EMERGENCY RULE #21-E09

Administrative Procedures – Emergency Rule Filing

Instructions:

In accordance with Title 3 Chapter 25 of the Vermont Statutes Annotated and the "Rule on Rulemaking" (CVR 04-000-001) adopted by the Office of the Secretary of State, this emergency filing will be considered complete upon filing and acceptance of these forms with the Office of the Secretary of State, the Legislative Committee on Administrative Rules and a copy with the Chair of the Interagency Committee on Administrative Rules.

All forms requiring a signature shall be original signatures of the appropriate adopting authority or authorized person, and all filings are to be submitted at the Office of the Secretary of State, no later than 3:30 pm on the last scheduled day of the work week.

The data provided in text areas of these forms will be used to generate a notice of rulemaking in the portal of "Proposed Rule Postings" online, and the newspapers of record if the rule is marked for publication. Publication of notices will be charged back to the promulgating agency.

This emergency rule may remain in effect for a total of 180 days from the date it first takes effect.

Certification Statement: As the adopting Authority of this rule (see 3 V.S.A. § 801(b)(11) for a definition), I believe there exists an imminent peril to public health, safety or welfare, requiring the adoption of this emergency rule.

The nature of the peril is as follows (*PLEASE USE ADDITIONAL SHEETS IF SPACE IS INSUFFICIENT*). The General Assembly has authorized and directed the Board of Pharmacy to adopt an emergency rule on this topic until such time a permanent rule is adopted through conventional process. Act 178(2020),Sec. 12(b).

I approve the contents of this filing entitled:

Interim Rules for Clinical Pharmacy

/s/James C. Condos , on 7/1/2021

(signature) (date)

Printed Name and Title:

James C. Condos
Secretary of State

RECEIVED BY: _____

- ☐ Coversheet
- ☐ Adopting Page
- ☐ Economic Impact Analysis
- ☐ Environmental Impact Analysis
- ☐ Strategy for Maximizing Public Input
- ☐ Scientific Information Statement (if applicable)
- ☐ Incorporated by Reference Statement (if applicable)
- ☐ Clean text of the rule (Amended text without annotation)
- ☐ Annotated text (Clearly marking changes from previous rule)

1. TITLE OF RULE FILING:
   Interim Rules for Clinical Pharmacy

2. ADOPTING AGENCY:
   Secretary of State

3. PRIMARY CONTACT PERSON:
   (A PERSON WHO IS ABLE TO ANSWER QUESTIONS ABOUT THE CONTENT OF THE RULE).

   Name: Gabriel M. Gilman

   Agency: Office of Professional Regulation

   Mailing Address: 89 Main Street, 3rd Floor, Montpelier, VT 05620-3402

   Telephone: 802 828 - 2492 Fax: -

   E-Mail: gabriel.gilman@vermont.gov

   Web URL*(WHERE THE RULE WILL BE POSTED)*:
   https://sos.vermont.gov/pharmacy/statutes-rules-resources/

4. SECONDARY CONTACT PERSON:
   (A SPECIFIC PERSON FROM WHOM COPIES OF FILINGS MAY BE REQUESTED OR WHO MAY ANSWER QUESTIONS ABOUT FORMS SUBMITTED FOR FILING IF DIFFERENT FROM THE PRIMARY CONTACT PERSON).

   Name: Jennifer Rotblatt

   Agency: Office of Professional Regulation

   Mailing Address: 89 Main Street, 3rd Floor, Montpelier 05620-3402

   Telephone: 802 828 - 2191 Fax: -

   E-Mail: jennifer.rotblatt@vermont.gov

5. RECORDS EXEMPTION INCLUDED WITHIN RULE:
   (DOES THE RULE CONTAIN ANY PROVISION DESIGNATING INFORMATION AS CONFIDENTIAL; LIMITING ITS PUBLIC RELEASE; OR OTHERWISE EXEMPTING IT FROM INSPECTION AND COPYING?) No

   IF YES, CITE THE STATUTORY AUTHORITY FOR THE EXEMPTION:

   PLEASE SUMMARIZE THE REASON FOR THE EXEMPTION:

6. LEGAL AUTHORITY / ENABLING LEGISLATION:

(THE SPECIFIC STATUTORY OR LEGAL CITATION FROM SESSION LAW INDICATING WHO THE ADOPTING ENTITY IS AND THUS WHO THE SIGNATORY SHOULD BE. THIS SHOULD BE A SPECIFIC CITATION NOT A CHAPTER CITATION).
26 V.S.A. § 2023(c) (specifying content); Act 178(2020), Sec 12(b)(granting legal authority for emergency adoption of this rule); 3 V.S.A. § 123(a)(11) (specifying adopting entity).

7. EXPLANATION OF HOW THE RULE IS WITHIN THE AUTHORITY OF THE AGENCY:
The agency is specifically directed by Act 178(2020), Sec. 12(b) to adopt this rule.

8. CONCISE SUMMARY (**150 WORDS OR LESS**):

This rule provides regulatory structure for the implementation of certain clinical pharmacy services set out in 26 V.S.A. § 2023.

9. EXPLANATION OF WHY THE RULE IS NECESSARY:

The rule is necessary because the General Assembly has ordered the agency to adopt it to facilitate the expansion of clinical pharmacy services.

10. EXPLANATION OF HOW THE RULE IS NOT ARBITRARY:
The rule expresses a reasoned approach, approved by the Board of Pharmacy at duly warned public meetings involving relevant stakeholders, to accomplishing the protections required by 26 V.S.A. § 2023(c). The rule is concise and directly responsive, section-by-section, to the statutory instructions given to the agency.

11. LIST OF PEOPLE, ENTERPRISES AND GOVERNMENT ENTITIES AFFECTED BY THIS RULE:

Pharmacies, Pharmacists, Pharmacy Patients, Primary Care Providers, Vermont Department of Health, Department of Public Safety, Hospitals, Clinics.

12. BRIEF SUMMARY OF ECONOMIC IMPACT (150 WORDS OR LESS):

The rule establishes regulatory guardrails to facilitate the orderly implementation of clinical pharmacy practices set out in 26 V.S.A. § 2023. To the extent it can be expected to have any economic impact independent of that resulting from the statute, the rule may tend to protect consumers from untoward commercial incentives influencing the clinical judgment of pharmacists and therefore to

ensure appropriate consumer choice. We do not have credible means of quantifying the impact, which should be minimal in net.

13. A HEARING IS NOT SCHEDULED .

14. HEARING INFORMATION
(THE FIRST HEARING SHALL BE NO SOONER THAN 30 DAYS FOLLOWING THE POSTING OF NOTICES ONLINE).

IF THIS FORM IS INSUFFICIENT TO LIST THE INFORMATION FOR EACH HEARING PLEASE ATTACH A SEPARATE SHEET TO COMPLETE THE HEARING INFORMATION NEEDED FOR THE NOTICE OF RULEMAKING.

Date:

Time: AM

Street Address:

Zip Code:

Date:

Time: AM

Street Address:

Zip Code:

15. DEADLINE FOR COMMENT (NO EARLIER THAN 7 DAYS FOLLOWING LAST HEARING):

16. EMERGENCY RULE EFFECTIVE: 07/01/2021

17. EMERGENCY RULE WILL REMAIN IN EFFECT UNTIL
(A DATE NO LATER THAN 180 DAYS FOLLOWING ADOPTION OF THIS EMERGENCY RULE):
12/28/2021

18. NOTICE OF THIS EMERGENCY RULE SHOULD BE PUBLISHED IN THE WEEKLY NOTICES OF RULEMAKING IN THE NEWSPAPERS OF RECORD.

19. KEYWORDS (PLEASE PROVIDE AT LEAST 3 KEYWORDS OR PHRASES TO AID IN THE SEARCHABILITY OF THE RULE NOTICE ONLINE).

pharmacy

prescribing

collaborative practice agreement

clinical pharmacy

Administrative Procedures – Adopting Page

Instructions:

This form must accompany each filing made during the rulemaking process:

Note: To satisfy the requirement for an annotated text, an agency must submit the entire rule in annotated form with proposed and final proposed filings. Filing an annotated paragraph or page of a larger rule is not sufficient. Annotation must clearly show the changes to the rule.

When possible the agency shall file the annotated text, using the appropriate page or pages from the Code of Vermont Rules as a basis for the annotated version. New rules need not be accompanied by an annotated text.

1. TITLE OF RULE FILING:
   Interim Rules for Clinical Pharmacy
2. ADOPTING AGENCY:
   Secretary of State
3. TYPE OF FILING (*PLEASE CHOOSE THE TYPE OF FILING FROM THE DROPDOWN MENU BASED ON THE DEFINITIONS PROVIDED BELOW*):

   - **AMENDMENT** - Any change to an already existing rule, even if it is a complete rewrite of the rule, it is considered an amendment as long as the rule is replaced with other text.
   - **NEW RULE** - A rule that did not previously exist even under a different name.
   - **REPEAL** - The removal of a rule in its entirety, without replacing it with other text.

   This filing is **A NEW RULE** .

4. LAST ADOPTED (*PLEASE PROVIDE THE SOS LOG#, TITLE AND EFFECTIVE DATE OF THE LAST ADOPTION FOR THE EXISTING RULE)*:
   n/a

State of Vermont
Agency of Administration
Office of the Secretary
Pavilion Office Building
109 State Street
Montpelier, VT 05609-0201
www.aoa.vermont.gov

[phone] 802-828-3322
[fax] 802-828-3320

Susanne R. Young, Secretary

MEMORANDUM

TO: **Jim Condos, Secretary of State**

FROM: **Kristin Clouser, ICAR Chair/Deputy Secretary of Administration**

Kristin L. Clouser Digitally signed by Kristin L. Clouser Date: 2021.07.07 08:36:33 -04'00'

DATE: **July 7, 2021**

RE: **Emergency Rule Titled 'Interim Rules for Clinical Pharmacy' by the Secretary of State, Office of Professional Regulation**

The use of rulemaking procedures under the provisions of 3 V.S.A. §844 is appropriate for this rule. I have reviewed the proposed rule provided by the Secretary of State, Office of Professional Regulation and agree that emergency rulemaking is necessary.

Administrative Procedures – Economic Impact Analysis

Instructions:

In completing the economic impact analysis, an agency analyzes and evaluates the anticipated costs and benefits to be expected from adoption of the rule; estimates the costs and benefits for each category of people enterprises and government entities affected by the rule; compares alternatives to adopting the rule; and explains their analysis concluding that rulemaking is the most appropriate method of achieving the regulatory purpose.

Rules affecting or regulating schools or school districts must include cost implications to local school districts and taxpayers in the impact statement, a clear statement of associated costs, and consideration of alternatives to the rule to reduce or ameliorate costs to local school districts while still achieving the objectives of the rule (see 3 V.S.A. § 832b for details).

Rules affecting small businesses (excluding impacts incidental to the purchase and payment of goods and services by the State or an agency thereof), must include ways that a business can reduce the cost or burden of compliance or an explanation of why the agency determines that such evaluation isn't appropriate, and an evaluation of creative, innovative or flexible methods of compliance that would not significantly impair the effectiveness of the rule or increase the risk to the health, safety, or welfare of the public or those affected by the rule.

