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April 9, 2020

VIA USPS EXPRESS OVERNIGHT MAIL AND EMAIL

The Honorable Steve Sisolak, Governor, Nevada
c/o Kyle E. N. George, Interim General Counsel (via Communications Director rmcinerney@gov.nv.gov)
State Capitol Bldg.
101 N. Carson Street
Carson City NV 89701

Nevada State Board of Pharmacy
Helen Park, President
c/o Brett Kandt, General Counsel (bkandt@pharmacy.nv.gov)
985 Damonte Ranch Pkwy., Ste. 206
Reno NV 89521

Re: March 23, 2020, Emergency Regulation on Prescribing and Dispensing Chloroquine and Hydroxychloroquine During COVID-19 Pandemic

Greetings Governor Sisolak and President Park,

I have been retained by the Nevada Osteopathic Medical Association (NOMA) and Dr. Bruce Fong as its President to seek an amendment of the Emergency Regulation adopted by the Honorable Steve Sisolak, Governor of Nevada, and the State Board of Pharmacy (BOP) on March 23, 2020, restricting the use of chloroquine and/or hydroxychloroquine in the treatment of COVID-19. (*See* Proposed Amendment to the Emergency Regulation attached hereto as **Exhibit "A"**.) I am requesting that you immediately pass upon the validity of the Emergency Regulation and amend its provisions to lift the restriction on the use of these drugs, so that anyone suffering from

this disease can receive treatment if prescribed by a licensed health practitioner, regardless of hospitalization. The regulation, or its proposed application, interferes with or impairs, or threatens to interfere with or impair, the legal rights or privileges of my client. If the regulation is not amended ***by 5 p.m. on Monday, April 13***, we will promptly file a legal challenge, in court, to have the regulation declared invalid under, among other things, NRS 233B.110. The regulation is invalid because there was no emergency or justification for its enactment under NRS Chapter 233B, is preempted by Federal Law, constitutes the practice of medicine by the BOP, and violates the constitutional and statutory rights of patients to receive lawful treatments for a deadly disease as recommended by their healthcare providers.

I. Background.

On February 4th, the Federal Department of Health and Human Services determined that a significant public health threat existed which affected national security, due to a new virus named SARS-CoV-2, which causes the illness COVID-19.[1] On March 6th, the President of the United States signed the Coronavirus Preparedness and Response Supplemental Appropriations Act, which contained more than $8 billion in funding.[2] On March 12th, Governor Sisolak issued a proclamation declaring a state of emergency, and called upon the agencies of this State to supplement the efforts and capabilities of all localities to save lives and protect the health and safety of Nevada citizens in coordination with the Federal Government.

On March 14th, Governor Sisolak activated the State Emergency Operations Center, and formed a medical advisory team consisting of the State's Chief Medical Officer ("CMO") and four additional medical experts. On March 23rd, the BOP sought and received endorsement by

[1] https://www.fda.gov/media/136534/download

[2] https://www.hhs.gov/about/news/2020/03/24/hhs-awards-100-million-to-health-centers-for-covid-19-response.html

Governor Sisolak for its statement of emergency, by letter of the same date, in order to adopt emergency regulations restricting the issuance, filling, and dispensing of chloroquine and hydroxychloroquine for patients outside of a hospital setting. Specifically, the BOP cited "the hoarding and stockpiling" of these drugs during the COVID-19 pandemic, and the "resulting shortage of supplies of these drugs for legitimate medical purposes."

Hoarding and stockpiling of this medication is a valid concern. But this concern can be properly accounted for in a manner that does not restrict a patient's rights afforded under Nevada law. The notion that individuals testing positive for this virus cannot be treated in the manner recommended by their doctor because they have not reached the point where they must be hospitalized, is unthinkable. It is also unlawful.

