

April 8, 2022

Dear Kansas Healthcare Professionals,

The Kansas State Board of Healing Arts (“KSBHA” or “Board”) is aware of a letter dated March 31, 2022, on Senate Chamber letterhead mailed by a current Kansas state Senator who is also a physician, to numerous hospitals and healthcare professionals in the state. It is the KSBHA’s understanding that this letter has caused some confusion and concern amongst those in the Kansas medical professional community regarding prescribing FDA approved drugs off label, including for the prevention and treatment of COVID-19. A letter of this type is unprecedented. This letter serves as the KSBHA’s response and for clarification.

Off label drug prescribing is not uncommon, existed prior to the pandemic, and is not prohibited explicitly by federal or state law. The Board cautions healthcare professionals to ensure that they are complying with the standard of care<sup>1</sup> and standards of professional conduct in regard to any prescription order for off-label use of drugs. All off-label drug prescribing investigations the Board has (including those related to treatment of COVID-19) are reviewed under the same legal standard – whether the standard of care was met. The legal definition of the standard of care is “to exercise reasonable and ordinary care and diligence. But the particular decisions and acts required to satisfy that duty of care vary, *i.e.*, the required skill depends on the patient’s situation and the physician’s medical specialty.” *Biglow v. Eidenberg*, 308 Kan. 873, 887 (2018); *Foster ex rel. Foster v. Klaumann*, 296 Kan. 295, 302 (2013). In general terms, it is what a reasonable physician would have done under the same or similar circumstance. **This is incredibly fact dependent.** On March 24, 2022, the Kansas Attorney General released an opinion which is consistent with the Board’s legal opinion on this issue. (See Attachment 1, Kan. Op. Att’y Gen. No. 2022-4 (2022)).

In the Senator’s March 31, 2022, letter, he purports, “The standard of care [for COVID-19] is early treatment with FDA-approved medications regardless of their labelled uses. Delays in institution of these treatments are no longer acceptable.” This is simply his opinion; and his opinion has not altered the legal standard. It is not up to one individual to determine the standard of care. In his letter the Senator also references that Senate Substitute for HB 2280 has passed the Senate Public Health and Welfare Committee and the Senate as a whole. For clarification, **Senate Substitute for HB 2280 has not completed the legislative process and the bill is not currently effective law.** In the event it does become law in its current form, it does not mandate any specific prevention or treatment to be provided by a prescriber for COVID-19.

While the Board hopes the Senator’s letter was in good faith, the Board understands the source of confusion it may have caused the Kansas medical community. The Board values legal and factual accuracy and hopes this letter serves as clarification. In conclusion, nothing in Kansas or federal law prohibits the off-label prescribing of FDA approved drugs (including Ivermectin or Hydroxychloroquine) for the prevention or treatment of COVID-19. But in so prescribing, physicians

<sup>1</sup> A licensee has a duty to use the learning and skill ordinarily used by other members of the same field [of healthcare] in the same or similar communities and circumstances. In using this learning and skill, the licensee must also use ordinary care and diligence. Pattern Jury Instructions for Kansas – Civil 4<sup>th</sup>, 123.01, Duty of Health Care Provider (2014).

and other prescribers are bound by the standard of care in the treatment of patients which is dependent on the facts of each case.

This letter was approved by the full board in an open meeting on April 8, 2022.

Sincerely,



Thomas Estep, M.D.  
President



Susan Gile  
Acting Executive Director

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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 16<sup>th</sup> 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.<sup>1</sup> 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.<sup>2</sup> While the FDA is charged with approving drugs, it does not have the authority to constrain the practice of medicine.<sup>3</sup> 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.<sup>4</sup> 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.<sup>5</sup> 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.”<sup>6</sup> The Board emphasizes that healthcare professionals must comply with the standard of care.<sup>7</sup> In the COVID-19 Response and Reopening for Business Liability Protection Act<sup>8</sup>, 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

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

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

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

<sup>4</sup> *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).

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

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

<sup>7</sup> *Id.*

<sup>8</sup> K.S.A. 2021 Supp. 60-5501 et. seq.

