

## CONCISE EXPLANATORY STATEMENT

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In accordance with the Administrative Procedures Act, R.I. Gen. Laws § 42-35-2.6, the following is a concise explanatory statement:

**AGENCY:** Rhode Island Department of Health (RIDOH)

**DIVISION:** N/A

**RULE IDENTIFIER:** 216-RICR-20-20-6

**RULE TITLE:** Off Label Prescribing of Medications for COVID-19

**REASON FOR RULEMAKING:**

COVID-19, the new disease caused by the novel coronavirus SARS-CoV-2, has been deemed a global pandemic. It continues to spread and threatens to overwhelm the state's ability to respond. Aggressive and sustained efforts are necessary to slow the spread of COVID-19 to lessen the strain on the health care system. This regulation limits the authority to prescribe medication off-label to treat or prevent COVID-19, absent peer reviewed justification or FDA guidance, to physicians specialized in Infectious Disease and/or Critical Care.

**ANY FINDINGS REQUIRED BY LAW AS A PREEQUISITE TO THE EFFECTIVENESS OF THE RULE:** N/A

**TESTIMONY AND COMMENTS:**

During public comment, it was suggested that a provision be added to create a mechanism that supports pharmacists dispensing protocols. RIDOH has determined that this suggestion will not be implemented as there are other regulatory mechanisms that resolve this issue.

**CHANGES TO THE TEXT OF THE RULE:** N/A

**REGULATORY ANALYSIS:**

In the development of this rule, consideration was given to:

1) alternative approaches; 2) overlap or duplication with other statutory and regulatory provisions; and 3) significant economic impact on small business.

No alternative approach, duplication, or overlap was identified based on available information. RIDOH has determined that the benefits of the rule justify its costs.