In cases of communicable diseases, patients are afforded rights as to their isolation, quarantine, *and* treatment. And while the State is prohibited by law from forcing patients to be treated (*see* NRS 441A.160 and 441A.530), the State, and any of its agencies or boards, are correspondingly prohibited from interfering with patient treatment, in any manner. *See* NRS 441A.200. The people of this State have a right to receive approved treatment for a communicable disease, from the physician, clinic, or other person of their choice. *See* NRS 441A.200. Forcing patients to wait to receive their doctor's recommended treatment until they are hospitalized is both unlawful and unconscionable.

In addition to the procedural issues under NRS Chapter 233B, all three of the concerns the BOP has relied on as the basis for its emergency enactment have been resolved at the Federal level. The President has acquired supplies of chloroquine and hydroxychloroquine, the Federal Strategic National Stockpile (SNS) has authorized distribution of its supply to supplement states, and drug

manufacturers who regularly manufacture these drugs have already re-stocked, ramped-up production, and begun donating their supplies.

On March 25th, the World Health Organization (WHO) provided several new ICD-10 codes for COVID-19, and specifically, for cases where: (a) the virus is identified; and (b) for instances where the virus is not identified, for: (i) clinically-epidemiologically diagnosed COVID-19 cases; (ii) probable COVID-19 cases; and (iii) suspected COVID-19 cases.[3] (*See* WHO COVID-19 codes attached hereto as **Exhibit "B"**.) As part of the clinical coding of COVID-19 using the ICD-10 code, WHO further delineated confirmed cases from suspected or probable cases, where it requested codes to be added for various symptoms, and also codes for reporting intervention, procedure, isolation, and laboratory examination. WHO has provided numerous codes to encourage the reporting of not just confirmed, but suspected, probable, and negative cases, and further guidance on when it is appropriate to test.[4] All of these pertain to the medical determination made for each patient by his or her healthcare provider.

On March 28, the FDA issued an Emergency Use Authorization (EUA), declaring that circumstances exist which justify the authorization of the emergency use of drugs and biologics for the prevention and treatment of COVID-19.[5] As part of that authorization, the FDA found chloroquine and hydroxychloroquine to be effective in treating COVID-19 and reasonably safe for the purposes specified, and has permitted the emergency use of chloroquine phosphate and hydroxychloroquine sulfate for the treatment of COVID-19. As such, the BOP's Emergency Regulation must be amended to avoid problems of preemption.

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[3] https://www.who.int/classifications/icd/covid19/en/

[4] https://www.who.int/classifications/icd/covid19/en/

[5] https://www.fda.gov/media/136534/download

Further, the FDA stated that it would make available and would distribute provisions of chloroquine phosphate and hydroxychloroquine sulfate from the Federal Strategic National Stockpile (SNS) to state healthcare systems and healthcare providers, in accordance with the Federal Factsheets provided. This EUA was meant not only to provide an emergency approval for use of these drugs for treatment of COVID-19, but also to let states know that the Federal Government could distribute those supplies directly to the states from the SNS.

The role of the SNS is to supplement state and local supplies during public health emergencies and can be used as a "short-term stopgap buffer when the immediate supply of adequate amounts of these materials may not be immediately available."[6] The stockpile has responded to influenza pandemics in the past and has begun responding here.

While the SNS is in place to supplement the needs of each state, the Trump Administration has also made it clear that states must also assess their own supply levels, and ***exhaust those reserves first, before requesting more from the SNS.***[7] This makes it even more clear that the BOP must lift this restriction and allow ***all*** patients to begin receiving treatment as prescribed by their practitioner. Chapter 441A of NRS and NAC requires symptomatic patients of communicable diseases to be immediately tested and reported, and we must begin treating our patients with what is first available at the state level before we can access the federal supply.

For all of the above reasons, NOMA respectfully requests that the BOP amend the adopted Emergency Regulations to comply with NRS 233B, 630, 639, and 441A.200, and to account for the FDA's EUA. Specifically, the adopted Emergency Regulation must be amended to permit the

[6] https://www.phe.gov/about/sns/Pages/default.aspx

[7] https://www.washingtonpost.com/politics/2020/04/03/jared-kushner-stands-trump-proceeds-offer-very-trumpian-claim-about-stockpiles/

issuance, filling, or dispensing of chloroquine and/or hydroxychloroquine prescriptions written following a COVID-19 diagnosis using an ICD-10 code provided by the WHO and the Center for Disease Control (CDC), regardless of whether the patient is hospitalized.

