## SESSION OF 2022

# SUPPLEMENTAL NOTE ON SENATE SUBSTITUTE FOR HOUSE BILL NO. 2280

As Amended by Senate Committee on Public

Health and Welfare

#### **Brief\***

Senate Sub. for HB 2280, as amended, concerns prescribing and dispensing of drugs for off-label use and religious exemptions for childhood vaccines.

# Prescribing of Off-Label Medications

The bill would allow prescribers to prescribe U.S. Food and Drug Administration (FDA)-approved drugs, including, but not limited to, hydroxychloroquine sulfate and ivermectin, for the off-label use of preventing or treating COVID-19 infection. The bill would allow such prescriptions even if the patient has not been exposed to or tested positive for COVID-19. Such authorization would not apply to any controlled substances described in law relating to crimes involving controlled substances.

The bill would provide that recommendations, prescriptions, uses, or opinions of a prescriber related to treatment of COVID-19, including treatment that is not recommended or regulated by the State Board of Healing Arts (BOHA), the Kansas Department of Health and Environment (KDHE), or the FDA, would not be considered unprofessional conduct.

<sup>\*</sup>Supplemental notes are prepared by the Legislative Research Department and do not express legislative intent. The supplemental note and fiscal note for this bill may be accessed on the Internet at http://www.kslegislature.org

# **Definitions**

The bill would define the following terms:

- "COVID-19" would mean the disease caused by the novel coronavirus identified as SARS-CoV-2;
- "Disciplinary Action" would mean a licensing board's revocation, limitation, suspension, or denial of a license, a licensee being publicly censured or placed under probationary conditions, or any other discipline issued by a licensing board for unprofessional conduct;
- "Off-label use" would mean prescribing prescription drugs for treatments other than those stated in the labeling approved by the FDA;
- "Prescriber" would mean a person licensed by BOHA to practice medicine and surgery in this state or a "mid-level practitioner" as defined in the Pharmacy Act of the State of Kansas; and
- "Unprofessional conduct" would mean "professional incompetency" as defined in statute governing the regulation of nursing and "unprofessional conduct" as defined in statute concerning BOHA.

# Dispensing of Off-Label Medications

The bill would amend the Pharmacy Act of the State of Kansas (Act) to prohibit pharmacists from refusing to fill or refill any prescription if the basis of such refusal is based on a known or assumed diagnosis of a COVID-19 infection or its prophylactic treatment.

# Exemptions for Vaccines

The bill would amend law relating to child care facilities and schools to provide that children and students enrolling in a child care facility, school, or preschool or day care facility operated by a school, would be exempt from immunizations required by the Secretary of Health and Environment if such immunizations would violate sincerely held religious beliefs. The bill would provide that, in the case of a child care facility, the person maintaining a child care facility or, in the case of a school or preschool or day care operated by a school, a school district's Board of Education, such an exemption would be granted without inquiring into the sincerity of the request.

The bill would specify that "religious beliefs," as they relate to immunization exemptions in the bill, include, but are not limited to, theistic and non-theistic moral and ethical beliefs as to what is right and wrong that are sincerely held with the strength of traditional religious views.

The bill would also make technical amendments, including replacing the word "pupil" with "student."

The bill would be in effect upon publication in the Kansas Register.

# **Background**

HB 2280, as introduced, would have updated statutes relating to the powers, duties, and functions of the State Board of Pharmacy. On February 8, 2022, the Senate Committee on Public Health and Welfare inserted the provisions of SB 381, as amended by the Senate Committee, (immunization requirements) and the provisions of SB 398 (prescription off-label use) and recommended a substitute bill.

[Note: The contents of HB 2280, as amended by the Senate Committee, were inserted into Sub. for SB 238 during

the conference committee process. The bill was passed by the Legislature and signed into law by the Governor on May 19, 2021.]

On February 10, 2022, the bill was withdrawn from the Calendar and rereferred to the Senate Committee.

On March 8, 2022, the Senate Committee amended the bill to:

- Clarify that nothing in the bill would be construed as preventing a pharmacist from refusing to fill or refill any prescription if, in the pharmacist's professional judgment and discretion, such pharmacist is of the opinion that it should not be filled or refilled, unless such refusal is based solely on a known or assumed diagnosis of a COVID-19 infection or its prophylactic treatment;
- Remove the retroactive application of the bill's provisions for off-label prescriptions to any disciplinary action accruing on or after March 12, 2020;
- Remove the requirement for licensing boards for prescribers to independently review all disciplinary action for acts accruing between March 12, 2020, and the bill's effective date; and
- Remove the requirement for the licensing boards for prescribers to reconsider and rescind such disciplinary action.

# SB 381 – Prescriptions for Off-label Use

SB 381 was introduced by the Senate Committee on Public Health and Welfare at the request of Senator Hilderbrand.

#### Senate Committee on Public Health and Welfare

In the Senate Committee hearing, Senator Steffen and nine private citizens provided **proponent** testimony, stating that doctors should not be limited in the range of potential treatment options available for preventing and treating COVID-19 and that patients should have access to the medications prescribed to them.

Several hundred private citizens submitted written-only proponent testimony.

A representative of the Kansas Medical Society provided neutral testimony, stating that patient autonomy should be balanced with best practices and standard of care and expressing concern the bill would remove the ability to bring certain claims against unprofessional conduct or substandard care.

A representative of the Kansas State Board of Healing Arts provided written-only neutral testimony.

Written-only opponent testimony was submitted by the the University of Kansas Health System on behalf of Ascension Via Christi Health, University of Kansas School of Health Professions, and University of Kansas physicians.

The Senate Committee amended the bill to remove language relating to pharmacists, including "a pharmacist shall dispense," and to specify that pharmacists are prohibited from refusing to fill or refill any prescription used to treat or prevent a COVID-19 infection.

The Senate Committee also amended the bill to add the contents of SB 398.

The Senate Committee placed the contents of SB 381, as amended, into HB 2280 and recommended a substitute bill be passed.

### Fiscal Information

According to the fiscal note prepared by the Division of the Budget on SB 381, as introduced, the BOHA indicates reviewing investigations related to the enactment of the bill would be time consuming but could be done with existing resources.

The State Board of Pharmacy (Board) indicates the bill could have a fiscal effect on expenditures as well as on licensees and registrants and that prescribing and dispensing of drugs, or failing to do so, could cause an increase in the number of complaints received by the Board. Complaints would require investigation and an increase in Board resources such as time and staff. The Board notes, in the past, such issues have created substantial fiscal impact to the Board, but the effect on the Board's expenditures cannot be determined.

Any fiscal effect associated with SB 381 is not reflected in *The FY 2023 Governor's Budget Report*.

# SB 398 – Immunization Requirements

SB 398 was introduced by the Senate Committee on Public Health and Welfare at the request of Senator Steffen.

Senate Committee on Public Health and Welfare

The Senate Committee had not held a hearing on SB 398 at the time it was amended into SB 381.

## Fiscal Information

According to the fiscal note prepared by the Division of the Budget on SB 398, the Kansas Department for Children and Families, State Department of Education, and KDHE indicate the bill would have no fiscal effect on the agencies.

Prescriptions for off-label use; COVID-19; vaccines; religious exemptions