$1422

Joseph S. Gilbert, Esq. - NSB 9033
Roger O'Donnell, Esq. – NSB 14593
JOEY GILBERT LAW
201 W. Liberty Street, Suite 210
Reno, Nevada 89501
Tel: 775.284.7000
Fax: 775.284.3809
joey@joeygilbertlaw.com; roger@joeygilbertlaw.com
Counsel for Plaintiff, Nevada Osteopathic Medical Association

IN THE SECOND JUDICIAL DISTRICT COURT OF THE STATE OF NEVADA

IN AND FOR WASHOE COUNTY

NEVADA OSTEOPATHIC MEDICAL ASSOCIATION, Nevada Domestic Nonprofit Cooperative Corporation; and BRUCE FONG, DO, HMD, an individual; Plaintiffs/Petitioners, vs. THE HONORABLE STEPHEN F. SISOLAK, as Governor of the State of Nevada; STATE OF NEVADA, NEVADA STATE BOARD OF PHARMACY, an administrative agency of the State of Nevada; and STATE OF NEVADA, CHIEF MEDICAL OFFICER, IHSAN AZZAM, Ph.D., M.D., Defendants/Respondents.	Case No.: Dept. No.: **COMPLAINT FOR EMERGENCY DECLARATORY RELIEF** **Exempt from Arbitration NAR 3(A), NAR 5** • **Action for Declaratory Relief** • **Action Presenting a Significant Issue of Public Policy** • **Action Seeking Equitable or Extraordinary Relief**

The NEVADA OSTEOPATHIC MEDICAL ASSOCIATION, a Nevada Domestic Nonprofit Cooperative Corporation ("NOMA") and BRUCE FONG, D.O., an individual ("Fong") (NOMA and Fong, individually and collectively, "Plaintiffs"), by and through their undersigned attorneys of record, hereby file this Complaint for Emergency Declaratory Relief asking the Court to declare the Nevada State Board of Pharmacy's March 23, 2020, Emergency Regulation restricting the use of hydroxychloroquine and/or chloroquine void and invalid and

either prohibit its enforcement or mandate that the Board of Pharmacy rescind it and/or amend it.

JURISDICTION AND VENUE

1. This Court has jurisdiction over this action. *See e.g.,* NRS 233B.110; NRS 241.037; Nevada's Uniform Declaratory Judgments Act, NRS 30.010, et. seq.; and NRS 33.010.

2. Plaintiff NOMA is made up of one or more physicians that are citizens of the State of Nevada, reside in the Second Judicial District of Washoe County, and/or conduct business in the State of Nevada.

3. Plaintiff Fong is an individual residing in Washoe County, Nevada, and is the President of NOMA.

4. Plaintiffs' claims, or some part thereof, arise out of Defendants' activities within the jurisdiction of the Second Judicial District Court of Washoe County.

5. Venue is proper in the Second Judicial District Court of Washoe County. *See* NRS 13.020 and/or NRS 13.040.

PARTIES

6. Plaintiff NOMA is a Domestic Nonprofit Cooperative Corporation organized under the laws of the State of Nevada, with its principal place of business in Washoe County, Nevada.

7. Plaintiff Fong is an individual residing and doing business in Washoe County, Nevada, and is an Osteopathic physician licensed by the Nevada State Board of Osteopathic Medicine.

8. Defendant, the Honorable Stephen F. Sisolak, is the duly elected Governor of the State of Nevada (the "Governor" or "Governor Sisolak").

9. Defendant, the State of Nevada, Nevada State Board of Pharmacy is an administrative agency of the State of Nevada and consists of seven members appointed by the Governor ("BOP").

10. Defendant, State of Nevada, Chief Medical Officer, Ihsan Azzam, Ph.D., M.D., is the Chief Medical Officer of the State of Nevada, is in the unclassified service of the State

and serves at the pleasure of the Director of the Department of Health and Human Services ("CMO").

11. Governor Sisolak, the BOP, and the CMO are individually and collectively referred to herein as the "Defendants".

BASIS FOR EMERGENCY RELIEF

12. Because this matter pertains to a declared state of emergency, Plaintiffs hereby request a speedy hearing on the declaratory judgment claims presented herein. *See* NRCP 57 (stating, "[t]he court may order a speedy hearing of a declaratory-judgment action").

FACTUAL ALLEGATIONS

13. On January 31, 2020, the Secretary of the U.S. Department of Health and Human Services ("HHS") 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 ("COVID-19").[1]

14. COVID-19 is an infectious disease caused by the most recently discovered coronavirus, which is from a family of viruses that are known to cause SARS.[2] An infectious disease is one caused by pathogenic microorganisms, which spread, either directly or indirectly, from one person to another, and such term includes a communicable disease. *See* NRS 441A.063. The SARS virus is classified as a communicable disease. *See* NAC 441A.040.

15. On March 6, 2020, the President of the United States signed the Coronavirus Preparedness and Response Supplemental Appropriations Act, which contained more than $8 billion in funding[3], of which $515,162 was earmarked to support eight Nevada health centers. *See* **Exhibit "1"**.

16. On March 12, 2020, Governor Sisolak issued a proclamation declaring a state of emergency pursuant to NRS Chapter 414 and called upon the agencies of this State to

---

[1] https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx
[2] https://www.who.int/news-room/q-a-detail/q-a-coronaviruses
[3] https://www.hhs.gov/about/news/2020/03/24/hhs-awards-100-million-to-health-centers-for-covid-19-response.html

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. *See* **Exhibit "2**".

17. On March 14, 2020, Governor Sisolak activated the State Emergency Operations Center, and formed a medical advisory team consisting of the CMO and four additional medical experts.[4]

18. If the CMO is not licensed to practice medicine in this State, and the CMO here is not, he shall not, in carrying out the duties of CMO, engage in the practice of medicine. *See* NRS 439.130.[5]

19. 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; NRS 439.975. However, the scope of the emergency team's power only extends administratively and does not supersede the health authority having jurisdiction over the emergency or health event. *See* NRS 439.975.

20. On March 23, 2020, based upon the recommendation provided by the Governor's COVID-19 Medical Advisory Team, the BOP sought and received endorsement by Governor Sisolak for its own statement of emergency, by letter of the same date, in order to adopt emergency regulations restricting the "prescribing and dispensing" of chloroquine and hydroxychloroquine for patients outside of a hospital setting. *See* **Exhibit "3"**. 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" as the basis for its statement of emergency. *Id*. The BOP further claimed that hydroxychloroquine is under investigation for use in the treatment of COVID-19, but that its safety and efficacy have not been established. *Id*. However, the BOP failed to provide any evidence, let alone sufficient

---

[4]http://gov.nv.gov/News/Press/2020/Governor_Sisolak_Forms_Medical_Advisory_Team_to_Provide_Guidance_on_COVID-19/

[5] https://www.washingtontimes.com/news/2018/sep/11/ihsan-azzam-nevada-chief-medical-officer-not-licen/

evidence, in support of these claims, or its reasons for the existence of an emergency necessitating or justifying the emergency action taken.

21. On March 23, 2020, that same day, and without providing supporting evidence sufficient to reasonably determine the existence of an emergency and having failed to provide even minimally effective public notice, the BOP held an emergency meeting to hear the "Discussion and Possible Action on Adoption of Emergency Regulations pursuant to NRS 233B.0613 to Restrict the Prescribing and Dispensing of Chloroquine or Hydroxychloroquine in Response to Covid-19 (**FOR POSSIBLE ACTION)**." *See* **Exhibit "4" (**the "Agenda" at p. 2, item 3) (emphasis in original); *see also* NRS 241.015; NRS 241.020.

22. The Agenda states that a public notice of the emergency meeting was given the same day as the meeting. However, any such notice failed to meet the minimum requirements set forth in NRS 241.020 and 233B.0614, as even the BOP members were only provided notification of the meeting via email at 2:59 p.m., with the meeting held by teleconference at 3:30 p.m. *See* **Exhibit "5"**. In this, the BOP did not take comments from the general public as required under NRS 241.020. *See* NRS 241.020 (stating that, "[n]o action may be taken upon a matter raised under this item of the agenda until the matter itself has been specifically included on a future agenda as an item…").