Concurrently, NOMA hereby requests the BOP immediately issue a declaratory order and pass upon the validity of the adopted Emergency Regulation, and, specifically, as to its interference with and impairment of the right of a licensed practitioner to practice medicine (NRS 630 and NAC 630), and the right of a patient, specifically with an infectious and communicable disease, to receive approved treatment from its physician (NRS 441A and NAC 441A). *See* NRS 233B.110, 233B.120, and NAC 639.150.

Furthermore, NOMA hereby petitions the BOP to immediately issue an advisory opinion as to the applicability of the adopted Emergency Regulation to practitioners and pharmacists, and specifically, the practitioner's ability to issue, and the pharmacist's ability to fill and dispense chloroquine and/or hydroxychloroquine to patients with a prescription for treatment of a COVID-19 diagnosis, regardless of whether the patient is hospitalized. *See* NRS 233B.110, 233B.120, and NAC 639.150.

As of April 9, 2020, at least 71 Nevadans have died of COVID-19, some perhaps, needlessly due to lack of outpatient access to medications that may mitigate or ameliorate disease progression when administered before hospital admission. The right to approved treatment is a choice and a right that must remain with the practitioner and patient that cannot be restricted by the BOP.

II. The Regulation in Invalid

a. No Emergency Exists to Justify the BOP's Enactment Under NRS Chapter 233B's Emergency Provisions.

The adoption of the Emergency Regulation does not comply with the provisions of NRS 233B.0613, in that no notice of hearing was made, no notice of the proposed regulation was provided, the proposed language was adopted the same day it was introduced, and the final filing with the Secretary of State declares it to be in effect for a period of longer than 120 days. As no emergency exists which may justify non-compliance with the procedural requirements of NRS Chapter 233B, and as NRS 233B.0617 provides that no regulation is valid unless adopted in substantial compliance with the provisions of NRS 233B, NOMA hereby objects to this regulation on the grounds of noncompliance with the procedural requirements of NRS 233B.060 to 233B.0617, inclusive.

b. The Emergency Regulation is Preempted by Federal Law.

The Emergency Regulation is preempted by Federal law. Preemption is premised on the Supremacy Clause found in Article VI of the U.S. Constitution. There are multiple types of preemption: express, field, and conflict. English v. General Electric Co., 496 U.S. 472, 78-79 (1990). The most obvious form of preemption here is conflict preemption---namely, as currently worded, the regulation "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Hines v. Davidowitz, 312 U.S. 52, 67 (1981).

Here, the objectives of Congress include the regulation of pharmaceutical drugs while striking a balance with the practice of medicine, which neither the FDA nor the FDCA regulate.

Cf. 21 U.S.C. 396. For this reason, it is clearly established Federal law that the practice of prescribing drugs or devices for "off-label" uses is allowed by the FDA and the FDCA.[8]

The U.S. Supreme Court has recognized as much, quoting the following passage with approval: "Off-label use is widespread in the medical community and often is essential to giving patients optimal medical care, both of which medical ethics, FDA, and most courts recognize." Buckman Co. v. Plaintiffs' Legal Committee, 531 U.S. 341, 351 n. 5 (2001). And the Ninth Circuit Court of Appeals has followed suit. U.S. v. Kaplan, 836 F.3d 1199, 1210-11 (9th Cir. 2006) (acknowledging the existence of an off-label use "privilege" under FDCA for prescriptions of drugs and devices); In re Gilead Sciences Securities Litigation, 536 F.3d 1049, 1051 n.2 (9th Cir. 2008) (physicians are free under FDCA to prescribe drugs off-label).

Even prior to the FDA's EUA, the off-label prescription of chloroquine and/or hydroxychloroquine by a physician to treat COVID-19 is regarded under the Federal regulatory scheme as the lawful practice of medicine.

