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## TITLE 216 – DEPARTMENT OF HEALTH

### CHAPTER 20 - COMMUNITY HEALTH

#### SUBCHAPTER 20 - DRUGS

##### PART 6 – OFF LABEL PRESCRIBING OF MEDICATIONS FOR COVID-19

#### **x.1 Authority**

- A. These regulations are promulgated pursuant to the authority conferred under R.I. Gen. Laws §§ 23-1-1 and 23-1-18, and are established for the purpose of allowing off-label prescribing to treat COVID-19.

#### **x.2 Definitions**

- A. Wherever used in this Part, the terms listed below shall be construed in the following manner:
1. "COVID-19" means the new disease caused by novel coronavirus SARS-CoV-2.
  2. "Off-label prescribing" means the prescribing of an FDA-approved medication for reasons other than indicated or approved by the FDA.
  3. "Practitioner" means any person licensed in the state of Rhode Island to provide health care services and to prescribe medication.

#### **x.3 Off-label prescribing of medications for treatment or prevention of COVID-19**

- A. No practitioner shall prescribe any medication for COVID-19, either for treatment or prevention, unless treatment or prevention of COVID-19, or similar infectious disease, is within such practitioner's usual and customary scope of practice.
- B. Any practitioner who chooses to prescribe an FDA-approved medication for the off-label purpose of treating COVID-19 shall:
1. Indicate on the prescription the applicable ICD-10 diagnosis code.
  2. Indicate on the prescription a telephone number at which the dispensing authority (e.g., pharmacist) may reach the health care provider to address questions relative to dose and treatment.

3. Document in the associated patient's medical record that the specific risks and benefits of the off-label treatment were discussed with the patient.
  4. Document in the associated patient's medical record the clinical rationale for the off-label prescribing, citing:
    - a. At least one peer-reviewed article that justifies the clinical decision for the off-label prescribing, in the event that the FDA publishes such guidance.
    - b. Applicable FDA guidance justifying the clinical decision for the off-label prescribing, in the event that the FDA publishes such guidance.
- C. This Part does not apply to physicians, licensed to practice medicine in the state of Rhode Island pursuant to Title 5, Chapter 37 of the R.I. Gen. Laws, who are board certified in the American Board of Medical Specialties (ABMS) specialties of Infectious Disease and/or Critical Care.