23. As stated in its Agenda, the BOP declared that "[i]n regulating the practice of pharmacy, the Nevada State Board of Pharmacy has a duty to carry out and enforce the provisions of Nevada law to protect the health, safety and welfare of the public." *See* Exhibit "4".

24. On March 23, 2019, citing NRS 639.070 as its statutory authority, the BOP passed an Emergency Administrative Regulation that "restricts the prescribing and dispensing of chloroquine and hydroxychloroquine during the COVID-19 outbreak." *See* **Exhibit "6"** (the "Emergency Regulation").

25. The Emergency Regulation prohibits physicians from issuing, and pharmacists from filling and/or dispensing, chloroquine and/or hydroxychloroquine to an individual for a COVID-19 diagnosis outside of a hospital setting.

26. By adopting the Emergency Regulations, the BOP is, in effect, both impermissibly practicing medicine and illegitimately restricting where the practice of medicine can occur. *See, e.g.,* NRS 630.020; NRS 630.049. In short, the Emergency Regulation restricts a patient's right to approved treatment for a communicable disease pursuant to a valid prescription.

27. The practice of medicine in Nevada requires licensure. *See, e.g.,* NRS 630.160; NRS 630A.230.

28. The BOP does not have the authority to prescribe medication, cannot prohibit the prescription of medication, and certainly cannot interfere with a physician's treatment of patients in any setting. *See, e.g.,* NRS 630.160; NRS 630.020; NRS 639.0124; NRS 639.0709; NRS 441A.200.

29. It is physicians, under the license issued them by their respective medical licensing boards, who are granted the authority and privilege to practice medicine in Nevada. *See, e.g.,* NRS 630.160.

30. The Nevada Legislature has limited the BOP's authority to adopting regulations governing the practice of pharmacy, the sale and dispensing of drugs, and those pertaining to the practice of pharmacy that are necessary for the protection of the public. *See* NRS 639.070. However, the regulations adopted by the BOP cannot be inconsistent with Nevada law. *See* NRS 639.070(1)(a).

31. Nevada statute expressly defines the "practice of medicine" to mean "**to diagnose, treat, correct, prevent, <u>or prescribe</u>** for any human disease, ailment, injury, infirmity, deformity or other condition, physical or mental, by any means or instrumentality . . . . " *See* NRS 630.0209(1) (emphasis added).

32. The practice of medicine in Nevada is not limited to the hospital setting—it occurs no matter where the physician meets the patient. *See* NRS 630.049.

33. The ability of a physician, specifically a primary care physician, to diagnose and treat his or her patient is essential and fundamental to the practice of medicine, and a primary care physician may be the one able to most accurately recognize an immediate and significant

decline in a patient's health, and suggest therapeutic intervention when it is needed most. Such a decline could be the beginning of a cascade of events that could ultimately result in the patient's death. And with COVID-19, if the therapeutic window is missed, there is likely no second chance. *See* **Exhibit "7"**.

34. Not only did the BOP overstep its authority by enacting the Emergency Regulation, each of its stated concerns supporting the Emergency Regulation was, or has been, addressed and/or resolved at the federal level.

35. Specifically: (1) WHO has issued several approved ICD-10 codes for COVID-19; (2) chloroquine and hydroxychloroquine were already drugs approved for use by the FDA, which meant that the FDA authorized their prescription by physicians for both approved and off-label uses; (3) the FDA then provided further assurances of these drugs by issuing an Emergency Use Authorization ("EUA") that provided emergency approval of these drugs for use in the treatment of COVID-19; (4) the President of the United States then acquired additional supplies of these drugs; (5) the Federal Strategic National Stockpile ("SNS") authorized the distribution of its own supply of these drugs to supplement each state's respective stockpile; and (6) drug manufacturers who regularly manufactured these drugs have already re-stocked, ramped-up production, and begun donating their supplies.

36. On March 25, 2020, 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.[6] *See* **Exhibit "8"**.

37. As part of ICD's clinical coding of COVID-19, further delineation was made between confirmed cases and suspected or probable cases, whereby additional codes are to be

---

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

provided by physicians for a patient's respective symptoms, and also those codes necessary for reporting intervention, procedure, isolation, and laboratory examination. *Id*.

38. The distinction of codes encourages the reporting of not just confirmed, but suspected, probable, and negative cases, and guidance was even provided on when it is appropriate to test.[7]

39. Each of these instances pertain specifically to a medical determination made by a healthcare provider, on an individual basis for each patient.

40. On March 27, 2020, pursuant to Section 564(b)(1)(C) of the Federal Food, Drug and Cosmetic Act ("Act") (*see* 21 U.S.C. § 360bbb-3), the Secretary of HHS declared that "circumstances exist justifying the authorization of emergency use of drugs and biologics during the COVID-19 outbreak…." *See* **Exhibit "9"**.

41. As such, on March 28, 2020, RADM Denise Hinton, Chief Scientist of the FDA, declared that after "[h]aving reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I of [the EUA], …that chloroquine phosphate and hydroxychloroquine sulfate (as described in the Scope of Authorization of this Letter (Section II) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness," and "these products are authorized for the treatment of 2019 coronavirus disease (COVID-19) when administered by a HCP [health care provider] pursuant to a valid prescription of a licensed practitioner as described in the Scope of Authorization (section II) of this letter." *See* **Exhibit "10"** (the "EUA").

42. As part of the EUA's 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. *Id*.

---

[7] *Id*.

43. Specifically, "FDA is issuing this EUA to facilitate the availability of chloroquine phosphate and hydroxychloroquine sulfate during the COVID-19 pandemic to treat patients for whom a clinical trial is not available, or participation is not feasible." *Id*.

44. Prior to the EUA, chloroquine phosphate and hydroxychloroquine sulfate were already drugs approved for use by the FDA[8], and were already being used by physicians in the treatment of COVID-19[9].

45. The authorization provided under the EUA is separate and distinct from the authorization provided to a licensed practitioner by the FDA to prescribe an FDA-approved drug to its patient for an off-label use in the treatment of an illness or disease.

46. "From the FDA perspective, once the FDA approves a drug, healthcare providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient…. In situations like these, you and your healthcare provider may talk about using an approved drug for an unapproved use to treat your disease or medical condition."[10]

47. 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.[11] The United States 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); *see also 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).

---

[8] https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=BasicSearch.process
[9] https://clinicaltrials.gov/ct2/results?cond=COVID-19
[10] https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label
[11] https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label/

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

49. The Nevada Legislature has even declared that "all functions of emergency management in this state be coordinated to the maximum extent with the comparable functions of the Federal Government, including its various departments and agencies…." *See* NRS 414.020(2).

50. And, as part of the statutory mandate to adopt regulations governing the control of communicable diseases, the State Board of Health has specifically adopted the recommendations, guidelines, and publications of various federal agencies as set forth in NAC 441A.200, which provide recommended guidance for the "investigation, prevention, suppression and control of communicable diseases," of which district health officers and the CMO are required to implement. *See* NRS 441A.120; NAC 441A.200; *see also* NRS 441A.050.

51. In addition to the FDA's authorization of off-label use of approved drugs, 21 U.S.C. § 360bbb-3 provides that the Secretary of the HHS may authorize, during the effective period of an emergency use declaration, the emergency unapproved use of an approved product.

52. "Hydroxychloroquine sulfate and [medical grade chloroquine phosphate] are oral prescription drugs approved to treat malaria and other diseases. Although there are no currently approved treatments for COVID-19, both drugs have shown activity in laboratory studies against coronaviruses, including SARS-CoV-2 (the virus that causes COVID-19)"... and "[a]necdotal reports suggest that these drugs may offer some benefit in the treatment of hospitalized COVID-19 patients."[12]

53. There is an adequate supply of these drugs. For example: "Sandoz and Bayer are the latest companies stepping up to strengthen the U.S. response to COVID-19, and [the Assistant Secretary for Preparedness and Response] is working with additional companies

[12] https://www.hhs.gov/about/news/2020/03/29/hhs-accepts-donations-of-medicine-to-strategic-national-stockpile-as-possible-treatments-for-covid-19-patients.html

willing to donate doses of these drugs…. Use of the donated medication is expected to help ease supply pressures for the drug, and the FDA is also working with manufacturers of these products to increase production to ensure these drugs also remain available for patients dependent on them for treatment of malaria, lupus, and rheumatoid arthritis."[13]

54. On March 29, 2020, the HHS accepted 30 million doses of hydroxychloroquine sulfate donated by Sandoz, and one million doses of medical grade chloroquine phosphate donated by Bayer Pharmaceuticals, for possible use in treating patients hospitalized with COVID-19 or for use in clinical trials.[14]

55. Further, the Federal Emergency Management Authority ("FEMA") stated that it would make available and would distribute provisions of chloroquine phosphate and hydroxychloroquine sulfate from the SNS to state healthcare systems and healthcare providers, to be used in accordance with the Federal Factsheets provided.[15]

56. Chapter 441A of NRS and NAC mandate that persons of this State have access to testing and treatment and, if a physician deems it appropriate for that individual, that physician must be permitted and able to prescribe hydroxychloroquine and chloroquine.

57. As a result of the March 23, 2020, adoption of the Emergency Regulation, not only are pharmacists prohibited from filling and dispensing chloroquine and/or hydroxychloroquine to patients with valid prescriptions, but hospitals are refusing to admit, test, and/or treat symptomatic individuals and individuals who have tested positive for COVID-19 if their symptoms are not yet severe enough to require hospitalization.

58. Not only has the BOP purported to practice medicine and adopted a regulation that restricts access to a potential life-saving treatment, but it has done so in the midst of a global crisis and healthcare pandemic, to the detriment of Nevada citizens. This unlawful action must be corrected.

---

[13] *Id.*
[14] *Id*.
[15] *Id*.

CLAIM ONE
(Declaratory Relief)

59. The allegations above are incorporated as if fully set forth here.

60. A justiciable controversy exists that warrants declaratory judgment pursuant to Nevada's Uniform Declaratory Judgments Act, under NRS 30.010 to 30.160 inclusive because the Emergency Regulation interferes with and impairs Plaintiff's rights, status, and other legal relations.

61. NRS 233B.110 provides that the validity or applicability of any regulation may be determined in a proceeding for a declaratory judgment when it is alleged that the regulation interferes with or impairs legal rights or privileges.

62. NRS 441A.200 creates three statutory rights: (1) the right of an individual to receive approved treatment for a communicable disease; (2) the right of an individual to receive approved treatment from any physician, clinic, or person of his or her choice; and (3) the right of a physician to provide treatment to an individual with a communicable disease. *See* NRS 441A.200.

63. The Emergency Regulation violates the rights of Plaintiffs and Nevada citizens by: (1) restricting the right of an individual to receive approved treatment for a communicable disease; (2) restricting the right of an individual to receive approved treatment from the physician, clinic, or person of his or her choice; (3) restricting the right of a physician to provide treatment to an individual with a communicable disease outside of a hospital setting; (4) empowering and authorizing pharmacists to interfere with the right of a person to receive approved treatment for a communicable diseases from their physician of their choice; (5) empowering and authorizing pharmacists to interfere with the right of a physician to provide approved treatment for a communicable disease; (6) restricting a physician's authority and privilege to practice medicine; and (7) impermissibly restricting where the practice of medicine may take place.

64. Licensed physicians in Nevada have the right to provide—and the people of this State have the right to receive—approved treatments for COVID-19, regardless of whether a

person has been hospitalized. No person—not Governor Sisolak, not the BOP, and not the CMO—is empowered or authorized interfere with these rights.

65. The Emergency Regulation, as adopted, interferes with and impairs the legal rights and privileges of Plaintiffs and patients in Nevada, and more particularly it:

a) Unlawfully restricts Plaintiffs' privilege and authority to practice medicine;

b) Unlawfully restricts Plaintiffs' right to provide approved treatment to individuals with a communicable disease;

c) Unlawfully restricts Plaintiffs' privilege and authority to practice medicine at any place where the patient is located;

d) Unlawfully restricts a patent's right to receive approved treatment for a communicable disease from the physician, clinic, or person of his or her choice; and,

e) Unlawfully empowers and authorizes pharmacists to interfere with the rights of a patient testing positive for COVID-19 to receive hydroxychloroquine and/or chloroquine pursuant to a valid prescription.

66. The Emergency Regulation, as adopted, exceeds the statutory authority of Defendants and results in the unauthorized practice of medicine, specifically:

a) NRS 630.020 does not authorize Defendants to practice medicine and adoption of the Emergency Regulation by Defendants constitutes the practice of medicine and a violation of this statutory provision; and

b) NRS 639.070 does not authorize Defendants to adopt regulations that are inconsistent with the laws of this State, nor does it authorize Defendants to adopt regulations that constitute the practice of medicine.

67. The Emergency Regulation was not narrowly tailored in any way to carry out any legitimate government interest at stake and, as adopted, violates numerous constitutional and statutory provisions, specifically:

a) The Emergency Regulation is preempted by federal law and impermissibly restricts the issuance, filling, and dispensing of an FDA-approved drug issued

pursuant to a valid prescription;

b) The Emergency Regulation violates Plaintiffs' and their patients' constitutional rights to privacy—the right of an individuals to protect their health by making autonomous decisions about medical treatment with a physician of their choice is a fundamental right that cannot be abridged or dictated by Defendants and no justification was provided by the BOP that would warrant such an intrusion, not even a declaration by the Governor of a state of emergency;

c) The Emergency Regulation violates Plaintiffs' and their patients' constitutional right to equal protection under Amendment XIV, Section 1, of the U.S. Constitution—particularly because the Emergency Regulation (and its subsequent waiver) authorizes hospital physicians to issue, fill, and dispense a drug, while prohibiting non-hospital physicians from doing so; and,

d) The Emergency Regulation violates Plaintiff's and their patient's due process right under Article I, Section 8, of the Nevada Constitution, and Amendment V, Section 1, and Amendment XIV, Section 1, of the U.S. Constitution—in particular because it restricts the practice of medicine under a valid medical license without due process.

68. NRS 233B.0617 provides that no regulation is valid unless adopted in substantial compliance with the procedural requirements of NRS 233B.060 to 233B.0617, inclusive (the "Nevada Administrative Procedure Act"). The Emergency Regulation was not adopted in substantial compliance with the procedural requirements of the Nevada Administrative Procedure Act, for example:

a) Proper notice of the proposed Emergency Regulation, or the meeting adopting it, was not given (*see* NRS 233B.060; NRS 233B.0613);

b) No evidentiary support for the purported emergency supporting the Emergency Regulation existed (*see* NRS 233B.0613);

c) The Emergency Regulation was made impermissibly effective for a period of longer than 120 days (*see* NRS 233B.0613(4)); and,

d) No explanatory statement describing the Emergency Regulation (or the reason for it) was filed with the Legislative Counsel within 5 working days of the emergency meeting and adoption of the Emergency Regulation, in violation of NRS 233B.0658.

69. NRS 241.036 provides that any action of a public body taken in violation of Nevada's open meeting law is void. The Emergency Regulation was adopted in violation of Chapter 241 of NRS ("Nevada's Open Meeting Law"). For example:

a) Defendants held a closed emergency meeting and did not permitting all persons to attend (*see* NRS 241.020);

b) Adoption of the Emergency Regulation contravened Plaintiffs' right to receive notice of the meeting, to attend the meeting, and to provide general comments on the Agenda items (*see* NRS 241.020);

c) No valid emergency existed and no sufficient supporting material was presented to determine that an emergency actually existed (*see* NRS 241.020(3));

d) No valid exception to Nevada's Open Meeting Law existed (*see* NRS 241.030);

70. Plaintiff requests the Court issue a declaratory judgment finding that the Emergency Regulation:

a) Impermissibly interferes with and impairs the rights of Plaintiffs to practice medicine and the corresponding rights of Nevada patients;

b) Is invalid because exceeds the Defendants' statutory and regulatory authority;

c) Is invalid because it violates the Nevada Constitution;

d) Is invalid because it violates the United States Constitution;

e) Is invalid because it was adopted in violation of the Nevada Administrative Procedure Act;

f) Is void because it was adopted in violation of Nevada's Open Meeting Law; and

g) Is pre-empted by federal law.

///

CLAIM TWO
(Injunctive Relief)

71. The allegations above are incorporated as if fully set forth here.

72. A justiciable controversy exists that warrants injunctive relief pursuant to NRS 33.010 because further implementation and enforcement of the Emergency Regulation by Defendants during this litigation will produce great and irreparable injury to Plaintiffs and Nevada citizens in violation or the rights set forth herein, rendering any judgment ineffectual.