1. TITLE OF RULE FILING:

   Interim Rules for Clinical Pharmacy

2. ADOPTING AGENCY:

   Secretary of State

3. CATEGORY OF AFFECTED PARTIES:

   LIST CATEGORIES OF PEOPLE, ENTERPRISES, AND GOVERNMENTAL ENTITIES POTENTIALLY AFFECTED BY THE ADOPTION OF THIS RULE AND THE ESTIMATED COSTS AND BENEFITS ANTICIPATED:

   Patients may find it more convenient and less expensive to access clinical services at pharmacies than at clinical locations. This rule makes that possible and mitigates the risk of undue commercial influence in the clinical judgment of pharmacists offering those services.

4. IMPACT ON SCHOOLS:

INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON PUBLIC EDUCATION, PUBLIC SCHOOLS, LOCAL SCHOOL DISTRICTS AND/OR TAXPAYERS CLEARLY STATING ANY ASSOCIATED COSTS:

None.

5. ALTERNATIVES: *CONSIDERATION OF ALTERNATIVES TO THE RULE TO REDUCE OR AMELIORATE COSTS TO LOCAL SCHOOL DISTRICTS WHILE STILL ACHIEVING THE OBJECTIVE OF THE RULE.*

   The content of this rule is directed by statute, and the rule is not expected to materially affect schools.

6. IMPACT ON SMALL BUSINESSES:
   INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON SMALL BUSINESSES (EXCLUDING IMPACTS INCIDENTAL TO THE PURCHASE AND PAYMENT OF GOODS AND SERVICES BY THE STATE OR AN AGENCY THEREOF):

   Adoption of this rule is the final step in facilitating the provision of specific clinical services in pharmacies. Pharmacy businesses will be able to offer expanded services to their customers and patients.

7. SMALL BUSINESS COMPLIANCE: *EXPLAIN WAYS A BUSINESS CAN REDUCE THE COST/BURDEN OF COMPLIANCE OR AN EXPLANATION OF WHY THE AGENCY DETERMINES THAT SUCH EVALUATION ISN'T APPROPRIATE.*

   The content of this rule is directed by statute. Pharmacy businesses that do not find it economically rational to offer the clinical services are not required to do so.

8. COMPARISON:
   COMPARE THE IMPACT OF THE RULE WITH THE ECONOMIC IMPACT OF OTHER ALTERNATIVES TO THE RULE, INCLUDING NO RULE ON THE SUBJECT OR A RULE HAVING SEPARATE REQUIREMENTS FOR SMALL BUSINESS:
   The content of this rule is directed by statute.

9. SUFFICIENCY: *EXPLAIN THE SUFFICIENCY OF THIS ECONOMIC IMPACT ANALYSIS.*
   The rule in question is a necessary component of the implementation of the General Assembly's accomplished decision, expressed in 26 V.S.A. § 2023, that certain clinical services should be available through pharmacies and pharmacists. This rule is necessary to execute the instruction of the General Assembly, but the rule does not alter in any manner the probable economic impact of the body's made choice.

Administrative Procedures – Environmental Impact Analysis

Instructions:

In completing the environmental impact analysis, an agency analyzes and evaluates the anticipated environmental impacts (positive or negative) to be expected from adoption of the rule; compares alternatives to adopting the rule; explains the sufficiency of the environmental impact analysis.

Examples of Environmental Impacts include but are not limited to:

- Impacts on the emission of greenhouse gases
- Impacts on the discharge of pollutants to water
- Impacts on the arability of land
- Impacts on the climate
- Impacts on the flow of water
- Impacts on recreation
- Or other environmental impacts

1. TITLE OF RULE FILING:

   Interim Rules for Clinical Pharmacy

2. ADOPTING AGENCY:

   Secretary of State

3. GREENHOUSE GAS: *EXPLAIN HOW THE RULE IMPACTS THE EMISSION OF GREENHOUSE GASES (E.G. TRANSPORTATION OF PEOPLE OR GOODS; BUILDING INFRASTRUCTURE; LAND USE AND DEVELOPMENT, WASTE GENERATION, ETC.):*
   None.

4. WATER: *EXPLAIN HOW THE RULE IMPACTS WATER (E.G. DISCHARGE / ELIMINATION OF POLLUTION INTO VERMONT WATERS, THE FLOW OF WATER IN THE STATE, WATER QUALITY ETC.):*
   None.

5. LAND: *EXPLAIN HOW THE RULE IMPACTS LAND (E.G. IMPACTS ON FORESTRY, AGRICULTURE ETC.):*
   None.

6. RECREATION: *EXPLAIN HOW THE RULE IMPACT RECREATION IN THE STATE:*
   None.

7. CLIMATE: *EXPLAIN HOW THE RULE IMPACTS THE CLIMATE IN THE STATE:*
   None.

8. OTHER: *EXPLAIN HOW THE RULE IMPACT OTHER ASPECTS OF VERMONT'S ENVIRONMENT:*
   None.

9. SUFFICIENCY: *EXPLAIN THE SUFFICIENCY OF THIS ENVIRONMENTAL IMPACT ANALYSIS.*
   This rule explains how clinical providers may work together and protects patients from inappropriate commercial influence in pharmacist prescribing practices. No element of it reasonably would be expected to benefit or harm the environment.

Administrative Procedures – Public Input

Instructions:

In completing the public input statement, an agency describes the strategy prescribed by ICAR to maximize public input, what it did do, or will do to comply with that plan to maximize the involvement of the public in the development of the rule.

This form must accompany each filing made during the rulemaking process:

1. TITLE OF RULE FILING:

   Interim Rules for Clinical Pharmacy

2. ADOPTING AGENCY:

   Secretary of State

3. PLEASE DESCRIBE THE STRATEGY PRESCRIBED BY ICAR TO MAXIMIZE PUBLIC INVOLVEMENT IN THE DEVELOPMENT OF THE PROPOSED RULE:

   ICAR has not opined on this emergency rule. The rule was discussed at duly warned public meetings of the Board of Pharmacy, with the awareness and constructive participation of relevant stakeholders. A copy of it will be emailed to all pharmacists.