Further, the Legislature has determined that in an instance where the Governor declares a state of Emergency, the policy of this State is that all functions of emergency management are to be coordinated to the maximum extent with the comparable functions of the Federal Government, including its various agencies, so as to provide the most effective preparation and use of the Nation's resources. *See* NRS 414.020. As the health authority with jurisdiction over emergencies of this nature, the State Board of Health (BOH) has adopted, and all local health authorities are required to follow, ***all*** federal recommendations, guidelines and publications, including those specified in NAC 441A.200. *See* NRS 414A et all.

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[8] (https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label)

The prohibition of two medications approved by a Federal Agency by the adopted Emergency Regulation conflicts with Federal Law and is thus invalid.

c. The Emergency Regulation Constitutes the Practice of Medicine by the BOP.

By adopting the Emergency Regulations, the BOP is, in effect, both practicing medicine and restricting where patients may receive treatment. The BOP does not have the authority to prescribe or prohibit the prescription of drugs, nor interfere with the treatment of patients in any setting. It is the physician, under the license issued to him or her by their respective medical licensing boards, who is granted the authority to practice medicine. *See* NRS 630.160.

The Legislature has granted the BOP authority to adopt regulations pertaining to the practice of pharmacy and the sale and dispensing of drugs. *See* NRS 639.070. The "practice of pharmacy" includes the performance or supervision of activities associate with dispensing and distributing a drug, interpreting and evaluating prescriptions, participating in drug evaluation and drug research, selection of the source and storage of a drug, the development, implementation, and maintenance of written guidelines and protocols for collaborative practice and collaborative drug therapy management, and performing tests for those collaborative agreements, but it does *not* include the changing of a prescription by a pharmacists or practitioner without the consent of the prescribing practitioner. *See* NRS 639.0124.

Conversely, the "practice of medicine" means to *diagnose, treat, correct, prevent, or prescribe for any human disease, by any means* (emphasis added). *See* NRS 630.020. The practice of medicine also includes applying principles and techniques of medical science in the diagnosis or prevention of any such conditions. *See* NRS 630.020. Further, the Legislature has found the purpose of licensing practitioners is for the protection of the public health, safety, and general

welfare of the people of this State. *See* NRS 630.045. The practice of medicine does not take place only in a hospital setting, it occurs no matter where the physician meets the patient. *See* NRS 630.049.

The ability of a practitioner to diagnose and treat his or her patient is not an academic theory or a theoretical notion, it is in fact the practice of medicine, and it is this doctor-patient relationship at stake. A primary care physician knows and cares for his or her patient in more detail than a pharmacists or even a hospital physician; it is the patient's primary care physician that is able to accurately recognize a significant decline in the patient's health and suggest therapeutic intervention when it's needed most. Such a decline could be the beginning of a cascade of events that could ultimately result in the patient's death. If the therapeutic window is missed, there is likely no second chance. (*See* NOMA Newsletter attached hereto as **Exhibit "C"**.)

d. The Emergency Regulation Violates the Constitutional and Statutory Rights of Patients to Make Decisions with and Receive Treatment from their Healthcare Provider.

The right a patient to determine treatment with their primary care physician is an intimate decision about their own body, and any intrusion is a clear violation of a fundamental right. No justification was provided by the BOP that would warrant such an intrusion, not even declaration by the Governor of a state of emergency. Nor was the adopted Emergency Regulation narrowly tailored in any way to carry out any government interest at stake, and thus violates the due process clause of the 5th and 14th Amendment of United States Constitution, comparable provisions of the Nevada Constitution and the Constitutional Right of Privacy recognized in Roe vs Wade and its progeny. *See* 410 U.S. 113, 152-53 (1973).