73. NRS 33.010 provides that an injunction may be granted in cases: (1) when it shall appear by the complaint that plaintiff is entitled to the relief demanded, and that such relief or any part thereof consists in restraining the commission or continuance of the act complained of, either for a limited time or perpetually; (2) when it shall appear by the complaint that the commission or continuance of some act, during the litigation, would produce great or irreparable injury to the plaintiff; and/or (3) when it shall appear, during the litigation, that the defendant is doing or threatens some act in violating of the plaintiff's rights respecting the subject of the action, and tending to render the judgment ineffectual.

74. Therefore, the Court should grant a temporary restraining order, and ultimately preliminary and permanent injunctions, prohibiting further implementation and enforcement of the Emergency Regulation.

WHEREFORE, Plaintiffs request the following relief, and respectfully pray this Court to:

A. Assume jurisdiction over this action;

B. Issue a declaration that the Emergency Regulation:

1. Impermissibly interferes with and impairs the rights of Plaintiffs to practice medicine and the corresponding rights of Nevada patients;
2. Is invalid because exceeds the Defendants' statutory and regulatory authority;
3. Is invalid because it was adopted in violation of the Nevada Administrative Procedure Act;
4. Is void because it was adopted in violation of Nevada's Open Meeting Law;

5. Is invalid because it violates the Nevada Constitution;
6. Is invalid because it violates the United States Constitution; and
7. Is pre-empted by federal law.

C. Enter judgment against Defendants and in favor of Plaintiff on all claims asserted in this Complaint;

D. Grant a temporary restraining order, preliminary injunction, and/or permanent injunction restraining Defendants, their agents, employees, and successors in office or position from further implementing and enforcing the Emergency Regulation;

E. Award to Plaintiffs all attorney's fees and costs permitted under Nevada law; and,

F. Grant any other relief the Court deems just and proper.

AFFIRMATION

The undersigned does hereby affirm that this document does not contain the social security number of any person

DATED: April 21, 2020.

JOEY GILBERT LAW

By: */s Joseph S. Gilbert*
Joseph S. Gilbert, Esq.
Roger O'Donnell, Esq
Attorneys for Plaintiffs/Petitioners

LIST OF EXHIBITS

EXHIBIT NUMBER	DESCRIPTION	# of PAGES (incl. Cover Sheet)
1	March 11, 2020, Letter from CDC	5
2	Governor's Declaration of Emergency, March 12, 2020	4
3	Nevada State Board of Pharmacy, Declaration of Emergency, March 23, 2020	3
4	Nevada State Board of Pharmacy, Agenda, March 23, 2020	3
5	March 23, 2020, email re: Emergency Board Meeting	2
6	Emergency Regulation, effective 3-23-2020, expires 9-23-2020	7
7	NOMA Statement of Bruce Fong, DO	4
8	WHO COVID-19 coding	5
9	Emergency Use Authorization Declaration	3
10	FDA Emergency Use Authorization	9

EXHIBIT 1

EXHIBIT 1

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

Date: March 11, 2020

To: State Health Officers

From: Sherri Berger, Chief Operating Officer
Centers for Disease Control and Prevention (CDC)

Subject: Immediate Plans for Coronavirus Disease 2019 Supplemental Funding to Jurisdictions

On Friday, March 6, 2020, the President signed the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020. The supplemental contains more than $8 billion, of which $950 million is specifically directed for grants or cooperative agreements to states, localities, territories, tribes, tribal organizations, or health service providers to tribes to carry out surveillance, epidemiology, laboratory capacity, infection control, mitigation, communications, and other preparedness and response activities. The purpose of this letter is to provide you with early guidance so you can begin drafting your spend plan as quickly as possible.

CDC is committed to helping ensure that jurisdictions have adequate resources for an appropriate response. The continued support for and expansion of critical public health activities at the state, local, tribal, and territorial levels are essential to meet the needs in this quickly evolving response. CDC will support accelerated planning and operational readiness for the Coronavirus Disease 2019 (COVID-19) preparedness and response, as well as develop tools and strategies, provide technical assistance and program support, and ensure ongoing communication and coordination among federal, state, local, tribal, and territorial public health agencies and partners throughout the response.

CDC is working within the Administration to access funds as quickly as possible for initial jurisdiction awards, as described below. CDC's plan is to use the "Cooperative Agreement for Emergency Response: Public Health Crisis Response" (CDC-RFA-TP18-1802)[1] to provide more than $560 million to CDC's current 62 Public Health Emergency Preparedness (PHEP) recipients, allocating 90 percent of your fiscal year (FY) 2019 award[2], plus the three additional jurisdictions with current awards through the above cooperative agreement. Congressional direction also states CDC must allocate these initial awards within 30 days of the bill's passage and jurisdictions must submit their spend plan to CDC within 45 days of the bill's passage.

---

[1] This cooperative agreement's recipients include all PHEP jurisdictions plus: Philadelphia, Houston, and the Cherokee nation.

[2] See attachment A for a list of FY 2019 awards.

Spend plans must be submitted to CDC with signatures from your preparedness director, laboratory director, and state epidemiologist (or their designees). The spend plan must include a plan for implementation and scale-up of laboratory testing and data collection to enable identification and tracking of COVID cases, and a plan for immediate implementation of real-time reporting. The spend plan should describe the use of award funds for up to twelve months from the date of award and may include reimbursement of allowable costs incurred beginning on January 20, 2020.

Funds from this initial award will be made available for a variety of activities including, but not limited to:

- Epidemiology
- Surveillance
- Laboratory
- Case identification
- Public health management and risk assessment of travelers and other persons with potential COVID-19 exposures and confirmed diagnoses
- Travelers health
- Data management
- Equipment, supplies, and shipping
- Infection control
- Surge staffing
- Distribution and use of medical material
- Emergency operations and coordination
- Risk communication

On Monday, March 16, 2020, CDC will make guidance available for jurisdictions to use the funding. Your jurisdiction's project officer at CDC for the "Cooperative Agreement for Emergency Response: Public Health Crisis Response" will be the main point of contact.

We look forward to working with you to make this initial award process as efficient as possible.

Sincerely,

Sherri Berger, MSPH
Chief Operating Officer, CDC

Enclosure

FY 2019 Public Health Emergency Preparedness Grant Award Amounts

Recipient	Fiscal Year 2019 Awards	90% of Total Award
Alabama	$9,054,221	$8,148,798.90
Alaska	$5,447,600	$4,902,840.00
American Samoa	$411,385	$370,246.50
Arizona	$12,446,524	$11,201,871.60
Arkansas	$6,894,830	$6,205,347.00
California	$41,896,344	$37,706,709.60
Colorado	$10,368,137	$9,331,323.30
Connecticut	$7,842,523	$7,058,270.70
Delaware	$5,075,000	$4,567,500.00
District of Columbia	$6,831,442	$6,148,297.80
Florida	$30,329,229	$27,296,306.10
Georgia	$16,429,205	$14,786,284.50
Guam	$532,702	$479,431.80
Hawaii	$5,075,000	$4,567,500.00
Idaho	$5,075,000	$4,567,500.00
Illinois	$16,296,979	$14,667,281.10
Indiana	$11,527,724	$10,374,951.60
Iowa	$7,053,143	$6,347,828.70
Kansas	$6,600,607	$5,940,546.30
Kentucky	$8,293,772	$7,464,394.80
Louisiana	$8,672,294	$7,805,064.60
Maine	$5,075,000	$4,567,500.00
Marshall Islands	$408,616	$367,754.40
Maryland	$11,399,141	$10,259,226.90
Massachusetts	$12,943,677	$11,649,309.30
Michigan	$16,185,611	$14,567,049.90
Micronesia	$467,114	$420,402.60
Minnesota	$11,164,582	$10,048,123.80
Mississippi	$6,527,773	$5,874,995.70
Missouri	$10,987,397	$9,888,657.30
Montana	$5,075,000	$4,567,500.00
Nebraska	$5,329,627	$4,796,664.30
Nevada	$7,258,599	$6,532,739.10
New Hampshire	$5,447,600	$4,902,840.00
New Jersey	$15,400,178	$13,860,160.20
New Mexico	$6,638,183	$5,974,364.70
New York	$18,544,755	$16,690,279.50
North Carolina	$15,356,128	$13,820,515.20
North Dakota	$5,075,000	$4,567,500.00
Northern Marianas	$410,851	$369,765.90
Ohio	$17,356,642	$15,620,977.80
Oklahoma	$7,693,590	$6,924,231.00

Oregon	$8,109,807	$7,298,826.30
Palau	$374,215	$336,793.50
Pennsylvania	$18,782,276	$16,904,048.40
Puerto Rico	$6,522,620	$5,870,358.00
Rhode Island	$5,447,600	$4,902,840.00
South Carolina	$9,917,925	$8,926,132.50
South Dakota	$5,075,000	$4,567,500.00
Tennessee	$11,198,104	$10,078,293.60
Texas	$39,141,025	$35,226,922.50
Utah	$7,157,125	$6,441,412.50
Vermont	$5,447,600	$4,902,840.00
Virgin Islands	$465,667	$419,100.30
Virginia	$14,857,347	$13,371,612.30
Washington	$12,756,443	$11,480,798.70
West Virginia	$5,556,448	$5,000,803.20
Wisconsin	$11,333,547	$10,200,192.30
Wyoming	$5,075,000	$4,567,500.00
New York City	$18,790,865	$16,911,778.50
Los Angeles	$20,235,667	$18,212,100.30
Chicago	$9,715,194	$8,743,674.60
Total	**$622,858,200**	**$560,572,380.00**

EXHIBIT 2

EXHIBIT 2

State of Nevada

Executive Department

DECLARATION OF EMERGENCY

WHEREAS, Nevada Revised Statutes, Chapter 414, authorizes the Governor to issue a proclamation declaring a state of emergency when a natural emergency or disaster of major proportions has occurred within this state, and the assistance of state agencies is needed to supplement the efforts and capabilities of political subdivisions to save lives, protect property, and protect the health and safety of persons in this state, particularly through a coordinated response; and

WHEREAS, the Centers of Disease Control and Prevention (CDC) are responding to an outbreak of a respiratory illness that has since been confirmed in numerous countries, including the United States; and

WHEREAS, the respiratory disease has been named coronavirus disease 2019, abbreviated as COVID-19; and

WHEREAS, the World Health Organization declared the COVID-19 outbreak a pandemic; and

WHEREAS, the State of Nevada has been coordinating with the federal government, as well as local health authorities, health care facilities, and providers of health care to prepare for, and identify possible cases of COVID-19 in the State of Nevada; and

WHEREAS, the nearby states of California, Washington, Oregon, Arizona, and Utah have been impacted by COVID-19 and have already declared a state of emergency; and

WHEREAS, there are multiple confirmed and presumptive cases of COVID-19 in the State of Nevada; and

WHEREAS, the Nevada Department of Health and Human Services is working with local health authorities to identify any other potential cases of COVID-19 in the State; and

WHEREAS, the Chief Medical Officer has reported that a public health emergency exists in the State; and

WHEREAS, the Governor has determined that the State of Nevada is experiencing events that require a coordinated response for the health and safety of the public; and

WHEREAS, Article 5, Section 1 of the Nevada Constitution provides: "The supreme executive power of this State, shall be vested in a Chief Magistrate who shall be Governor of the State of Nevada."

NOW THEREFORE, I, Steve Sisolak, Governor of the State of Nevada, pursuant to the authority vested in me by the Constitution and laws of the State of Nevada, hereby declare an emergency and direct all state agencies to supplement the efforts of all impacted and threatened counties to save lives, protect property, and protect the health and safety of persons in this state. Under my authority, I will perform and exercise such other functions, powers, and duties as are necessary to promote and secure the safety and protection of the civilian population.

IT IS HEREBY ORDERED THAT:

SECTION 1: The State Emergency Operations Center be activated to coordinate a response to minimize the impacts, and prevent the further transmission of, COVID-19 to persons in this state; and

SECTION 2: An Emergency Team be established to coordinate the response to COVID-19; and

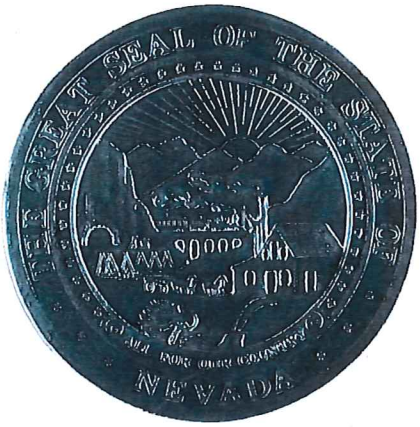
SECTION 3: The Emergency Team will consult with the Nevada Tribal Emergency Coordinating Council to ensure a coordinated response to COVID-19; and

SECTION 4: The Administrator of the State Purchasing Division, pursuant to Nevada Administrative Code 333.114, to the extent necessary, may authorize an emergency purchase for any amount, or provide the using agency with written authorization for the emergency purchase, including, without limitation, a description of the justification for authorizing the emergency purchase, and suspend the standard procurement process to allow the purchase of food, supplies, services, and equipment; and

SECTION 5: Law enforcement, including the Nevada Attorney General, will diligently monitor and investigate a coordinated increase in prices for goods or services, and particularly goods or services necessary for the health and safety of the public or that result in economic hardships, making false representations, "bait and switch" practices, failure to disclose material facts in conjunction with the sale of goods or services, or the use of coercion, duress, or intimidation in a transaction in violation of consumer protection laws; and

SECTION 6: Law enforcement, including the Nevada Attorney General, will diligently ensure that persons or corporations act and perform in a lawful manner which ensures the safety, health, comfort, or repose of any considerable number of the public, do not offend public decency, or in any way renders a considerable number of persons insecure in life or the use of property.

SECTION 7: This declaration will remain in effect until the Chief Medical Officer notifies the Governor that the health event has been abated and the Governor issues an order terminating the emergency.



IN WITNESS WHEREOF, I have hereunto set my hand and caused the Great Seal of the State of Nevada to be affixed at the State Capitol in Carson City, this 12th day of March, in the year two thousand twenty.

Governor of the State of Nevada

Barbara K. Cegavske

Secretary of State

Deputy Secretary of State

EXHIBIT 3

EXHIBIT 3

Nevada State Board of Pharmacy

985 Damonte Ranch Parkway, Suite 206 • Reno, NV 89521
(775) 850-1440 • FAX (775) 850-1444
E-mail: dwuest@pharmacy.nv.gov • Web Page: bop.nv.gov

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.

EXHIBIT 4

EXHIBIT 4

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206, Reno, Nevada 89521

(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444

• Web Page: bop nv.gov

Date Posted: March 23, 2020

AGENDA

◈ PUBLIC NOTICE ◈

The Nevada State Board of Pharmacy will conduct an emergency meeting pursuant to NRS 241.020 (3) via teleconference beginning on Monday March 23, 2020 at 3:30 pm.

Public comment may be submitted through pharmacy@pharmacy.nv.gov or by telephonic appearance.

Teleconference Line
1-669-900-6833
Meeting ID: 113 761 560

Please Note:

In regulating the practice of pharmacy, the Nevada State Board of Pharmacy has a duty to carry out and enforce the provisions of Nevada law to protect the health, safety and welfare of the public.

The Nevada State Board of Pharmacy may address agenda items out of sequence to accommodate persons appearing before the Board or to aid in the efficiency or effectiveness of the meeting;

The Nevada State Board of Pharmacy may combine two or more agenda items for consideration; and

The Nevada State Board of Pharmacy may remove an item from the agenda or delay discussion relating to an item on the agenda at any time.

Public comment is welcomed by the Board, but will be heard during the public comment item and may be limited to five minutes per person. The president may allow additional time to a given speaker as time allows and in his or her sole discretion.