4. PLEASE LIST THE STEPS THAT HAVE BEEN OR WILL BE TAKEN TO COMPLY WITH THAT STRATEGY:

   A copy of the rule will be emailed to all pharmacists. As the larger Administrative Rules of the Board of Pharmacy are redrafted at duly warned meetings of the Board, interested members of the public will have ample opportunity to be heard, even before the formal rulemaking process commences. This emergency rule, or some version of it, will become part of the larger Administrative Rules of the Board of Pharmacy when the next iteration of those Rules is adopted through conventional process.

5. BEYOND GENERAL ADVERTISEMENTS, PLEASE LIST THE PEOPLE AND ORGANIZATIONS THAT HAVE BEEN OR WILL BE INVOLVED IN THE DEVELOPMENT OF THE PROPOSED RULE:

Vermont Pharmacists Association, Vermont Medical Society, Department of Vermont Health Access, Department of Health, Board of Pharmacy, Office of Professional Regulation

Clean Copy

Interim Rules for Clinical Pharmacy

[Emergency adoption authorized by Act 178(2020), Sec. 12(b) and effective July 1, 2021]

1. Collaborative Practice Agreements: Required Elements

Collaborative Practice Agreements involving clinical pharmacy prescribing shall conform to 26 V.S.A. § 2023 and the requirements of the Administrative Rules of the Board of Pharmacy, § 1.10(a)(8). In addition, a collaborative practice agreement involving clinical pharmacy prescribing must:

a. permit prescribing only in the presence of a bona fide, established prescriber-patient relationship between a collaborating practitioner and patients receiving clinical care pursuant to the agreement;
b. contain the name(s), license number(s), and dated signature(s) of each covered practitioner;
c. specify start and end dates separated by not more than one year;
d. describe the scope of clinical pharmacy services and/or prescribing to be provided, including any limitations on the scope of those services; and
e. be readily available to any patient or regulatory authority that may request it.

2. Conflicts of Interest & Commercial Incentives

A pharmacist practicing clinical pharmacy shall avoid circumstances that would lead a reasonable and informed observer to suspect the pharmacist's prescribing judgment is influenced other than by the best interests of patients. In addition:

a. **Gift Ban.** Pharmacists shall comply with 18 V.S.A. § 4631a and shall not accept gifts or things of value from drug manufacturer or wholesalers.
b. **Commercial Inducement Ban.** A pharmacy shall not require, induce, encourage, incentivize, or otherwise attempt to influence a pharmacist to alter prescribing practices for commercial purposes, including without limitation by promoting preferred brands, establishing prescribing quotas, steering patients based on commercial relationships, or initiating automatic prescription renewal without an express written request from a patient. A pharmacist subject to such inducements shall not practice clinical pharmacy.

3. Short-term Prescribing by Pharmacists

A pharmacist extending a previous prescription shall do so in a manner consistent with 26 V.S.A. § 2023(b)(6) and only after taking steps reasonable under the circumstances to verify a patient's claim to hold an established prescription. Short-term prescribing of controlled drugs is prohibited. When determining whether short-term prescribing is clinically appropriate, a pharmacist shall consider the risk profile of a drug, including potential toxicity and misuse, and shall weigh potential risks against risks associated with interruption of access.

4. **Privacy**

A pharmacy that offers clinical services shall provide patients space appropriate to private clinical consultation about confidential health information. At a minimum, consultation space shall:

a. shield a patient who may be required to partially disrobe, for example, to receive a vaccine, from the view of others;
b. be suitably isolated to offer confidence that health consultations, carried out at ordinary conversational volume, cannot be overheard;
c. not be subject to audio or video surveillance of which a patient may be unaware, for example, by store security equipment.

VERMONT **GENERAL ASSEMBLY**

The Vermont Statutes Online

Title 26 : Professions And Occupations

Chapter 036 : Pharmacy

Subchapter 001 : General Provisions

(Cite as: 26 V.S.A. § 2023)

§ 2023. Clinical pharmacy; prescribing

(a) In accordance applicable with rules adopted by the Board, a pharmacist may engage in the practice of clinical pharmacy, including prescribing as set forth in subsection (b) of this section, provided that a pharmacist shall not:

(1) prescribe a regulated drug as defined in 18 V.S.A. § 4201;

(2) prescribe a biological product as defined in 18 V.S.A. § 4601, other than an insulin medication, an influenza vaccine or vaccine to mitigate a significant public health risk, or, pursuant to a collaborative practice agreement, another vaccine; or

(3) initiate antibiotic therapy, except pursuant to a collaborative practice agreement.

(b) A pharmacist may prescribe in the following contexts:

(1) Collaborative practice agreement. A pharmacist may prescribe, for the patient or patients of a prescribing practitioner licensed pursuant to this title, within the scope of a written collaborative practice agreement with that primary prescriber.

(A) The collaborative practice agreement shall require the pharmacist and collaborating practitioner to contemporaneously notify each other of any change in the patient's pharmacotherapy or known medical status.

(B) Under a collaborative practice agreement, a pharmacist may select or modify antibiotic therapy for a diagnosed condition under the direction of the collaborating practitioner.

(2) State protocol.

(A) A pharmacist may prescribe, order, or administer in a manner consistent with valid State protocols that are approved by the Commissioner of Health after consultation with the Director of Professional Regulation and the Board and the ability for public comment:

(i) opioid antagonists;

(ii) epinephrine auto-injectors;

(iii) tobacco cessation products;

(iv) tuberculin purified protein derivative products;

(v) self-administered hormonal contraceptives;

(vi) dietary fluoride supplements;

(vii) influenza vaccines;

(viii) in the event of a significant public health risk, an appropriate vaccine to mitigate the effects on public health after finding that existing channels for vaccine administration are insufficient to meet the public health need;

(ix) emergency prescribing of albuterol or glucagon while contemporaneously contacting emergency services; and

[Subdiv. (b)(2)(A)(x) repealed July 1, 2021.]