"During a catastrophic disaster response, healthcare providers still have the duty to provide ethical and effective medical care despite being overwhelmed by the circumstances.... Despite these challenges, the healthcare system must continue to operate even with limited or inadequate resources to protect the health of the community."[9] The Department of Health and Human Services (DHHS) and the Division of Public and Behavioral Health (DPBH) are required to take such measures as may be necessary to prevent the spread of sickness and disease. *See* NRS 439.170.

When the Governor determines there is a public health emergency, he must issue an executive order and designate an emergency team who is charged with working with each state agency and board to disseminate and share information. *See* NRS 439.970 and 439.975. However, the scope of its power only extends administratively, and does **not** supersede the health authority having jurisdiction over the emergency or health event. *See* NRS 439.975.

The BOH is responsible for providing the procedures for investigating and reporting cases or suspected cases of communicable diseases, and the procedures for testing, isolating, and quarantining a person or group of persons who have been exposed to or have or are suspected of having the disease. *See* NRS 441A.120. And while the BOH must ensure that any testing, treatment, isolation, or quarantine be carried out in the least restrictive manner or environment that is appropriate and acceptable under current medical and public health practices, it remains the responsibility of the practitioner to determine and provide approved treatment. *See* NRS 441A.120 and NAC 441A.180.

Likewise, it is not the decision of the CMO. The Legislature provides that if the CMO is not licensed to practice medicine in this State, that he shall not, in carrying out the duties of the

[9] Nevada Crisis Standards of Care Plan. Pg. 1. (2017).

Chief Medical Officer, engage in the practice of medicine. *See* NRS 439.130. Thus, it is not the decision of the CMO nor the BOP to make such a decision regarding treatment.

In fact, in cases of communicable diseases, the State is prohibited by law from forcing patients to be treated (*see* NRS 441A.160 and 441A.530), and the State, and any of its agencies or boards, are correspondingly prohibited from interfering with patient treatment, in any manner. *See* NRS 441A.200. The people of this State have a right to receive approved treatment for a communicable disease, from the physician, clinic, or other person of their choice. *See* NRS 441A.200.

III. Conclusion.

Patients in a life-threatening situation have a right to make choices with their doctor about lawfully available treatments; certainly, this is fundamental. The Emergency Regulation, as adopted, not only runs afoul of Nevada law and is preempted by Federal Law, but would undoubtedly be subject to strict scrutiny – and it would undoubtedly fail to survive that scrutiny. We urge the BOP to amend the Emergency Regulation to lift the restriction on the use of these drugs, so that anyone suffering from this disease can receive treatment if prescribed by a licensed health practitioner, regardless of hospitalization. A proposed amended regulation is attached as **Exhibit "A"**.

Respectfully,

JOEY GILBERT LAW

JOSEPH S. GILBERT, ESQ.

cc: Attorney General, Aaron Ford | via USPS Express Overnight Mail 100 N. Carson St., Carson City, NV 89701
| via Email aginfo@ag.nv.gov

EXHIBIT "A"

PROPOSED AMENDMENT TO THE

EMERGENCY REGULATION OF THE

STATE BOARD OF PHARMACY

April 9, 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; authorizing 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 amendment to the emergency regulations adopted on March 23, 2020, by the Governor and on behalf of the State Board of Pharmacy, shall authorize the prescribing and dispensing of chloroquine and/or hydroxychloroquine for a COVID-19 diagnosis and an ICD-1O code as prescribed by the World Health Organization and the Center for Disease Control. The provisions of this emergency regulation likewise apply to healthcare providers and patients respectively.

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

1. A prescription for chloroquine or hydroxychloroquine may *[*~~*not*~~*]* be issued, filled, or dispensed to *[*~~*an outpatient*~~*]* *any patient*:

   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 than 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.

EXHIBIT "B"

See attached "COVID-19 coding in ICD-10" document.

COVID-19 coding in ICD-10

25 March 2020

This document provides information about the new codes for COVID-19 and includes clinical coding examples in the context of COVID-19. It includes a reference to the WHO case definitions for surveillance.