31, 2022.<sup>9</sup> 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.”<sup>10</sup>

### 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.<sup>11</sup> The virus spreads through the air in the same manner as other respiratory viruses.<sup>12</sup> As of March 14, 2022, Kansas recorded 768,820 cases of COVID-19, with 8,028 deaths attributed to the virus.<sup>13</sup> Currently, the only FDA approved drug for the treatment of COVID-19 is remdesivir, which was approved on October 22, 2020.<sup>14</sup> 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.<sup>15</sup> 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.<sup>16</sup> A physician may be subject to discipline for committing professional incompetency or for an act of unprofessional or dishonorable conduct.<sup>17</sup> Professional incompetency for purposes of this opinion relates to the adherence to the applicable standard of care.<sup>18</sup> 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;”<sup>19</sup> “[p]rescribing, dispensing,

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<sup>9</sup> K.S.A. 2021 Supp. 60-5503.

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

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

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

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

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

<sup>15</sup> 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](https://ago.nebraska.gov/sites/ago.nebraska.gov/files/docs/opinions/21-017_0.pdf) (last accessed 3/15/22).

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

<sup>17</sup> K.S.A. 2021 Supp. 65-2836(b).

<sup>18</sup> K.S.A. 65-2837(a)(1)-(2).

<sup>19</sup> 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 . . . ;”<sup>20</sup> or “[u]sing experimental forms of therapy without proper informed patient consent, without conforming to generally accepted criteria or standard protocols . . . .”<sup>21</sup> 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.”<sup>22</sup>

### 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.”<sup>23</sup> Physician assistants may “prescribe drugs pursuant to a written agreement as authorized by the supervising physician”<sup>24</sup> and subject to rules and regulations adopted by BOHA.<sup>25</sup> A physician assistant may be subject to discipline for the commission of an act of unprofessional conduct<sup>26</sup> or professional incompetency.<sup>27</sup> 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.”<sup>28</sup> Professional incompetency is related to adherence to the applicable standard of care.<sup>29</sup> Additionally, a physician assistant may be subject to discipline for acting “outside the scope of authority given the physician assistant by the supervising physician.”<sup>30</sup>

### 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.<sup>31</sup> An APRN may prescribe drugs “pursuant to a written protocol as authorized by a responsible physician.”<sup>32</sup> An APRN may be subject to discipline for

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<sup>20</sup> K.S.A. 65-2837(b)(23).

<sup>21</sup> K.S.A. 65-2837(b)(27).

<sup>22</sup> K.S.A. 2021 Supp. 65-2836(p).

<sup>23</sup> K.S.A. 65-28a02(4).

<sup>24</sup> 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.

<sup>25</sup> 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.

<sup>26</sup> K.S.A. 65-28a05(a).

<sup>27</sup> K.S.A. 65-28a05(c).

<sup>28</sup> K.A.R. 100-28a-8(j).

<sup>29</sup> K.A.R. 100-28a-7.

<sup>30</sup> K.S.A. 68-28a05(o).

<sup>31</sup> K.S.A. 65-1113.

<sup>32</sup> 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”<sup>33</sup> which includes “failure to adhere to the applicable standard of care.”<sup>34</sup>

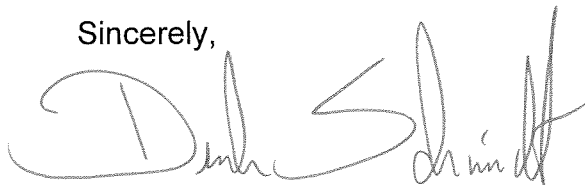
In other words, a *factual* question arises because the ‘particular decisions and acts required to satisfy that duty of care vary . . . . What constitutes negligence in a particular situation is judged by the professional standards of the particular area of medicine involved.’ As a result, the applicable 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.’<sup>35</sup>

### 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.”<sup>36</sup> 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,



Derek Schmidt  
Kansas Attorney General



Sarah L. Shipman  
Deputy Attorney General

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<sup>33</sup> K.S.A. 65-1120(a).

<sup>34</sup> K.S.A. 65-1120(e).

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

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