(x) tests for SARS-CoV for asymptomatic individuals or related serology for individuals by entities holding a Certificate of Waiver pursuant to the Clinical Laboratory Amendments of 1988 (42 U.S.C. § 263a).

(B)(i) State protocols shall be valid if signed by the Commissioner of Health and the Director of Professional Regulation, and the Board of Pharmacy shall feature the active protocol conspicuously on its website.

(ii) The Commissioner of Health may invalidate a protocol if the Commissioner finds that the protocol's continued operation would pose an undue risk to the public health, safety, or welfare and signs a declaration to that effect. Upon such a declaration, the Director shall remove the invalidated protocol from the Board website and shall cause electronic notice of the protocol's discontinuation to be transmitted to all Vermont drug outlets.

(3) Accessory devices. A pharmacist may prescribe accessory-type devices, such as spacers, needles, and diabetic testing supplies, where clinically indicated in the judgment of the pharmacist.

(4) Prescriber-authorized substitution. A prescribing practitioner licensed pursuant to this title may authorize a pharmacist to substitute a drug with another drug in the same therapeutic class that would, in the opinion of the pharmacist, have substantially equivalent therapeutic effect even though the substitute drug is not a therapeutic equivalent drug, provided:

(A) the prescriber has clearly indicated that drug product substitution is permissible by indicating "therapeutic substitution allowed" or similar designation;

(B) the drug product substitution is intended to ensure formulary compliance with the patient's health insurance plan or otherwise to minimize cost to the patient;

(C) the patient's voluntary, informed consent is obtained in writing; and

(D) the pharmacist or designee notifies the prescriber which drug was dispensed as a substitute within five days of dispensing.

(5) Over-the-counter availability. A pharmacist may prescribe over-the-counter drugs where appropriate to reduce costs to the patient, such as by drawing from a health savings account or flexible spending account.

(6) Short-term extensions.

(A) A pharmacist may extend a previous prescription in the absence of a collaborative practice agreement or a State protocol so long as the pharmacist provides only sufficient quantity to the patient until the patient is able to consult with another practitioner, not to exceed a five-day supply or the smallest available unit, and takes all reasonable measures to notify the patient's primary care provider of record or the appropriate original prescriber, if the original prescriber is different from the primary care provider of record.

(B) A short-term extension shall be provided on a one-time basis.

(c) Board rules shall:

(1) specify the required elements of a collaborative practice agreement;

(2) prohibit conflicts of interest and inappropriate commercial incentives related to prescribing, such as reimbursement based on brands or numbers of prescriptions filled, renewing prescriptions without request by a patient, steering patients to particular brands or selections of products based on any commercial relationships, or acceptance of gifts offered or provided by manufactures in violation of 18 V.S.A. § 4631a;

(3) define appropriate bounds of short-term extension prescribing; and

(4) establish minimum standards for patient privacy in clinical consultation. (Added 2015, No. 173 (Adj. Sess.), § 6, eff. June 8, 2016; 2019, No. 178 (Adj. Sess.), § 11, eff. Oct. 1, 2020; 2019, No. 178 (Adj. Sess.), § 12a, eff. July 1, 2021.)

No. 178. An act relating to professional regulation.

(S.220)

It is hereby enacted by the General Assembly of the State of Vermont:

* * * Office of Professional Regulation * * *

Sec. 1. 3 V.S.A. § 122 is amended to read:

§ 122. OFFICE OF PROFESSIONAL REGULATION

The Office of Professional Regulation is created within the Office of the Secretary of State. The Office shall have a director who shall be appointed by the Secretary of State and shall be an exempt employee. The following boards or professions are attached to the Office of Professional Regulation:

* * *

(28) Audiologists and Hearing Aid Dispensers

* * *

(41) ~~Audiologists and~~ Speech-Language Pathologists

* * *

Sec. 2. 3 V.S.A. § 123 is amended to read:

§ 123. DUTIES OF OFFICE

(a) The Office shall provide administrative, secretarial, financial, investigatory, inspection, and legal services to the boards. The services provided by the Office shall include:

* * *

(3) any and all other matters and occurrences as the Board may properly require by ~~rules and regulations~~ rule.

* * *

~~Subchapter 6. Wholesale Distributors and Manufacturers~~

* * *

Sec. 12. PROTOCOL IMPLEMENTATION; TARGET DATES; RULEMAKING

(a) On or before July 1, 2021, the Commissioner of Health shall:

(1) approve State protocols respecting opioid antagonists, self-administered hormonal contraceptives, and influenza vaccines in accordance with the procedure for establishing valid protocols set forth in 26 V.S.A. § 2023(b)(2) in Sec. 11 of this act; or

(2) provide affirmative notice to the Senate Committees on Government Operations and on Health and Welfare and the House Committees on Government Operations and on Health Care that the Commissioner was unable to approve those protocols by that date.

(b) On or before July 1, 2021, the Board of Pharmacy shall adopt rules consistent with the provisions of 26 V.S.A. § 2023(c) as set forth in Sec. 11 of this act. If the Board is unable to adopt rules by that date, the Board shall adopt an emergency rule until such time as it completes the rulemaking process.

VERMONT **GENERAL ASSEMBLY**

The Vermont Statutes Online

Title 3 : Executive

Chapter 005 : Secretary Of State

Subchapter 003 : Professional Regulation

(Cite as: 3 V.S.A. § 123)

§ 123. Duties of Office

(a) The Office shall provide administrative, secretarial, financial, investigatory, inspection, and legal services to the boards. The services provided by the Office shall include:

(1) Sending, receiving, and processing applications for licenses.