1 New ICD-10 codes for COVID-19

- U07.1 COVID-19, virus identified
- U07.2 COVID-19, virus not identified
    - Clinically-epidemiologically diagnosed COVID-19
    - Probable COVID-19
    - Suspected COVID-19

Details of the updates to ICD-10 are available online at https://www.who.int/classifications/icd/icd10updates/en/

2 Clinical Coding of COVID-19 with ICD-10

	No symptoms	With symptoms	ICD-10 codes
Confirmed cases	Positive test result only, patient showing no symptoms		U07.1
	Positive test result	COVID-19 documented as cause of death	U07.1*
	Positive test result	Use additional code(s) for respiratory disease (e.g. viral pneumonia J12.8) or signs or symptoms of respiratory disease (e.g. shortness of breath R06.0, cough R05) as documented	U07.1 + codes for symptoms *

*Use intervention/procedure codes to capture any mechanical ventilation or extracorporeal membrane oxygenation and identify any admission to intensive care unit

*Use additional codes for isolation (Z29.0) or laboratory examination (Z01.7) as required for the specific case

	Patient presents with acute respiratory illness	Contact or suspected exposure	ICD-10 codes
Suspected/probable cases	No other etiology; history of travel	√	U07.2; Z20.8 + codes for symptoms*
	Contact with confirmed or probable case	√	U07.2; Z20.8 + codes for symptoms*
	No other etiology: hospitalization required		U07.2 + codes for symptoms*
	COVID-19 documented without any further information re: testing		U07.2 + codes for any symptoms*

*Use intervention/procedure codes to capture any mechanical ventilation or extracorporeal membrane oxygenation and identify any admission to intensive care unit

*Use additional codes for isolation (Z29.0) or laboratory examination (Z01.7) as required for the specific case

	Presenting clinical scenario	ICD-10 codes
COVID-19 ruled out	Patient presents with acute respiratory illness; testing is negative, and COVID-19 is ruled out	Code the relevant stated infection/diagnosis + Z03.8 *Observation for other suspected diseases and conditions*
	Self-referral: after assessment no reason to suspect disease and further investigations deemed unnecessary	Code Z71.1 *Person with feared complaint in whom no diagnosis is made*

Testing for COVID-19	Based on clinical judgement, clinicians may order a test for the SARS-CoV-2 virus in a patient who does not strictly meet the case definition.	Code Z11.5 *Special screening examination for other viral diseases*

3 Mortality Coding of COVID-19 with ICD-10

Both categories, U07.1 (COVID19, virus identified) and U07.2 (COVID19, virus not identified) are suitable for cause of death coding. Similarly, new codes were created for ICD-11.

COVID-19 is reported on a death certificate as any other cause of death, and rules for selection of the single underlying cause are the same as for influenza (COVID-19 not due to anything else).

For recording on a death certificate, no special guidance needs to be given. The respiratory infection may evolve to pneumonia that may evolve to respiratory failure and other consequences. Potentially contributing comorbidity (immune system problem, chronic diseases...) is reported in part 2, and other aspects (perinatal, maternal...) in frame B, in line with the rules for recording.

A manual plausibility check is recommended for certificates where COVID-19 is reported, in particular for certificates where COVID-19 was reported but not selected as the single underlying cause of death.

4 WHO COVID-19 Case definitions for Global Surveillance[1] 24 March 2020

Confirmed cases

A confirmed case is a person with laboratory confirmation of infection with the COVID-19 virus, irrespective of clinical signs and symptoms.

[1] https://www.who.int/publications-detail/global-surveillance-for-human-infection-with-novel-coronavirus-(2019-ncov)

Suspected cases

A) a patient with acute respiratory illness (that is, fever and at least one sign or symptom of respiratory disease, for example, cough or shortness of breath) AND with no other etiology that fully explains the clinical presentation AND a history of travel to or residence in a country, area or territory that has reported local transmission of COVID-19 disease during the 14 days prior to symptom onset

OR

B) a patient with any acute respiratory illness AND who has been a contact of a confirmed or probable case of COVID-19 disease during the 14 days prior to the onset of symptoms

OR

C) a patient with severe acute respiratory infection (that is, fever and at least one sign or symptom of respiratory disease, for example, cough or shortness breath) AND who requires hospitalization AND who has no other etiology that fully explains the clinical presentation.

