RHODE ISLAND GOVERNMENT REGISTER PUBLIC NOTICE OF PROPOSED RULEMAKING

DEPARTMENT OF HEALTH

Title of Rule: Off-Label Prescribing of Medications for COVID-19

Rule Identifier: 216-RICR-20-20-6

Rulemaking Action: Proposed Amendment

Important Dates:

Date of Public Notice: 07/16/2020 End of Public Comment: 08/17/2020

Authority for this Rulemaking:

R.I. Gen. Laws § 23-1-1 R.I. Gen. Laws § 23-1-18

Summary of Rulemaking Action:

Limit off-label prescribing to treat and/or prevent COVID-19 absent peer-reviewed justification or FDA guidance.

Additional Information and Comments:

All interested parties are invited to request additional information or submit written or oral comments concerning the proposed amendment until August 17, 2020 by contacting the appropriate party at the address listed below:

Paula Pullano
Department of Health
3 Capitol Hill
Room 410
Providence, RI 02908
Paula.Pullano@health.ri.gov

In accordance with R.I. Gen. Laws § 42-35-2.8, an oral hearing will be granted if requested by twenty-five (25) persons, by an agency or by an association having at least twenty-five (25) members. A request for an oral hearing must be made within thirty (30) days of this notice.

Regulatory Analysis Summary and Supporting Documentation:

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 this rule justify its costs.

For full regulatory analysis or supporting documentation see agency contact person above.	1