(2) Issuing, recording, renewing, and reinstating all licenses as ordered by the boards, an appellate officer, the Director, an administrative law officer, or a court.

(3) Revoking or suspending licenses as ordered by the boards, the Director, an administrative law officer, or a court.

(4) Keeping all files and records of the boards, including minutes of meetings.

(5) Compiling and maintaining a current register of all licensees.

(6) Compiling and maintaining statistical information for each board, including the number of applications received; the number of licenses, certificates, registrations, and permits issued, renewed, and reinstated; examination results; the number and disposition of inspections and complaints; and the number of board meetings.

(7) Collecting and depositing all fees into the Professional Regulatory Fee Fund.

(8) Arranging payment of all expenses incurred by the boards within the limits of the funds appropriated to them.

(9) Standardizing, to the extent feasible and with the advice of the boards, all applications, licenses, and other related forms and procedures, and adopting uniform procedural rules governing the investigatory and disciplinary process for all boards set forth in section 122 of this chapter.

(10) Notifying the public and board members of all meetings and examinations to be held by the boards and arranging for places for those meetings and examinations.

(11) Assisting the boards in developing rules consistent with the principles set forth in 26 V.S.A. chapter 57. Notwithstanding any provision of law to the contrary, the

Secretary of State shall serve as the adopting authority for those rules.

(12) With the assistance of the boards, establishing a schedule of license renewal and termination dates so as to distribute the renewal work in the Office as effectively as possible.

(A) Licenses may be issued and renewed according to that schedule for periods of up to two years.

(B) A person whose initial license is issued within 90 days prior to the set renewal date shall not be required to renew the license until the end of the first full biennial licensing period following initial licensure.

(13) To the extent that resources permit, providing other administrative services that are necessary or desirable for the efficient operation of the boards.

(b) The Director shall consult with each board and prepare a consolidated budget for the Office. The consolidated budget shall also contain funds deemed to be required by the Director for the administration of this chapter. The Director shall submit the consolidated budget to the Secretary of State.

(c) The Director may purchase examination materials and contract with examination providers to administer examinations.

(d) The Director may adopt procedures for the effective administration of this section.

(e) The Secretary of State shall contract with and appoint one or more attorneys licensed to practice in this State to serve as administrative law officers under subsection 129(j) of this title or appellate officers under section 130a of this title.

(f) Classified State employees who are employed as investigators by the Secretary of State who have successfully met the standards of training for a Level III law enforcement officer under 20 V.S.A. chapter 151 shall have the same powers as sheriffs in criminal matters and the enforcement of the law and in serving criminal process, and shall have all the immunities and matters of defense now available or hereafter made available to sheriffs in a suit brought against them in consequence for acts done in the course of their employment.

[Subsection (g) effective until April 1, 2021; see also subsection (g) effective April 1, 2021 .]

(g) The Office of Professional Regulation shall establish uniform procedures applicable to all of the professions and boards set forth in section 122 of this chapter, providing for:

(1) appropriate recognition of education, training, or service completed by a member of the U.S. Armed Forces toward the requirements of professional licensure; and

(2) expedited issuance of a professional license to a person who is licensed in

good standing in another regulatory jurisdiction and:

(A) whose spouse is a member of the U.S. Armed Forces and who has been subject to a military transfer to Vermont; and

(B) who left employment to accompany his or her spouse to Vermont.

[Subsection (g) effective April 1, 2021; see also subsection (g) effective until April 1, 2021 .]

(g)(1) The Office shall establish uniform procedures applicable to all of the professions and boards set forth in section 122 of this chapter, providing for:

(A) appropriate recognition of education, training, or service completed by a member of the U.S. Armed Forces toward the requirements of professional licensure; and

(B) expedited issuance of a professional license to a person who is licensed in good standing in another regulatory jurisdiction; and

(i) whose spouse is a member of the U.S. Armed Forces and who has been subject to a military transfer to Vermont; and

(ii) who left employment to accompany his or her spouse to Vermont.

(2) The Director may evaluate specific military credentials to determine equivalency to credentials required for professions attached to the Office. The determinations shall be adopted through written policy that shall be posted on the Office's website.

(h) Notwithstanding any provision of Title 26 of the Vermont Statutes Annotated to the contrary, the Office, on behalf of the Director or a board, may use electronic mail to send notices and reminders that would otherwise be sent by mail, except certified mail, and may use online services to elicit information and sworn attestations that would otherwise be obtained on a paper form.

(i)(1) The Director shall actively monitor the actions of boards attached to the Office and shall ensure that all board actions pursued or decided are lawful, consistent with State policy, reasonably calculated to protect the public, and not an undue restraint of trade.

(2) If the Director finds an exercise of board authority or discretion does not meet those standards, the Director may, except in the case of disciplinary actions:

(A) provide written notice to the board explaining the perceived inconsistency, which notice shall have the effect of staying that action and implementing any alternative prescribed by the Director;

(B) schedule a public meeting with the board to resolve questions about the action and explore alternatives; and

(C) within 60 days following that meeting, issue a written directive finding that:

(i) the exercise of board authority or discretion is consistent with State policy, in which case the action shall be reinstated;

(ii) the exercise of board authority or discretion is inconsistent with State policy in form, but may be modified to achieve consistency, in which case the board may issue a modified action consistent with the Director's recommendation; or

(iii) the exercise of board authority or discretion is inconsistent with State policy in purpose, in which case any alternative prescribed by the Director shall stand as the regulatory policy of the State.

