

EXHIBIT 10

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TEMPORARY ADMINISTRATIVE ORDER
INCLUDING STATEMENT OF NEED & JUSTIFICATION

BP 7-2020

CHAPTER 855
BOARD OF PHARMACY

FILED

06/15/2020 4:34 PM
ARCHIVES DIVISION
SECRETARY OF STATE
& LEGISLATIVE COUNSEL

FILING CAPTION: Prohibits dispensing of certain drugs for COVID19 prevention and treatment

EFFECTIVE DATE: 06/15/2020 THROUGH 09/20/2020

AGENCY APPROVED DATE: 06/15/2020

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Filed By:
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Rules Coordinator

NEED FOR THE RULE(S):

On 6/15/2020, the FDA revoked the emergency use authorization (EUA) that allowed for chloroquine phosphate and hydroxychloroquine sulfate donated to the Strategic National Stockpile to be used to treat certain hospitalized patients with COVID-19 when a clinical trial was unavailable, or participation in a clinical trial was not feasible. The agency determined that the legal criteria for issuing an EUA are no longer met. Based on its ongoing analysis of the EUA and emerging scientific data, the FDA determined that chloroquine and hydroxychloroquine are unlikely to be effective in treating COVID-19 for the authorized uses in the EUA. Additionally, in light of ongoing serious cardiac adverse events and other potential serious side effects, the known and potential benefits of chloroquine and hydroxychloroquine no longer outweigh the known and potential risks for the authorized use. Furthermore, hydroxychloroquine continues to remain on the FDA's drug shortage list.

JUSTIFICATION OF TEMPORARY FILING:

New clinical evidence has determined that there are potential serious patient health risks associated with the inappropriate use of these drugs.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE:

FDA News Release - <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and>

ADOPT: 855-007-0085

SUSPEND: Temporary 855-007-0085 from BP 3-2020

RULE TITLE: Prescriptions for Chloroquine and Hydroxychloroquine during COVID-19 Public Health Emergency

RULE SUMMARY: Related to dispensing chloroquine/hydroxychloroquine prescriptions during COVID-19 public health emergency.

RULE TEXT:

Prescription orders for chloroquine or hydroxychloroquine for the prevention or treatment of COVID-19 infection may

only be dispensed if written for a patient enrolled in a clinical trial by an authorized investigator.

STATUTORY/OTHER AUTHORITY: ORS 689.205

STATUTES/OTHER IMPLEMENTED: