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For Filing Administrative Regulations

Agency: Nevada State

Board of Pharmacy

FOR EMERGENCY
REGULATIONS ONLY

Effective date 3-23-2020

Expiration date 9-23-2020

Governor's signature

Classification:

PROPOSED ☐ ADOPTED BY AGENCY x EMERGENCY

Brief description of action:

The proposed amendment

Authority citation other than 233B: NRS 639.070

Notice Date: March 23, 2020 Date of Adoption by Agency: March 23, 2020

Hearing Date: March 23, 2020

Nevada State Board of Pharmacy

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March 23, 2020

VIA EMAIL AND HAND DELIVERY

The Honorable Steve Sisolak, Governor
101 North Carson Street – Suite 1
Carson City, NV 89701

RE: Emergency regulation on prescribing and dispensing chloroquine and hydroxychloroquine during COVID-19 pandemic

Dear Governor Sisolak:

The Nevada State Board of Pharmacy (Board) has determined that an emergency exists due to the hoarding and stockpiling of chloroquine and hydroxychloroquine during the COVID-19 pandemic and the resulting shortage of supplies of these drugs for legitimate medical purposes.

Currently, hydroxychloroquine is under investigation for use in the treatment of COVID-19. At this time, safety and efficacy have not been established.[1]

> The FDA has been working closely with other government agencies and academic centers that are investigating the use of the drug chloroquine, which is already approved for treating malaria, lupus and rheumatoid arthritis, to determine whether it can be used to treat patients with mild-to-moderate COVID-19 to potentially reduce the duration of symptoms, as well as viral shedding, which can help prevent the spread of disease. Studies are underway to determine the efficacy in using chloroquine to treat COVID-19.[2]

Therefore, pursuant to NRS 233B.0613, the Board respectfully requests an emergency regulation in Chapter 639 of the Nevada Administrative Code that restricts the prescribing and dispensing of chloroquine and hydroxychloroquine during the COVID-19 outbreak. These restrictions include prohibiting the prescribing and dispensing of chloroquine and hydroxychloroquine for a COVID-19 diagnosis or any new diagnosis made after the effective date of the regulation, and requiring an ICD-10 code and a limit to a 30-day supply for any new prescription for these drugs. The provisions of this emergency regulation do not apply to a chart order for an inpatient in an institutional setting or to an existing course of treatment for a

diagnosis made before the effective date of the regulation. This emergency regulation is based upon recommendations from the Governor's COVID-19 Medical Advisory Team.

As this emergency regulation will ensure access for Nevada patients to chloroquine and hydroxychloroquine for legitimate medical purpose, your endorsement is requested. Thank you for your assistance and consideration.

Sincerely,

J. David Wuest, R.Ph.
Executive Secretary
Nevada State Board of Pharmacy

Endorsed:

Steve Sisolak
Governor

[1] Hydroxychlorquine. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. http://www.uptodate.com. Accessed March 20. 2020.

[2] Coronavirus (COVID-19) Update: FDA Continues to Facilitate Development of Treatments. 2020, March 19. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-continues-facilitate-development-treatments. Accessed March 20, 2020.

EMERGENCY REGULATION OF THE

STATE BOARD OF PHARMACY

March 23, 2020

EXPLANATION Matter in ***italics*** is new; matter in brackets
[~~*omitted material*~~] is material to be omitted.

Filing of an Emergency Administrative Regulation

AUTHORITY: NRS 639.070.

A REGULATION relating to pharmacy; restricting the prescribing and dispensing of chloroquine and hydroxychloroquine during the COVID-19 outbreak.

Explanation:

Existing law authorizes the State Board of Pharmacy to adopt regulations appertaining to the practice of pharmacy. (NRS 639.070). This emergency regulation prohibits the prescribing and dispensing of chloroquine and hydroxychloroquine for a COVID-19 diagnosis or any new diagnosis made after the effective date of the regulation, and requires an ICD-10 code and a limit to a 30-day supply for any prescription for these drugs. The provisions of this emergency regulation do not apply to a chart order for an inpatient in an institutional setting or to an existing course of treatment for a diagnosis made before the effective date of the regulation.

Chapter 639 of NAC is hereby amended by adding thereto the following provisions:

1. A prescription for chloroquine or hydroxychloroquine may not be issued, filled or dispensed to an outpatient:

a) For a COVID-19 diagnosis; or

b) For any new diagnosis made after the effective date of this regulation.

2. A prescription for chloroquine or hydroxychloroquine issued after the effective date of this regulation:

a) Must contain a confirmed, written ICD-10 diagnosis code from the prescriber; and

b) Must be limited to no more that a 30-day supply at any time.

3. The provisions of this regulation do not apply:

a) To a chart order for an inpatient in an institutional setting; or

b) To an existing course of treatment for a diagnosis made before the effective date of this regulation.

INFORMATIONAL STATEMENT OF ADOPTED REGULATIONS
AS REQUIRED BY NRS 233B.066

The informational statement required by NRS 233B.066 numerically conforms to the subsections of the statute as follows:

1. EXPLANATION OF THE NEED FOR THE ADOPTED REGULATION

Pursuant to the Governor's Declaration of Emergency issued March 12, 2020, the State is in an emergency status due to the COVID-19 pandemic. This has resulted in the hoarding and stockpiling of chloroquine and hydroxychloroquine during COVID-19 pandemic and the resulting shortage of supplies of these drugs for legitimate medical purposes. An emergency regulation is needed to an emergency regulation in Chapter 639 of the Nevada Administrative Code that restricts the prescribing and dispensing of chloroquine and hydroxychloroquine during the COVID-19 outbreak. These restrictions include prohibiting the prescribing and dispensing of chloroquine and hydroxychloroquine for a COVID-19 diagnosis or any new diagnosis made after the effective date of the regulation, and requiring an ICD-10 code and a limit to a 30-day supply for any new prescription for these drugs.

6. THE ESTIMATED ECONOMIC EFFECT OF THE REGULATION ON THE BUSINESS WHICH IT IS TO REGULATE AND ON THE PUBLIC. THESE MUST BE STATED SEPARATELY, AND IN EACH CASE MUST INCLUDE:

A) BOTH ADVERSE AND BENEFICIAL EFFECTS.

The Board anticipates that there will be no adverse or beneficial economic impact from this regulation on either the providers of pharmaceutical care that will be subject to the regulation nor on the public.

B) BOTH IMMEDIATE AND LONG-TERM EFFECTS.

The Board anticipates that there will be no immediate or long-term economic effect on either the providers of pharmaceutical care that will be subject to the regulation nor on the public, or that any such effects will be negligible.

7. THE ESTIMATED COST TO THE AGENCY FOR ENFORCEMENT OF THE PROPOSED REGULATION.

There will be no additional or special costs incurred by the Board for enforcement of this regulation.

8. A DESCRIPTION OF ANY REGULATIONS OF OTHER STATE OR GOVERNMENT AGENCIES WHICH THE PROPOSED REGULATION OVERLAPS OR DUPLICATES AND A STATEMENT EXPLAINING WHY THE DUPLICATION OR OVERLAPPING IS NECESSARY. IF THE REGULATION

OVERLAPS OR DUPLICATES A FEDERAL REGULATION, THE NAME OF THE REGULATING FEDERAL AGENCY.

The Board of Pharmacy is not aware of any similar regulations of other state or government agencies that the proposed regulation overlaps or duplicates.

9. IF THE REGULATION INCLUDES PROVISIONS WHICH ARE MORE STRINGENT THAN A FEDERAL REGULATION WHICH REGULATES THE SAME ACTIVITY, A SUMMARY OF SUCH PROVISIONS.

The Board of Pharmacy is not aware of any similar regulations of the same activity in which the federal regulation is more stringent.

10. IF THE REGULATION PROVIDES A NEW FEE OR INCREASES AN EXISTING FEE, THE TOTAL ANNUAL AMOUNT THE AGENCY EXPECTS TO COLLECT AND THE MANNER IN WHICH THE MONEY WILL BE USED.

This regulation does not provide a new or increase of fees.