(j)(1) The Office may inquire into the criminal background histories of applicants for initial licensure and for license renewal for the following professions:

(A) licensed nursing assistants, licensed practical nurses, registered nurses, and advanced practice registered nurses licensed under 26 V.S.A. chapter 28;

(B) private investigators, security guards, and other persons licensed under 26 V.S.A. chapter 59;

(C) real estate appraisers and other persons or business entities licensed under 26 V.S.A. chapter 69; and

(D) osteopathic physicians licensed under 26 V.S.A. chapter 33.

(2) Prior to acting on an initial or renewal application, the Office may obtain with respect to the applicant a Vermont criminal history record, an out-of-state criminal history record, and a criminal history record from the Federal Bureau of Investigation. Federal Bureau of Investigation background checks shall be fingerprint-supported, and fingerprints so obtained may be retained on file and used to notify the Office of future triggering events. Each applicant shall consent to the release of criminal history records to the Office on forms developed by the Vermont Crime Information Center.

(3) Applicants subject to background checks shall be notified that a check is required, if fingerprints will be retained on file, and that criminal convictions are not an absolute bar to licensure, and shall be provided such other information as may be required by federal law or regulation.

[Subsection (k) effective until April 1, 2021; see also subsection (k) effective April 1, 2021 .]

(k) When, by reason of disqualification, resignation, vacancy, or necessary absence, a board is unable to form a quorum or assign one or more members to assist in the investigation and prosecution of complaints or license applications, or to adjudicate a contested case, the Secretary of State may appoint ad hoc members, either as voting members to establish a quorum at a specific meeting or as nonvoting members to assist Office investigators and prosecutors.

[Subsection (k) effective April 1, 2021; see also subsection (k) effective until April 1, 2021 .]

(k) For any profession attached to it, the Office shall provide a pre-application determination of an individual's criminal background. This determination shall not be binding on the Office in a future application if the individual violates probation or parole or is convicted of another crime following the determination.

(1) The Office shall initiate this determination upon an individual's "second chance" determination request. This request shall provide documentation related to the individual's conviction or convictions, evidence of rehabilitation, and identification of the profession or professions for which the individual seeks licensure.

(2) The individual shall submit this request online, accompanied by the fee for preapplication determinations set forth in section 125 of this subchapter. If the individual thereafter applies for licensure, this preapplication fee shall be deducted from that license application fee.

(3) The Office shall:

(A) process a request within 30 days of receiving a complete request;

(B) assess the nature of the underlying conviction or convictions, the nexus to the profession or professions for which the individual seeks licensure, and the provided evidence of rehabilitation; and

(C) respond to the individual's request in writing.

[Subsection (l) effective April 1, 2021.]

(l) When, by reason of disqualification, resignation, vacancy, or necessary absence, a board is unable to form a quorum or assign one or more members to assist in the investigation and prosecution of complaints or license applications, or to adjudicate a contested case, the Secretary of State may appoint ad hoc members, either as voting members to establish a quorum at a specific meeting or as nonvoting members to assist Office investigators and prosecutors. (Added 1989, No. 250 (Adj. Sess.), § 1; amended 1997, No. 40, § 2; 1999, No. 133 (Adj. Sess.), § 51; 2003, No. 122 (Adj. Sess.), § 78g; 2005, No. 27, § 1; 2007, No. 163 (Adj. Sess.), § 1; 2009, No. 33, § 4; 2009, No. 103 (Adj. Sess.), § 1; 2011, No. 116 (Adj. Sess.), § 2; 2013, No. 27, § 1; 2013, No. 138 (Adj. Sess.), § 2; 2013, No. 141 (Adj. Sess.), § 11, eff. July 1, 2015; 2017, No. 48, § 1; 2017, No. 115 (Adj. Sess.), § 2, eff. Jan. 1, 2020; 2017, No. 144 (Adj. Sess.), § 1; 2019, No. 152 (Adj. Sess.), § 1, eff. April 1, 2021; 2019, No. 178 (Adj. Sess.), § 2, eff. Oct. 1, 2020.)

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Deadline For Public Comment

Deadline: Unavailable.

The deadline for public comment is unavailable for this rule. Contact the agency or primary contact person listed below for assistance.

Rule Details

Rule Number:	21-E09
Title:	Interim Rules for Clinical Pharmacy.
Type:	Emergency
Status:	Adopted
Agency:	Office of Professional Regulation, Office of the Secretary of State
Legal Authority:	26 V.S.A. § 2023(c), Act 178(2020), Sec 12(b), and 3 V.S.A. § 123(a)(11).
Summary:	This rule provides regulatory structure for the implementation of certain clinical pharmacy services set out in 26 V.S.A. § 2023.

Persons Affected:	Pharmacies, Pharmacists, Pharmacy Patients, Primary Care Providers, Vermont Department of Health, Department of Public Safety, Hospitals, Clinics.
Economic Impact:	The rule establishes regulatory guardrails to facilitate the orderly implementation of clinical pharmacy practices set out in 26 V.S.A. § 2023. To the extent it can be expected to have any economic impact independent of that resulting from the statute, the rule may tend to protect consumers from untoward commercial incentives influencing the clinical judgment of pharmacists and therefore to ensure appropriate consumer choice. We do not have credible means of quantifying the impact, which should be minimal in net.
Posting date:	Jul 02,2021

Hearing Information

There are not Hearings scheduled for this Rule

Contact Information

Information for Primary Contact

PRIMARY CONTACT PERSON - A PERSON WHO IS ABLE TO ANSWER QUESTIONS ABOUT THE CONTENT OF THE RULE.

