DRAFT; NOT YET EDITED; FOR COMMITTEE DISCUSSION

Potential Amendment to Sec. 11, 26 V.S.A. §§ 2022 and 2023

(clinical pharmacy prescribing)

CHAPTER 36. PHARMACY

Subchapter 1. General Provisions

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§ 2022. DEFINITIONS

As used in this chapter:

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(15)(A) "Practice of pharmacy" means:

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(vii) ~~optimizing drug therapy through~~ the practice of clinical pharmacy; and

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(B) "Practice of clinical pharmacy" or "clinical pharmacy" means:

(i) the health science discipline in which, in conjunction with the patient's other practitioners, a pharmacist provides patient care to optimize medication therapy and to promote disease prevention and the patient's health and wellness;

(ii) providing patient care services within the pharmacist's authorized scope of practice, including medication therapy management,

comprehensive medication review, and postdiagnostic disease state management services; ~~or~~

(iii) practicing pharmacy pursuant to a collaborative practice agreement; or

(iv) prescribing as provided under section 2023 of this subchapter.

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§ 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) initiate antibiotic therapy, except pursuant to a collaborative practice agreement; or

(3) prescribe a biological product as defined in 18 V.S.A. § 4601, other than an influenza vaccine or insulin medication.

(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 clinician licensed pursuant to this title, within the scope of a written collaborative practice agreement with that primary prescriber. The collaborative practice agreement shall require the

pharmacist and collaborating clinician to contemporaneously notify each other of any change in the patient's pharmacotherapy or known medical status.

(2) State protocol.

(A) A pharmacist may prescribe in a manner consistent with valid State protocols 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) hormonal contraceptives;

(vi) dietary fluoride supplements;

(vii) influenza vaccines; and

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

(B) State protocols shall be valid if signed by the Commissioner of Health and the Director of Professional Regulation. Active protocols shall be featured conspicuously on the website of the Board of Pharmacy. A protocol may be invalidated by a signed declaration by the Commissioner of Health finding that the protocol's continued operation would pose an undue risk to the

public health, safety, or welfare; whereupon the Director shall remove the invalidated protocol from the Board website and shall cause electronic notice of discontinuation to be transmitted to all Vermont drug outlets. This section does not preclude the Commissioner of Health from establishing protocols for other health needs not addressed above provided those protocals are adopted by the process above.

(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 clinician 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 pharmacist may prescribe in the absence of a collaborative practice agreement as described in subdivision (1) of this subsection or of a State protocol as described in subdivision (2) of this subsection a previously prescribed prescription. The pharmacist may only provide sufficient quantity to the patient until the patient is able to consult with another provider, not to exceed a five day supply or the smallest available unit, and shall take all reasonable measures to notify the patient's primary care provider of record.

(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.

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Sec. X. PROTOCOL IMPLEMENTATION; TARGET DATES; RULEMAKING

(a) The Commissioner of Health or the Director of Professional Regulation shall, by January 1, 2021, promulgate protocols respecting opioid antagonists, hormonal contraceptives, and vaccines. If unable to do so, the Commissioner and Director shall give affirmative notice to the House and Senate Committees on Government Operations.

(b) If the Board of Pharmacy is unable to adopt rules consistent with 26 V.S.A. § 2023(c) as set forth in Sec. 11 of this act by January 1, 2021, it shall adopt an emergency rule by that date.