1. Call to Order and Roll Call – Establishment of Quorum

2. Public Comment: No action may be taken upon a matter raised under this item of the agenda until the matter itself has been specifically included on a future agenda as an item. (NRS 241.020)

3. Discussion and Possible Action on Adoption of Emergency Regulation pursuant to NRS 233B.0613 to Restrict the Prescribing and Dispensing of Chloroquine or Hydroxychloroquine in Response to COVID-19. **(FOR POSSIBLE ACTION)**

4. Public Comment: No action may be taken upon a matter raised under this item of the agenda until the matter itself has been specifically included on a future agenda as an item. (NRS 241.020)

5. Adjournment

Note: We are pleased to make reasonable accommodations for members of the public who are disabled and wish to attend the meeting. If special arrangements for the meeting are necessary, please notify the Nevada State Board of Pharmacy, 985 Damonte Ranch Parkway, Suite 206, Reno, NV, 89521, or call Kristopher Mangosing at (775) 850-1440, as soon as possible.

Supporting materials or additional information regarding the meeting may be obtained from Kristopher Mangosing at (775) 850-1440, email kmangosing@pharmacy.nv.gov or 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada, 89521.

This notice has been posted at www.notice.nv.gov and **bop.nv.gov** pursuant to Governor's Declaration of Emergency Directive 006.

F I L E D
Electronically
CV20-00653
2020-04-21 04:10:27 PM
Jacqueline Bryant
Clerk of the Court
Transaction # 7844682 : yviloria

EXHIBIT 5

EXHIBIT 5

Mon 3/23/2020 2:59 PM

Kristopher Mangosing

March 23, 2020 Emergency Board Meeting

To David Wuest; Yenh Long; Brett Kandt; Shirley Hunting

Bcc 'gener@ssprx.com'; 'agoalie@nvbell.net'; 'jademjacobo@gmail.com'; 'hpark1@roseman.edu'; 'krystal.freitas02@gmail.com'; 'dickt007@gmail.com'; 'rolfz2@charter.net'

Message | April 2020 Emergency Meeting Agenda .pdf (263 KB) | Emergency Regulation - Chloroquine and Hydroxychloroquine COVID-19.pdf (65 KB)

Dear Board Members,

Attached is the Agenda and proposed language for the March 23, 2020 Emergency Board Meeting.

The call in information is:

Teleconference Line: +1 669 900 6833
Meeting ID: 113 761 560

Sincerely,

Kristopher Mangosing
Assistant Board Coordinator
Nevada State Board of Pharmacy

F I L E D
Electronically
CV20-00653
2020-04-21 04:10:27 PM
Jacqueline Bryant
Clerk of the Court
Transaction # 7844682 : yviloria

EXHIBIT 6

EXHIBIT 6

SECRETARY OF STATE
FILING DATA

FILED.NV.SOS
2020 MAR 24 PM12:41

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

985 Damonte Ranch Parkway, Suite 206 • Reno, NV 89521
(775) 850-1440 • FAX (775) 850-1444
E-mail: dwuest@pharmacy.nv.gov • Web Page: bop.nv.gov

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.

EXHIBIT 7

EXHIBIT 7

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-W6BjCNgJVTiIX0U/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

EXHIBIT 8

EXHIBIT 8

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 9

EXHIBIT 9

delegated herein prior to the effective date of this delegation.

Robert McGowan,

Chief of Staff, CDC.

[FR Doc. 2020–06471 Filed 3–26–20; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Ryan White HIV/AIDS Treatment Extension Act of 2009: Update to the List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May Be Exposed To Include Coronavirus Disease 2019 (COVID–19), the Disease Caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS–CoV–2)

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH), of the Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is adding coronavirus disease 2019 (COVID–19), the disease caused by severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2), to the *List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May be Exposed.* The list and companion guidelines are published by NIOSH pursuant to the Ryan White HIV/AIDS Treatment Extension Act of 2009. NIOSH encourages medical facilities to review the agency's guidelines describing the manner in which medical facilities should make determinations on whether an emergency response employee was exposed to COVID–19, the disease caused by SARS–CoV–2.

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Office of the Director, NIOSH; 1090 Tusculum Avenue, MS:C–48, Cincinnati, OH 45226; telephone (855) 818–1629 (this is a toll-free number); email *NIOSHregs@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Statutory Authority

The Ryan White Comprehensive AIDS Resources Emergency (CARE) Act of 1990 (Pub. L. 101–381) was reauthorized in 1996, 2000, 2006, and 2009. The most recent reauthorization, the Ryan White HIV/AIDS Treatment Extension Act of 2009 (Pub. L. 111–87), amended the Public Health Service Act (PHS Act, 42 U.S.C. 201–300ii) and, pursuant to Section 2695, requires the HHS Secretary to establish the following: A list of potentially life-threatening infectious diseases, including emerging infectious diseases, to which emergency response employees (ERE) may be exposed while responding to emergencies; guidelines describing circumstances in which EREs may be exposed to these diseases, taking into account the conditions under which emergency response is provided; and guidelines describing the manner in which medical facilities should make determinations about exposures to EREs.

In a **Federal Register** notice published on July 14, 2010, the HHS Secretary delegated this responsibility to the CDC Director.[1] The CDC Director further assigned the responsibility to the NIOSH Director and formally re-delegated the authority to develop the list and guidelines to NIOSH on August 27, 2018.[2]

Addition of COVID–19, the Disease Caused by the Virus SARS–COV–2, to the List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May Be Exposed

The list of potentially life-threatening infectious diseases maintained by NIOSH is available in a **Federal Register** notice published on November 2, 2011 (76 FR 67736), available on the NIOSH website at *https://www.cdc.gov/niosh/topics/ryanwhite/default.html.* With this notice the NIOSH *List of Potentially Life-Threatening Infectious Diseases to Which Emergency Response Employees May Be Exposed* is updated by the addition of the following:

C. Potentially Life-Threatening Infectious Diseases: Routinely Transmitted Through Aerosolized Droplet Means

■ COVID–19 (the disease caused by the virus SARS–CoV–2)

COVID–19, the disease caused by the virus SARS–CoV–2, is being added to the existing list. COVID–19, the disease caused by the virus SARS–CoV–2, is a potentially life-threatening emerging infectious disease that is thought to be spread primarily by respiratory droplets generated by an infectious person through events such as coughing or sneezing (*https://www.cdc.gov/coronavirus/2019-ncov/index.html*).

EREs may be exposed to COVID–19, the disease caused by the virus SARS-CoV–2, by a victim of an emergency who may be infected with SARS–CoV–2 while attending to, treating, assisting, or transporting the victim to a medical facility. Medical facilities should review the NIOSH guidelines describing the manner in which medical facilities should make determinations about exposures to life-threatening infectious diseases, including COVID–19, available on the NIOSH website at *https://www.cdc.gov/niosh/topics/ryanwhite/default.html.*

John J. Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.

[FR Doc. 2020–06458 Filed 3–26–20; 8:45 am]

BILLING CODE 4163–18–P

[1] 75 FR 40842.

[2] 83 FR 50379 (October 4, 2018).

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Emergency Use Authorization Declaration

ACTION: Notice of Emergency Use Authorization Declaration.

SUMMARY: The Secretary of Health and Human Services (HHS) is issuing this notice pursuant to section 564 of the Federal Food, Drug, and Cosmetic (FD&C) Act. On February 4, 2020, the Secretary determined pursuant to his authority under section 564 of the FD&C Act that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019–nCoV). The virus is now named SARS–CoV–2, which causes the illness COVID–19. On the basis of this determination, he also declared that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

DATES: The determination was effective February 4, 2020, and this declaration is effective March 24, 2020.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, M.D., MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human

Services, 200 Independence Avenue SW, Washington, DC 20201, Telephone (202) 205–2882 (this is not a toll free number).

SUPPLEMENTARY INFORMATION:

I. Background

Under section 564 of the FD&C Act, 21 U.S.C. 360bbb–3, the Commissioner of the Food and Drug Administration (FDA), acting under delegated authority from the Secretary of HHS, may issue an Emergency Use Authorization (EUA) authorizing (1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or (2) an unapproved use of an approved drug, approved or cleared device, or licensed biological product. Before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of four determinations: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a, chemical, biological, radiological, or nuclear ("CBRN") agent or agents; (2) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F–2 of the Public Health Service (PHS) Act sufficient to affect national security or the health and security of United States citizens living abroad; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces; or (4) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.

Based on any of these four determinations, the Secretary of HHS may then declare that circumstances exist that justify the EUA, at which point the FDA Commissioner may issue an EUA if the criteria for issuance of an authorization under section 564 of the FD&C Act are met. The Office of the Assistant Secretary for Preparedness and Response, HHS, requested that the FDA, HHS, issue an EUA for certain medical devices to allow the Department to take response measures based on information currently available about the virus that causes COVID–19. The determination of a public health emergency, and the declaration that circumstances exist justifying emergency use of certain medical devices by the Secretary of HHS, as described below, enable the FDA Commissioner to issue an EUA for these devices for emergency use under section 564 of the FD&C Act.

II. Determination by the Secretary of Health and Human Services

On February 4, 2020, pursuant to section 564 of the FD&C Act, I determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves a novel (new) coronavirus (nCoV) first detected in Wuhan City, Hubei Province, China in 2019 (2019–nCoV). The virus is now named SARS–CoV–2, which causes the illness COVID–19.

III. Declaration of the Secretary of Health and Human Services

On March 24, 2020, on the basis of my determination of a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involves the novel (new) coronavirus, SARS–CoV–2, I declared that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, pursuant to section 564 of the FD&C Act, subject to the terms of any authorization issued under that section.

Notice of the EUAs issued by the FDA Commissioner pursuant to this determination and declaration will be provided promptly in the **Federal Register** as required under section 564 of the FD&C Act.

Dated: March 24, 2020.

Alex M. Azar II,

Secretary of Health and Human Services.

[FR Doc. 2020–06541 Filed 3–25–20; 4:15 pm]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Alcohol Abuse and Alcoholism; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Special Emphasis Panel NIAAA Review Subcommittee Member Conflict Review Panel.

Date: April 7, 2020.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Suite 2118, Bethesda, MD 20817 (Telephone Conference Call).

Contact Person: Philippe Marmillot, Ph.D., National Institute on Alcohol Abuse and Alcoholism, National Institutes of Health, 6700B Rockledge Drive, Bethesda, MD 20817 301–443–2861 *marmillotp@mail.nih.gov.*

Name of Committee: National Institute on Alcohol Abuse and Alcoholism Initial Review Group Epidemiology, Prevention and Behavior Research Review Subcommittee.

Date: June 8, 2020.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Alcohol Abuse and Alcoholism, 6700B Rockledge Drive, Conference Room B, Bethesda, MD 20817.

Contact Person: Anna Ghambaryan, M.D., Ph.D., Scientific Review Officer, Extramural Project Review Branch Office of Extramural Activities National Institute on Alcohol Abuse and Alcoholism, 6700b Rockledge Drive, Room 2120, MSC 6902 Bethesda, MD 20892, 301–443–4032, *anna.ghambaryan@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.271, Alcohol Research Career Development Awards for Scientists and Clinicians; 93.272, Alcohol National Research Service Awards for Research Training; 93.273, Alcohol Research Programs; 93.891, Alcohol Research Center Grants; 93.701, ARRA Related Biomedical Research

EXHIBIT 10

EXHIBIT 10

March 28, 2020

Dr. Rick Bright, Ph.D.
Director
Biomedical Advanced Research and Development Authority (BARDA)
Office of Assistant Secretary for Preparedness and Response (ASPR)
U.S. Department of Health and Human Services (HHS)
330 Independence Ave, S.W.
Room 640G
Washington, D.C. 20201

Re: Request for Emergency Use Authorization For Use of Chloroquine Phosphate or Hydroxychloroquine Sulfate Supplied From the Strategic National Stockpile for Treatment of 2019 Coronavirus Disease

Dear Dr. Bright:

This letter is in response to your request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for emergency use of oral formulations of chloroquine phosphate and hydroxychloroquine sulfate for the treatment of 2019 coronavirus disease (COVID-19) when administered by a healthcare provider (HCP)[1] pursuant to a valid prescription of a licensed practitioner as described in the Scope of Authorization (section II) of this letter. The authorized chloroquine phosphate and hydroxychloroquine sulfate are limited to product supplied from the Strategic National Stockpile (SNS) to public health authorities[2], pursuant to Section 564 of the Federal Food, Drug and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) of the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.[3,4] Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS

[1] For purposes of this EUA, the term "healthcare provider" means licensed healthcare professionals who are acting within their professional scope of practice under the public health authority of official emergency response plans when administering the authorized product.
[2] "Public health authority" means the public agency or its delegate that has legal responsibility and authority for responding to a public health emergency, based on political or geographical (e.g., city, county, tribal, State, or Federal) or functional (e.g., law enforcement or public health range) or sphere of authority to prescribe, administer, deliver, distribute, or dispense oral chloroquine phosphate and hydroxychloroquine sulfate products during public health emergencies.
[3] On February 11, 2020, the virus tentatively named 2019-nCoV was formally designated as Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). Also on February 11, 2020, the disease caused by SARS-CoV-2 was

then declared that circumstances exist justifying the authorization of emergency use of drugs and biologics during the COVID-19 outbreak, pursuant to section 564 of the Act, subject to terms of any authorization issued under that section.[5]

Chloroquine phosphate and hydroxychloroquine sulfate are not FDA-approved for treatment of COVID-19. Some versions of chloroquine phosphate are approved by FDA for other indications—for prophylaxis and acute attacks of certain strains of malaria and for the treatment of extraintestinal amebiasis, but the chloroquine phosphate drug product covered by this letter has not been approved. Several versions of hydroxychloroquine sulfate are approved by FDA for prophylaxis of and treatment of malaria, treatment of lupus erythematosus, and treatment of rheumatoid arthritis. The safety profile of these drugs has only been studied for FDA approved indications, not COVID-19.

Based upon limited in-vitro and anecdotal clinical data in case series, chloroquine phosphate and hydroxychloroquine sulfate are currently recommended for treatment of hospitalized COVID-19 patients in several countries, and a number of national guidelines report incorporating recommendations regarding use of chloroquine phosphate or hydroxychloroquine sulfate in the setting of COVID-19. FDA encourages the conduct and participation in randomized controlled clinical trials that may produce evidence concerning the effectiveness of these products in treating COVID-19. FDA is issuing this EUA to facilitate the availability of chloroquine phosphate and hydroxychloroquine sulfate during the COVID-19 pandemic to treat patients for whom a clinical trial is not available, or participation is not feasible.

Having concluded that the criteria for issuance of this authorization under 564(c) of the Act are met, I am authorizing the emergency use of chloroquine phosphate and hydroxychloroquine sulfate, as described in the Scope of Authorization section of this letter (Section II) for treatment of COVID-19 when clinical trials are not available, or participation is not feasible, subject to the terms of this authorization.

Clinical trial data results, and any information derived from clinical trials, as well as clinical trial results from studies of other investigational medical products to treat COVID-19, will continue to inform this risk benefit assessment.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of chloroquine phosphate and hydroxychloroquine sulfate for the treatment of COVID-19 when administered as described in the Scope of Authorization (section II) meet the criteria for issuance of an authorization under Section 564(c) of the Act, because:

---

formally designated as Coronavirus Disease 2019 (COVID-19). This document uses the updated names.

[4] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. February 4, 2020.*

[5] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. March 27, 2020.*

1. The SARS-CoV-2 can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that chloroquine phosphate and hydroxychloroquine sulfate may be effective in treating COVID-19, and that, when used under the conditions described in this authorization, the known and potential benefits of chloroquine phosphate and hydroxychloroquine sulfate when used to treat COVID-19 outweigh the known and potential risks of such products; and

3. There is no adequate, approved, and available alternative to the emergency use of chloroquine phosphate and hydroxychloroquine sulfate for the treatment of COVID-19.[6]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to chloroquine phosphate and hydroxychloroquine sulfate for the treatment of COVID-19, as described in this section.

Authorized Chloroquine Phosphate

I am authorizing use of the following chloroquine phosphate product that is distributed from the SNS to public health authorities for response to the COVID-19 pandemic:

- Chloroquine phosphate that is not approved by FDA for any indication.[7]

- The chloroquine phosphate must be administered by a healthcare provider pursuant to a valid prescription of a licensed practitioner.