Level: Primary
Name: Gabriel Gilman
Agency: Office of Professional Regulation, Office of the Secretary of State
Address: 89 Main Street, 3rd Floor
City: Montpelier
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Zip: 05620-3402
Telephone: 802-828-2492
Fax:
Email: gabriel.gilman@vermont.gov

Website Address: https://sos.vermont.gov/pharmacy/statutes-rules-resources/

Information for Secondary Contact

SECONDARY CONTACT PERSON - A SPECIFIC PERSON FROM WHOM COPIES OF FILINGS MAY BE REQUESTED OR WHO MAY ANSWER QUESTIONS ABOUT FORMS SUBMITTED FOR FILING IF DIFFERENT FROM THE PRIMARY CONTACT PERSON.

Level: Secondary
Name: Jennifer Rotblatt
Agency: Office of Professional Regulation, Office of the Secretary of State
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Keyword Information

Keywords:

pharmacy
prescribing
collaborative practice agreement
clinical pharmacy

OFFICE OF THE SECRETARY OF STATE

VERMONT STATE ARCHIVES & RECORDS ADMINISTRATION (VSARA)

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	The Islander (islander@vermontislander.com)	Tel: 802-372-5600 FAX: 802-372-3025
	Vermont Lawyer (hunter.press.vermont@gmail.com)	Attn: Will Hunter

FROM: APA Coordinator, VSARA **Date of Fax:** July 6, 2021

RE: The "Proposed State Rules " ad copy to run on **July 15, 2021**

PAGES INCLUDING THIS COVER MEMO: **3**

NOTE **8-pt font in body. 12-pt font max. for headings - single space body. Please include dashed lines where they appear in ad copy. Otherwise minimize the use of white space. Exceptions require written approval.**

If you have questions, or if the printing schedule of your paper is disrupted by holiday etc. please contact VSARA at 802-828-3700, or E-Mail sos.statutoryfilings@vermont.gov, Thanks.

PROPOSED STATE RULES

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By law, public notice of proposed rules must be given by publication in newspapers of record. The purpose of these notices is to give the public a chance to respond to the proposals. The public notices for administrative rules are now also available online at https://secure.vermont.gov/SOS/rules/ . The law requires an agency to hold a public hearing on a proposed rule, if requested to do so in writing by 25 persons or an association having at least 25 members.

To make special arrangements for individuals with disabilities or special needs please call or write the contact person listed below as soon as possible.

To obtain further information concerning any scheduled hearing(s), obtain copies of proposed rule(s) or submit comments regarding proposed rule(s), please call or write the contact person listed below. You may also submit comments in writing to the Legislative Committee on Administrative Rules, State House, Montpelier, Vermont 05602 (802-828-2231).

Interim Rules for Clinical Pharmacy.

Vermont Proposed Rule: 21E09

AGENCY: Secretary of State, Office of Professional Regulation

CONCISE SUMMARY: This rule provides regulatory structure for the implementation of certain clinical pharmacy services set out in 26 V.S.A. § 2023.

FOR FURTHER INFORMATION, CONTACT: Gabriel Gilman, Office of Professional Regulation, 89 Main Street - 3rd Floor, Montpelier, VT 05620-3402 Tel: 802-828-2492 Email: gabriel.gilman@vermont.gov URL: https://sos.vermont.gov/pharmacy/statutes-rules-resources/.

FOR COPIES: Jennifer Rotblatt, Office of Professional Regulation, 89 Main Street - 3rd Floor, Montpelier, VT 05620-3402 Tel: 802-828-2191 Email: jennifer.rotblatt@vermont.gov

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Allocation and Apportionment of Vermont Net Income By Corporations.

Vermont Proposed Rule: 21P021

AGENCY: Agency of Administration, Department of Taxes

CONCISE SUMMARY: The 1998 Regulation has been superseded by statute in some respects. The amendments adjust the apportionment formula to be consistent with current law, and adjust the apportionment method for services and intangibles to accommodate statutory changes. Other changes provide specific definitions and examples, and provide clarity to the Department's interpretation of the tax on corporations.

FOR FURTHER INFORMATION, CONTACT: Will Baker, Department of Taxes, PO Box 429, Montpelier VT 05602 Tel: 802-828-2506 Fax: 802-828-5875 Email: will.baker@vermont.gov URL: https://tax.vermont.gov.

FOR COPIES: Rebecca Sameroff, Administration - Department of Taxes, PO Box 429 Montpelier VT 05602 Tel: 802-828-3763 Fax: 802-828-5875 Email: rebecca.sameroff@vermont.gov.

Vermont Hazardous Waste Management Regulations.

Vermont Proposed Rule: 21P022

AGENCY: Agency of Natural Resources

CONCISE SUMMARY: Vermont has maintained Hazardous Waste Management Regulations since 1980. This rule, which has been revised routinely since 1980 to remain equivalent to the federal RCRA subtitle C hazardous waste regulations, provides a regulatory framework for managing hazardous waste by identifying wastes subject to regulation as hazardous and establishing management standards for businesses that generate, transport, treat, store or dispose of them. In general, the rule is being revised to incorporate required new federal rules, clarify existing requirements, and address non-federal deficiencies identified in the current version (e.g., limiting the scope of the VT06 listing for pesticides, clarifying generator closure requirements, correcting typos). Changes include: adoption of the federal Generator Improvement, Electronic Manifest, and Hazardous Waste Pharmaceutical rules; revisions to hazardous waste import/export requirements; addition of new universal wastes; and revision of the used oil management standards.

FOR FURTHER INFORMATION, CONTACT: Anna Bourakovsky, Agency of Natural Resources, 1 National Life Drive, Davis 1, Montpelier VT 05620-3704 Tel: 802-477-2981 Email: anna.bourakovsky@vermont.gov URL: https://dec.vermont.gov/waste-management/hazardous/regulations.

FOR COPIES: Jordan Gonda, Agency of Natural Resources, 1 National Life Drive, Davis 1, Montpelier VT 05620-3704 Tel: 802-338-7522 Email: jordan.gonda@vermont.gov.
