter 800 Hazardous Drug handling for both general pharmacy and handling of hazardous drug and compounding with hazardous drugs?*
3. *Per state/federal regulations, what expectation is set for your reviewer by your firm?*
4. *How long does it take for your reviewer to prepare a report with findings to submit to the board/ agency?*
5. *Will your reviewer be able to contact the facility for clarification or updated documents?*
6. *Do your reviewers have experience and/or certificates in any of the following:*
    - *Current Manufacturing Practices (cMPG)*

- *United States Pharmacopeia (USP) 797 / Sterile Compounding*
- *United States Pharmacopeia (USP) 797 / Non-Sterile Compounding*
- *United States Pharmacopeia (USP) 800 / Hazardous Drugs*
- *FDA Guidance Documents*
- *FDA 483 Observation Process*
- *FDA Warning Letters*
- *FDA Drug and Device Recall Process*
- *State of New Hampshire Pharmacy Laws*
- *RSA 318 Pharmacy Laws*
- *RSA 348-B Controlled Substances*
- *RSA 146:4 Adulterated Drugs*
- *New Hampshire Pharmacy Administrative Rules*
- *Federal Regulations regarding Controlled Substances (21 CFR 1300)*
- *Common Prescription drugs that are Hazardous*
- *Common Prescription drugs that are abused or misused*
- *Common Prescription drugs that are used outside their FDA indication for performance enhancing or other nefarious or dangerous therapies*
- *Common Drugs that are essential copies of approved FDA Drugs*
- *Nuclear Pharmacy and pharmaceuticals*
- *Laws and Rules that pertain to Nuclear Pharmacies*

4. Notices

4.1. Sole Point of Contact

The sole point of contact for this RFI relative to the submission of requested information is:

State of New Hampshire
Office of Professional Licensure and
Certification
Denise M. Sherburne, Contract Specialist
7 Eagle Square
Concord, New Hampshire 03301
Email Denise.M.Sherburne@oplc.nh.gov
Phone: 603-271-3502

Other state personnel are NOT authorized to discuss this RFI before the submission deadline. The State will not be held responsible for oral responses to vendors regardless of source.

4.2. RFI Timetable

Request for Information Timetable		
Item	Action	Date
1.	Release RFI	February 3, 2023
2.	Vendor questions due	February 10, 2023 @ 2pm EST.
3.	Office's answers to Vendor questions posted	February 14, 2023
4.	RFI Responses due	February 24, 2023 @ 1:00 PM EST.

The State reserves the right to modify these dates at its sole discretion.

4.3. Vendor Questions and Answers

4.3.1. Vendor Questions

4.3.1.1. All questions about this RFI, including but not limited to requests for clarification, additional information, or any changes to the RFI may be made in writing, citing the RFI page number and part or subpart, and submitted by e-mail to OPLC.Contracts@oplc.nh.gov with a 'cc' to the OPLC Contract Specialist identified in Subsection 4.1.

4.3.1.2. The OPLC may consolidate or paraphrase questions for efficiency and clarity. Questions that are not understood will not be answered. Statements that are not questions will not receive a response.

4.3.1.3. The OPLC will not acknowledge receipt of questions.

4.3.1.4. The questions may be submitted by e-mail; however, the OPLC assumes no liability for assuring accurate and complete e-mail transmissions.

4.3.1.5. Questions should be received by the deadline given in Subsection 4.2, RFI Timetable.

4.3.2. Office Answers

The OPLC intends to issue responses to properly submitted questions by the deadline specified in Subsection 4.2, RFI Timetable. Oral answers given are non-binding. Written answers to questions submitted will be posted by addendum on the OPLC website. This date may be subject to change at the discretion of the OPLC.

4.4. RFI is not an RFP

4.4.1. This RFI is for informational purposes only and is not intended to result in a contract or vendor agreement with any respondent. This RFI is not a Request for Proposals, Bids, or Applications. The State is seeking vendor community insight and information prior to finalizing business, functional, operational, and technical requirements before considering the publishing of a Request for Proposal (RFP).

4.4.2. This RFI does not commit the State to publish an RFP or award a contract. The issuance of an RFP, as a result of information gathered from these responses, is solely at the discretion of the State. If an RFP is issued, it will be open to all qualified vendors, whether those vendors choose to submit a response to this RFI. This RFI is not a pre-qualification process.

4.5. Oral Presentations and Discussions

The OPLC may request vendors to make oral presentations based upon their submissions. Any and all costs associated with an oral presentation shall be borne entirely by the vendor. Vendors may be requested to provide demonstrations to **expound upon their responses** and proposed solutions

4.6. RFI Amendment

The OPLC reserves the right to amend this RFI, as it deems appropriate prior to the submission deadline on their own initiative or in response to issues raised through vendor questions. In the event of an amendment to the RFI, the OPLC, at its sole discretion, may extend the submission deadline. The amended language will be posted on the OPLC website.