- The chloroquine phosphate may only be used to treat adult and adolescent patients who weigh 50 kg or more and are hospitalized with COVID-19, for whom a clinical trial is not available, or participation is not feasible.[8]

The product is authorized to be accompanied by the following product-specific information pertaining to emergency use, which is required to be made available to healthcare providers and patients respectively:

---

[6] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.
[7] The authorized chloroquine phosphate may be accompanied by a package insert that is not approved labeling in the United States. Instead, refer to the authorized Fact Sheet for Healthcare Providers: Use of Chloroquine Phosphate Supplied from the Strategic National Stockpile for treatment of COVID-19 in Certain Hospitalized Patients. Note that Chloroquine phosphate's U.S. labeling that is FDA-approved for other indications, not COVID-19, does not include information regarding safety or effectiveness for COVID-19, see: https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=f398f8a9-92f3-47cb-81c2-6078806a464d
[8] For a listing of clinical trials, see: https://clinicaltrials.gov/

- Fact Sheet for Healthcare Providers: Emergency Use Authorization (EUA) of Chloroquine Phosphate Supplied from the Strategic National Stockpile for Treatment of COVID-19 in Certain Hospitalized Patients
- Fact Sheet for Patients and Parent/Caregivers: Emergency Use Authorization (EUA) of Chloroquine Phosphate For Treatment of COVID-19 in Certain Hospitalized Patients

The above described products are authorized to be administered under this EUA despite the fact that they do not meet certain requirements otherwise required by applicable federal law.

Authorized Hydroxychloroquine Sulfate

I am authorizing use of the following hydroxychloroquine sulfate product that is distributed from the SNS to public health authorities for response to the COVID-19 pandemic:

- FDA-approved hydroxychloroquine sulfate that is approved by FDA for other uses and accompanied by its FDA-approved labeling and authorized Fact Sheets.

- The hydroxychloroquine sulfate must be administered by a healthcare provider pursuant to a valid valid prescription of a licensed practitioner.

- The hydroxychloroquine sulfate may only be used to treat adult and adolescent patients who weigh 50 kg or more hospitalized with COVID-19 for whom a clinical trial is not available, or participation is not feasible.[9]

The product is authorized to be accompanied by the product information contained in hydroxychloroquine sulfate's approved package insert (for other indications)[10] and together with the following product-specific information pertaining to emergency use, which is required to be made available to healthcare providers and patients respectively:

- Fact Sheet for Healthcare Providers: Emergency Use Authorization (EUA) of Hydroxychloroquine Sulfate Supplied from the Strategic National Stockpile for Treatment of COVID-19 in Certain Hospitalized Patients
- Fact Sheet for Patients and Parent/Caregivers: Emergency Use Authorization (EUA) of Hydroxychloroquine Sulfate For Treatment of COVID-19 in Certain Hospitalized Patients

The above described product, when labeled consistently with the labeling of this product for its approved uses is authorized to be distributed to and administered under this EUA despite the fact that it does not meet certain requirements otherwise required by applicable federal law.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of chloroquine phosphate and hydroxychloroquine sulfate, when used for the treatment of SARS-CoV-2 and used consistently with the Scope of

[9] For a listing of clinical trials, see: https://clinicaltrials.gov/
[10] For hydroxychloroquine's package insert, see: https://dailymed.nlm.nih.gov/dailymed/

Authorization of this letter (Section II), outweigh the known and potential risks of these products.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that chloroquine phosphate and hydroxychloroquine sulfate may be effective for the treatment of COVID-19, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to Section 564(c)(2)(A) of the Act.

Having reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I of this letter, I have concluded that chloroquine phosphate and hydroxychloroquine sulfate (as described in the Scope of Authorization of this letter (Section II)) meets the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of these products under an EUA must be consistent with, and may not exceed, the terms of the Authorization, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), these products are authorized for the treatment of 2019 coronavirus disease (COVID-19) when administered by a HCP pursuant to a valid prescription of a licensed practitioner as described in the Scope of Authorization (section II) of this letter.

The EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under Section 564(b)(2) of the Act or when the EUA is revoked under Section 564(g) of the Act.

III. Waiver of Certain Requirements

Pursuant to Section 564(e)(3) of the Act, with respect to the emergency use of a product for which an authorization under this section is issued, FDA may waive or limit, to the extent appropriate given the circumstances of the emergency, requirements regarding current good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulation under this Act, including such requirements established under Section 501. FDA grants that waiver with respect to the products covered by this authorization.

IV. Conditions of Authorization

Pursuant to Section 564 of the Act, I am establishing the following conditions on this authorization:

A. SNS will distribute the authorized chloroquine phosphate and hydroxychloroquine sulfate under its direction to the extent such distributions are consistent with and do not exceed the terms of this letter, including distribution with the authorized labeling.

B. Through a process of inventory control, SNS will maintain records regarding distribution under its direction of the authorized chloroquine phosphate and hydroxychloroquine sulfate (i.e., lot numbers, quantity, receiving site, receipt date).

C. HHS will ensure that the terms of this EUA are made available to public health authorities through appropriate means.[11] HHS will provide public health authorities a copy of this letter of authorization and communicate to public health authorities any subsequent amendments that might be made to this letter of authorization and its authorized accompanying materials (e.g., Fact Sheets).

D. BARDA, ASPR, or other organization within HHS may request the authorization of additional chloroquine phosphate and hydroxychloroquine sulfate products under this EUA. Additional such products may be included in this authorization, without amendment of this EUA, upon concurrence of, Office of Infectious Diseases/OND/CDER, CTECS/OCD/CDER, and OCET/OCS/OC.

E. BARDA may request changes to this authorization, including to the authorized fact sheets for chloroquine phosphate and hydroxychloroquine sulfate products and to require patient outcomes reporting if and when a system is established, without amendment of this EUA, upon concurrence of, Office of Infectious Diseases /OND/CDER, CTECS/OCD/CDER, and OCET/OCS/OC.

F. HHS will inform public health authorities about the need to have a process in place for performing adverse event monitoring and compliance activities designed to ensure that adverse events and all medication errors associated with the use of the authorized chloroquine phosphate or hydroxychloroquine sulfate are reported to FDA, to the extent practicable given emergency circumstances, as follows: complete the MedWatch FDA Form online at www.fda.gov/medwatch/report.htm, or by using a postage-paid MedWatch Form 3500 (available at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home), or by calling 1-800-FDA-1088. Submitted reports should state: "use of chloroquine phosphate was under an EUA" or "use of hydroxychloroquine sulfate was under an EUA," as relevant. If and when HHS establishes a process for collecting outcomes data, HHS will inform public health authorities about such process.

G. SNS will ensure that the authorized chloroquine phosphate and hydroxychloroquine sulfate is distributed for use under its direction within the expiry dating on the manufacturer's labeling. If FDA authorizes any expiry dating extensions of the authorized chloroquine phosphate or hydroxychloroquine sulfate under this EUA, SNS will inform emergency response stakeholders receiving the authorized chloroquine phosphate or hydroxychloroquine sulfate of such extensions and any conditions related to such extensions under this EUA. SNS will maintain adequate records regarding the expiry dates by which authorized chloroquine phosphate and hydroxychloroquine sulfate may be used.

[11] For example, through hard copy, web posting, and/or mass media.

H. SNS will make available to FDA upon request any records maintained in connection with this EUA.

Healthcare Systems to Whom the Authorized Chloroquine Phosphate and Hydroxychloroquine Sulfate Is Distributed

I. Healthcare systems and healthcare providers receiving the chloroquine phosphate and/or hydroxychloroquine sulfate from the SNS will track adverse events and report to FDA in accordance with the Fact Sheet for Healthcare Providers. Complete and submit a MedWatch form (www.fda.gov/medwatch/report.htm), or Complete and submit FDA Form 3500 (health professional) or FDA Form 3500B (consumer/patient) by fax (1-800-FDA-0178). These forms can be found via link above. Call 1-800-FDA-1088 for questions. Submitted reports should state "chloroquine phosphate treatment under EUA" or "hydroxychloroquine sulfate treatment under EUA."

J. Through a process of inventory control, healthcare systems will maintain records regarding the dispensed authorized chloroquine phosphate and hydroxychloroquine sulfate (i.e., lot numbers, quantity, receiving site, receipt date) and maintain patient information and other relevant data as feasible (e.g., patient name, age, disease manifestation, other drugs administered, outcomes).

K. Healthcare systems will ensure that any records associated with this EUA are maintained until notified by SNS and/or FDA. Such records will be made available to FDA, SNS and BARDA for inspection upon request.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of drugs and biologics for prevention and treatment of COVID-19 is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

_____

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures