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March 24, 2022

ATTORNEY GENERAL OPINION NO. 2022- 4

The Honorable Ty Masterson
Kansas Senate President
300 SW 10th Room 333-E
Topeka, KS 66612

Re: Procedure, Civil—COVID-19 Response and Reopening for Business Liability Act—Definitions; Healthcare Provider Immunity; COVID-19 Public Health Emergency; Immunity Related to Qualified Products

Public Health—Healing Arts—Revocation, Suspension, Limitation or Denial of Licenses; Censure of Licensee; Grounds; Definitions

Public Health—Physician Assistants—Definitions; Revocation, Suspension, Limitation, Censure or Denial of License; Practice of Physician Assistant; Direction and Supervision of Physician; Prescription of Drugs; Rules and Regulations; Drug Defined

Public Health—Regulation of Nursing—Definitions; Grounds for Disciplinary Actions; Advanced Practice Registered Nurse; Rules and Regulations; Prescription of Drugs Authorized

Synopsis: Kansas law does not prohibit physicians and other authorized prescribers from prescribing FDA approved generic drugs such as ivermectin and hydroxychloroquine for off-label uses in the prevention or treatment of COVID-19 so long as the healthcare provider meets the standard of care obligations to the patient in the process. Cited herein: K.S.A. 2021 Supp. 60-5501; 60-5502; 60-5503; 60-5505; 65-1113; 65-1120; 65-1130; 65-2836; K.S.A. 65-2837; 65-2869; 65-2870; 65-28a02; 65-28a-05; 65-28a-08; K.A.R. 100-28a-8; 100-28a-7

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Dear Senator Masterson:

As Senate President and Senator for the 16th District you request our opinion on the following question of law: “Does Kansas law prevent physicians or other prescribers from prescribing FDA approved generic drugs such as ivermectin and hydroxychloroquine for off-label uses in the treatment of COVID-19?” For the reasons explained below, we opine that the answer is no if the physician or other authorized prescriber under the appropriate licensing statutes meets the standard of care and conduct obligations to the patient.

Food and Drug Administration & Off Label Usage

As one of its numerous responsibilities, the U. S. Food and Drug Administration (FDA) is charged with ensuring the safety and effectiveness of drugs and medical devices.¹ Prior to granting lawful use of a drug the FDA requires that manufacturers undergo rigorous application and approval processes demonstrating proof of both safety and efficacy for the intended use, which use is then set out on the product label.² While the FDA is charged with approving drugs, it does not have the authority to constrain the practice of medicine.³ Once drugs are approved by the FDA for lawful sale, medical professionals “exercise their independent medical judgment to prescribe FDA approved drugs to treat conditions other than those for which the drug is approved, if appropriate for a particular patient” which is commonly referred to as “off-label” usage.⁴ Off-label usage includes differing dosages than were initially tested or used in different patient populations from the clinical trials. Off-label usage also occurs where, in the medical judgement of the prescriber, it would benefit the patient when other drugs have failed. The United States Supreme Court has similarly recognized and affirmed the off-label use of FDA approved medical devices and noted further that the FDA has affirmed the validity of such off-label prescriptions.⁵ The Kansas Board of Healing Arts (BOHA) agrees, stating that “[o]ff label drug prescription is not uncommon, existed prior to the pandemic, and is not prohibited explicitly by federal or state law.”⁶ The Board emphasizes that healthcare professionals must comply with the standard of care.⁷ In the COVID-19 Response and Reopening for Business Liability Protection Act⁸, the Kansas Legislature recognized the potential need for off-label use of drugs during the COVID-19 pandemic. The legislature granted some civil immunity to healthcare providers for healthcare decisions made in response to COVID-19 between March 12, 2020 and March

¹ <https://www.fda.gov/regulatory-information/laws-enforced-fda> (last accessed 3/15/22).

² *Goico v. United States Gov't*, No. 20-1248-JAR, 2020WL 7078731, (D.Kan. Dec. 3, 2020).

³ *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 350 (2001) (citations omitted).

⁴ *Goico v. United States Gov't*, No. 20-1248-JAR, 2020WL 7078731, (D.Kan. Dec. 3, 2020). For a discussion by the FDA of off-label usage of FDA approved drugs see also <https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/understanding-unapproved-use-approved-drugs-label> (last accessed 3/5/22).