Probable case

A probable case is a suspected case for whom the report from laboratory testing for the COVID-19 virus is inconclusive.

EXHIBIT "C"

See attached "NOMA Newsletter".

Nevada Osteopathic Medical Association

Begin forwarded message:

From: NOMA <staff@nevadaosteopathic.org>
Date: March 28, 2020 at 11:03:37 PDT
To: bfong186@aol.com
Subject: A Bad Decision in Desperate Times
Reply-To: staff@nevadaosteopathic.org

March 28, 2020

Nevada Osteopathic Medical Association

A Bad Decision in Desperate Times

My Fellow Osteopathic Physicians:

By now many of you have heard about an emergency regulation signed by Governor Sisolak on Monday March 23rd that essentially ***bans the use of hydroxychloroquine and chloroquine from being prescribed for use against the COVID-19*** pandemic sweeping throughout the world today.

When reading the accompanying justification for an emergency regulation, one gets the impression that it was done due to doubts about the medications' safety and efficacy in regard to COVID-19, along with a concern regarding a shortage of these meds for other chronic conditions. However, when I called the Board of Pharmacy (BOP) I was given a different story that squarely blamed doctors for trying to self-prescribe and deplete the supply of medications.

Thus, the BOP proposed this emergency regulation on Sunday night (March 22) and had a public hearing the next day, at which time the Governor signed the proposed regulations. Please see the link for full text:
https://drive.google.com/file/d/1905SK7ox7YDaP1d-W6BjCNgJVTilX0U/view.

For the record, the frantic pace at which this regulation was pushed through clearly ***excluded*** any input from practicing physicians or the organizations and groups that represent their patients, interests and opinions. I have confirmed thru phone calls that neither NOMA nor the Nevada State Medical Association were given any notice of this proposed regulation.

In essence, as explained to me by the BOP, this change to the Nevada Administrative Code would prohibit the writing or dispensing of the aforementioned medications for a diagnosis of COVID-19

in an outpatient setting but allow for it to be used only in an inpatient setting. Also, as per the BOP, the hospital could then prescribe or dispense the medication for that same patient as an outpatient to continue care. Otherwise, new prescriptions for use of these compounds in the rheumatologic role could continue, but an ICD-10 code would be required and supply limited to 30-days.

Like any other physician trying to practice in these trying times, I fully understand and have severe issue with anyone hoarding needed medications or protective equipment that could help someone in need. From this perspective, I understand the BOP's position on this matter and their *utterly staunch opposition to any compromise* on this matter until further evidence is forthcoming for outpatient setting use of the hydroxychloroquine or chloroquine.

However, I am absolutely convinced that this rash decision by the BOP and Governor is an ***undeniable mistake*** that will prevent physicians from being able to administer a potentially curative therapy that could prevent both morbidity and mortality. My dear colleagues, this is a ***scope of practice issue*** and ***clearly interferes with a physician's decision*** on how to treat their patients.

I wholeheartedly am in opposition to this regulation for many reasons:
First, it is my most deep and heartfelt opinion that a treatment choice should ultimately be a decision left to physicians and their patient. When you are regularly seeing a patient, you know them better and understand their nuances more than a hospitalist or other triage person seeing this patient for the first time.

Second, this deeper knowledge of said patient will result in a better capability to realize that a patient's condition is worsening and when they really need to be hospitalized or have a specific intervention. This is especially the case with COVID-19, where a hospital triage screener is looking only at specific parameters to determine need for more acute care. Currently the recommendation outside of obvious symptoms such as dyspnea and chest pain, is that a patient who is suspected of having this illness is advised to return home to self-isolate and observe but if they worsen then return to hospital to be admitted. Clincally, since 80% of patients have limited illnesses, you are sending them home to run this course. However, with the remaining 20%, you are waiting for them to show signs of *significant worsening* before actually admitting to the hospital. The patient's primary care physician is a much better judge of this deteriorating situation than a stranger who has not had as much interaction with patient. In fact, often hospital triage and ER personnel are trying to deter admissions to reduce the potential of spread of the virus and such a delay could be critical to the outcome of a patient.

