



State of Vermont
Office of the Secretary of State

Office of Professional Regulation
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James C. Condos, Secretary of State
Christopher D. Winters, Deputy Secretary
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EMERGENCY REGULATORY ORDER TO VERMONT PHARMACIES & PHARMACISTS:

Employ Enhanced Drug Utilization Review to Curb Inappropriate Prescribing

During a declared state of emergency in Vermont as a result of COVID-19, the Director of Professional Regulation and the Commissioner of Health may issue such orders governing regulated professional activities and practices as may be necessary to protect the public health, safety, and welfare. If the Director or Commissioner finds that a professional practice, act, offering, therapy, or procedure by persons licensed or required to be licensed by Title 26 of the Vermont Statutes Annotated is exploitative, deceptive, or detrimental to the public health, safety, or welfare, or a combination of these, the Director or Commissioner may issue an order to cease and desist from the applicable activity, which, after reasonable efforts to publicize or serve the order on the affected persons, shall be binding upon all persons licensed or required to be licensed by Title 26 of the Vermont Statutes Annotated, and a violation of the order shall subject the person or persons to professional discipline, may be a basis for injunction by the Superior Court, and shall be deemed a violation of 3 V.S.A. § 127.

--Act 91 (H. 742) of 2020, Sec. 21

Findings

No legend drug is currently FDA-approved for treatment of COVID-19. Interest in drugs known or popularly believed to be under investigation for potential therapeutic utility versus COVID-19 has contributed to unjustified off-label use in patients for whom established risk exceeds speculative benefit, to drug hoarding, and to disruption in access for patients who require maintenance pharmacotherapies to protect health and life.

Existing Law

Board of Pharmacy Administrative Rule 10.2 provides that:

A prescription or drug order for a legend drug is not valid unless it is issued for a legitimate medical purpose arising from a prescriber-patient relationship which includes a documented patient evaluation adequate to establish diagnoses and identify underlying conditions and/or contraindications to the treatment. Treatment, including issuing a prescription or drug order, based solely on an online questionnaire or consultation outside of an ongoing clinical relationship does not constitute a legitimate medical purpose.

Board of Pharmacy Administrative Rule 10.30 requires that a pharmacist “review the patient record and each prescription drug order presented for dispensing for the purposes of promoting therapeutic appropriateness,” to identify, among other things, “drug-disease contraindications,” “incorrect drug dosage or duration of drug treatment,” and “clinical abuse and misuse.”

**Emergency Regulatory Order:
Employ Enhanced Drug Utilization Review to Curb Inappropriate Prescribing**

For the foregoing reasons, and on the basis of the foregoing authority and findings:

Vermont retail pharmacists and pharmacies shall, for any newly established outpatient prescription drug order for a drug known or popularly believed to be under investigation for COVID-19 indications, and specifically for

- azithromycin,
- baloxavir,
- chloroquine,
- hydroxychloroquine,
- lopinavir,
- oseltamivir,
- remdesivir,
- ritonavir,
- sarilumab,
- sirolimus, and
- tocilizumab:

1. Apply enhanced drug utilization review, by requiring that:
 - a. the prescription order includes a documented diagnosis from the prescriber;
 - b. the diagnosis and drug are plausibly within the scope of the prescriber's practice, if known;
 - c. the drug is reasonably indicated for the diagnosis, as indicated by FDA approval or support by credible literature, meaning literature upon which a reasonable professional competent in clinical pharmacology would rely; and
 - d. the drug is not prescribed in a quantity manifestly in excess of the patient's anticipated need.
2. Regard as illegitimate and refuse any newly established outpatient prescription drug order that does not satisfy the required elements of enhanced drug utilization review.
3. Take reasonable steps to protect access for patients already prescribed these medications for established maintenance needs, or who may be newly and legitimately diagnosed with conditions for which these drugs are indicated.
4. Report any clearly inappropriate prescribing activity to the Executive Officer for the Board of Pharmacy, at: carrie.phillips@vermont.gov.

April 10, 2020

BY:



S. Lauren Hibbert
Director of Professional Regulation