⁵ *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 350 (2001) (citations omitted).

⁶ Susan Gile, Acting Executive Director of the Kansas Board of Healing Arts, dated March 4, 2022, p.1.

⁷ *Id.*

⁸ K.S.A. 2021 Supp. 60-5501 et. seq.

31, 2022.⁹ Additionally the legislature provided for specific immunity in certain circumstances related to “medications used to treat COVID-19, including medications prescribed or dispensed for offlabel (sic) use to attempt to combat COVID-19.”¹⁰

COVID-19, Ivermectin, & Hydroxychloroquine

COVID-19 is a disease caused by the SARS-CoV-2 virus, a member of the coronavirus family, that can cause a variety of symptoms, from colds to severe respiratory illnesses and even death.¹¹ The virus spreads through the air in the same manner as other respiratory viruses.¹² As of March 14, 2022, Kansas recorded 768,820 cases of COVID-19, with 8,028 deaths attributed to the virus.¹³ Currently, the only FDA approved drug for the treatment of COVID-19 is remdesivir, which was approved on October 22, 2020.¹⁴ The drugs you cite in your question, ivermectin and hydroxychloroquine, have been studied for their possible efficacy in the prevention and treatment of COVID-19.¹⁵ The opinions offered by the Kansas Attorney General related to the off-label prescribing of drugs are limited to questions of law and not to factual considerations related to the prescribing of a particular drug for a particular condition.

Kansas Healing Arts Act

Under the Kansas Healing Arts Act, a physician is licensed to practice medicine and surgery or osteopathic medicine and surgery by the Kansas Board of Healing Arts.¹⁶ A physician may be subject to discipline for committing professional incompetency or for an act of unprofessional or dishonorable conduct.¹⁷ Professional incompetency for purposes of this opinion relates to the adherence to the applicable standard of care.¹⁸ Unprofessional conduct is defined by K.S.A. 65-2837 and for purposes of this opinion includes: “[m]aking a false or misleading statement regarding the licensee’s skill or the efficacy or value of the drug, treatment, or remedy prescribed by the licensee or at the licensee’s direction in the treatment of any disease or other condition of the body or mind;”¹⁹ “[p]rescribing, dispensing,

⁹ K.S.A. 2021 Supp. 60-5503.

¹⁰ K.S.A. 2021 Supp. 60-5505; 60-5502(k)(4).

¹¹ <https://www.cdc.gov/coronavirus/2019-ncov/your-health/about-covid-19/basics-covid-19.html> (last accessed 3/15/22).

¹² <https://www.cdc.gov/coronavirus/2019-ncov/your-health/about-covid-19/basics-covid-19.html> (last accessed 3/15/22).

¹³ <https://www.coronavirus.kdheks.gov/DocumentCenter/View/1529/February-28-Case-Summary-PDF?bidId=> (last accessed 3/15/22).

¹⁴ <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-frequently-asked-questions#drugs> (last accessed 3/15/22).

¹⁵ See Douglas J. Peterson Opinion 21-017 for a detailed discussion of the clinical trials and conflicting medical opinions related to the use of both ivermectin and hydroxychloroquine in the prevention and early treatment of COVID-19. https://ago.nebraska.gov/sites/ago.nebraska.gov/files/docs/opinions/21-017_0.pdf (last accessed 3/15/22).

¹⁶ See K.S.A. 65-2869 and K.S.A.65-2870; Attorney General Opinion No. 2020-2.

¹⁷ K.S.A. 2021 Supp. 65-2836(b).

¹⁸ K.S.A. 65-2837(a)(1)-(2).

¹⁹ K.S.A. 65-2837(b)(13).

administering or distributing a prescription drug or substance, including a controlled substance, in an improper or inappropriate manner, or for other than a valid medical purpose . . . ;”²⁰ or “[u]sing experimental forms of therapy without proper informed patient consent, without conforming to generally accepted criteria or standard protocols”²¹ Additionally, a physician may be disciplined if they have “prescribed, sold, administered, distributed or given a controlled substance to any person for other than medically accepted or lawful purposes.”²²