Third, in my humble opinion, since it is at this stage of *initial worsening* as an outpatient before hospitalization, that the patient may be developing ***viral pneumonia***, this is a ***critical window of therapeutic intervention***. If we have a reasonably effective anti-microbial agent(s) that can be used at this point, we can limit the spread and damage of said pneumonia and likely prevent its transition into Acute Respiratory Distress Syndrome and the severe complications associated with such including the increased chance of mortality. If we wait until a patient is admitted following the need to meet all of the current admission criteria to a hospital, we may lose the opportunity to stop the complications before they start. Normally all we can do once in the hospital is give supportive care. Even if we begin using the hydroxychloroquine or chloroquine after admission, we may still miss that critical therapeutic window.

Fourth, in the citation for the reason for this emergency regulation, it is noted that the medications had not had their safety and efficacy established. I would argue that these medications and related compounds have been in use for many decades (since the 1940's) in their roles as anti-malarial

agents even long before they were used in their current role as rheumatic agents. Therefore, their safety and side effect profiles are well known.

Regarding efficacy, there is always this argument that there are no controlled randomized placebo trials to refer to. People: "WAKE THE HELL UP!!!!" We are basically fighting a war against this disease, we do NOT have the luxury of time to conduct these trials where one group gets a drug and another a placebo (in fact to do this in this particular setting would be UNETHICAL!!). People are dying out there regardless of the true numbers and we have to rely on the clinical experiences of those who have already combatted this illness and review and use the most effective tools they have used to stop this. To restrict these agents currently would be akin to asking us as physicians to go into a gun fight with a knife or really nothing at all.

Right now, there are NO specifically indicated anti-microbial agents we can use for COVID-19 and even with the highest levels of supportive care in a hospital, we are only hoping on and relying on a patient's own immune system to do the fighting.
Specifically, hydroxychloroquine and chloroquine don't just have a handful of anecdotal reports of effectiveness (sometimes with miraculous results) but have *thousands of case reports of positive outcomes* from doctors in the hardest hit areas all over the world. *This alone should spur us to think, hey there is very likely something to this.* I would argue that the sheer number of case reports with positive outcomes alone takes this evidence out of the anecdotal category to one that suggests likely beneficial outcomes. And if so, this should be enough impetus to allow for us as physicians to at least consider making a clinical decision to prescribing the same (in combination with azithromycin) especially on a compassionate (when there is no other option) basis. Another way of saying this would be "the potential benefits outweigh the risks" and given the lack of other viable agents, we as conscientious physicians should consider all that we can possibly do to help our patients with this "Novel" virus.

Additionally, other states have already begun allowing the use of these drug combinations as they have recognized the above arguments. I strongly urge the BOP and Governor Sisolak to reconsider their decision to enact these restrictive measures especially once more supply of the medications becomes available. This current emergency regulation denies our ability to put our patients' interests first above all else which is a direct violation of the Hippocratic oath that all of us took upon graduating medical school.
For these reasons and our current dire emergency circumstances, I submit there is enough evidence to show at least some level of benefit as well as known safety and as such these medications should be allowed to be prescribed for those who are specifically showing early signs of compromise with COVID-19 (suspected viral pneumonia) in an outpatient setting to potentially prevent worsening of their conditions.

Andrew Taylor Still wrote over a hundred and twenty years ago: ***"Let us not be governed today by what we did yesterday, nor tomorrow by what we do today, for day by day we must show progress"***. Let us be true osteopaths and do what is best for our patients and make progress against this common foe of COVID-19.

What do you think?
Please share your comments and even suggestions on how to address this issue with us at: Info@nevadaosteopathic.org.

Sincerely Yours;

Bruce Fong, DO
President