4.7. Information Submissions

4.7.1. Information submitted in response to this RFI may be received no later than the time and date specified in Subsection 4.2. RFI responses may be sent by e-mail to OPLC.Contracts@oplc.nh.gov with a 'cc' to the Sole Point of Contact identified in Subsection 4.1. **Responses should include 'RFI-2023-ADMIN-02-PHARM' in the subject line.**

4.7.2. Responses to this RFI must be limited to 20 pages of text. The page limit excludes the cover page and table of contents. Respondents may include an appendix containing exhibits and diagrams. There is no page limit to the appendix.

4.8. Presentation and Identification

4.8.1. Overview

4.8.1.1. Respondents are asked to examine all documentation and other requirements.

4.8.1.2. The OPLC requests that submissions conform to all instructions, conditions and requirements included in the RFI.

4.8.1.3. Submissions should be received by the date and time specified in the RFI Timetable, Subsection 4.2. Submissions may be emailed to the Contract Specialist at the following email addresses:

4.8.1.3.1. To: OPLC.Contracts@oplc.nh.gov

4.8.1.3.2. Cc'd: Denise.M.Sherburne@oplc.nh.gov

4.8.1.4. The subject line may include the following information: RFI-2023-ADMIN-02-PHARM (email xx of xx).

4.8.1.5. The maximum size of file attachments per email is 10 MB. Proposals with file attachments exceeding 10 MB may be submitted via multiple emails.

4.9. Outline and Detail

4.9.1. **The Transmittal Cover Letter –** The Respondent shall submit a Transmittal Cover Letter in the following manner:

4.9.1.1. On the Respondent's organization's letterhead;

4.9.1.2. Identify the name, title, telephone number, and e-mail address of the person who will serve as the Respondent's representative for all matters relating to the RFI;

4.9.2. **Table of Contents -** The required elements of the Submission may be numbered sequentially and represented in the Table of Contents.

4.10. Non-Collusion

The Vendor's required signature on the Transmittal Cover Letter for a submission in response to this RFI, guarantees they have been established without collusion with other Vendors and without effort to preclude the Office from obtaining the best possible competitive proposal, if the Office publishes a Request for Proposals.

4.11. Prohibition on Collaborative Submissions

Submissions may only be submitted by one organization.

4.12. Property of Office

All material property submitted and received in response to this RFI will become the property of the OPLC and will not be returned to the vendor. The OPLC reserves the right to use any information presented in any submission provided that its use does not violate any copyrights or other provisions of law.

4.13. RFI Response Withdrawal

Prior to the Closing Date for receipt of submissions, a submission may be

withdrawn by submitting a written request for its withdrawal to Sole Point of Contact identified in Section 4.1.

4.14. **Public Disclosure**

4.14.1. Any information submitted as part of a response to this RFI may be subject to public disclosure under RSA 91-A. In addition, in accordance with RSA 9-F:1, may an RFP be published by the Office, and a contract awarded, that information will be made accessible to the public online via the website Transparent New Hampshire (www.nh.gov/transparentnh/). Accordingly, business financial information and proprietary information such as trade secrets, business and financials models and forecasts, and proprietary formulas are exempt from public disclosure under RSA 91-A:5, IV.

4.14.2. Insofar as a Vendor seeks to maintain the confidentiality of its confidential commercial, financial or personnel information, the Vendor may clearly identify in writing the information it claims to be confidential and explain the reasons such information may be considered confidential. This may be done by separate letter identifying by page number and RFI section number the specific information the Vendor claims to be exempt from public disclosure pursuant to RSA 91-A:5.

4.14.3. Each Vendor acknowledges that the Office is subject to the Right-to-Know Law New Hampshire RSA Chapter 91-A. The Office shall maintain the confidentiality of the identified confidential information insofar as it is consistent with applicable laws or regulations, including but not limited to New Hampshire RSA Chapter 91-A. In the event the Office receives a request for the information identified by a Vendor as confidential, the Office shall notify the Vendor and specify the date the Office intends to release the requested information. Any effort to prohibit or enjoin the release of the information shall be the Vendor's responsibility and at the Vendor's sole expense. If the Vendor fails to obtain a court order from a court of competent jurisdiction enjoining the disclosure, the Office may release the information on the date the Office specifies in their notice to the Vendor without incurring any liability to the Vendor. The Vendor is strongly encouraged to provide a redacted copy of their Proposal.

4.15. **Liability**

Vendors agree that in no event shall the State be either responsible for or held liable for any costs incurred by a Vendor in the preparation or submittal of or otherwise in connection with their submission.