Physician Assistant Licensure Act

A physician assistant is a person licensed by the BOHA who “provides patient services under the direction and supervision of a supervising physician.”²³ Physician assistants may “prescribe drugs pursuant to a written agreement as authorized by the supervising physician”²⁴ and subject to rules and regulations adopted by BOHA.²⁵ A physician assistant may be subject to discipline for the commission of an act of unprofessional conduct²⁶ or professional incompetency.²⁷ Unprofessional conduct is “prescribing, dispensing, administering, or distributing a prescription drug or substance . . . in an excessive, improper, or inappropriate manner or quantity, or not in the course of the licensee’s professional practice.”²⁸ Professional incompetency is related to adherence to the applicable standard of care.²⁹ Additionally, a physician assistant may be subject to discipline for acting “outside the scope of authority given the physician assistant by the supervising physician.”³⁰

Kansas Nurse Practice Act

Under the Kansas Nurse Practitioner Act, an advanced practice registered nurse (APRN) is a professional nurse who is licensed by the Kansas State Board of Nursing (KSBN) to function in an advanced role.³¹ An APRN may prescribe drugs “pursuant to a written protocol as authorized by a responsible physician.”³² An APRN may be subject to discipline for

²⁰ K.S.A. 65-2837(b)(23).

²¹ K.S.A. 65-2837(b)(27).

²² K.S.A. 2021 Supp. 65-2836(p).

²³ K.S.A. 65-28a02(4).

²⁴ K.S.A. 65-28a08(b)(1). K.S.A. 65-28a08(f) defines “drug” as those articles and substances defined as drugs in K.S.A. 65-1626 and K.S.A. 65-4101, and amendments thereto.

²⁵ K.S.A. 65-28a08(d)(2). See K.A. R. 100-28a-13 for the specific prescribing parameters for physician assistants. This Opinion assumes that the physician assistant has followed all relevant regulations for authority to prescribe the drugs in question.

²⁶ K.S.A. 65-28a05(a).

²⁷ K.S.A. 65--28a05(c).

²⁸ K.A.R. 100-28a-8(j).

²⁹ K.A.R. 100-28a-7.

³⁰ K.S.A. 68-28a05(o).

³¹ K.S.A. 65-1113.

³² K.S.A. 65-1130(d). The requirements for said protocols are set out in K.A.R. 60-11-104a. Drugs as defined in K.S.A. 65-1130 are those substances defined as drugs in K.S.A. 65-1626 and K.S.A. 65-4101 thus an APRN may prescribe permitted drugs pursuant to an appropriate protocol. This opinion assumes that all protocols have been adopted and followed.

committing “an act of professional incompetence”³³ which includes “failure to adhere to the applicable standard of care.”³⁴

In other words, a *factual* question arises because the ‘particular decisions and acts required to satisfy that duty of care vary What constitutes negligence in a particular situation is judged by the professional standards of the particular area of medicine involved.’ As a result, the applicable standard of care is generally established through expert testimony ‘except where lack of reasonable care . . . is apparent to an average layperson from common knowledge or experience.’³⁵

Standard of Care

Under Kansas law, the authorized prescribers discussed herein are all subject to discipline for failure to follow the standard of care in a particular circumstance. It is the healthcare provider’s duty “to use the learning and skill ordinarily used by other members of that same field of medicine in the same or similar communities and circumstances. In using this learning and skill, the [healthcare provider] must also use ordinary care and diligence. A violation of this duty is negligence.”³⁶ Ultimately, the determination as to whether a healthcare provider has met the standard of care is a factual determination.

Thus, we conclude that nothing in Kansas or federal law prohibits the off-label prescribing of FDA approved drugs such as ivermectin or hydroxychloroquine for the prevention or treatment of COVID-19. In so prescribing, physicians and other prescribers are bound by professional standards of care in the treatment of patients. Determinations as to standard of care are factual determinations based on the particular circumstances of treatment and, as such, is outside the scope of this opinion.

Sincerely,

/s/Derek Schmidt

Derek Schmidt
Kansas Attorney General

/s/Sarah L. Shipman

Sarah L. Shipman
Deputy Attorney General

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³³ K.S.A. 65-1120(a).

³⁴ K.S.A. 65-1120(e).

³⁵ *Russell v. May*, 400 P.3d 647, 658 (Kan. 2017).

³⁶ Pattern Jury Instructions for Kansas – Civil 4th, 123.01, Duty of Health Care Provider (2021 update).