SESSION OF 2008

CONFERENCE COMMITTEE REPORT BRIEF
SUBSTITUTE FOR SENATE BILL NO. 491

As Agreed to April 1, 2008

Brief*

Sub. for SB 491 would enact the Prescription Monitoring Program Act and would create the Prescription Monitoring Program Advisory Committee, the Methamphetamine Precursor Scheduling Task Force, and the Veterinary Prescription Monitoring Program Task Force. The bill also would require each pharmacy in Kansas to establish a continuous quality improvement program, and would amend existing law concerning nonresident pharmacies.

Prescription Monitoring Program. The State Board of Pharmacy would be required to establish and maintain a prescription monitoring program for scheduled substances and drugs of concern dispensed in Kansas or dispensed to an address in Kansas. "Scheduled substances" would be defined as those controlled substances included in Schedules II, III, or IV of the Federal Controlled Substances Act and the Kansas Uniform Controlled Substances Act. "Drugs of concern" would be defined as those drugs that demonstrate a potential for abuse and are designated as drugs of concern in rules and regulations to be promulgated by the Board of Pharmacy.

Each dispenser would be required to submit electronically to the Board of Pharmacy information for each prescription dispensed for a scheduled substance or a drug of concern. A "dispenser" would be defined as a practitioner or pharmacist who delivers a scheduled substance or drug of concern to an

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ultimate user and would not include the following: licensed hospital pharmacies that distribute such substances for the purpose of inpatient hospital care; medical care facilities as defined in KSA 65-425; practitioners or other authorized persons who administer such substances; registered wholesale distributors of such substances; veterinarians licensed by the Kansas Board of Veterinary Examiners who dispense or prescribe such substances; or practitioners exempted from the reporting requirements by the Board of Pharmacy.

The Prescription Monitoring Program database and any records maintained by the Board of Pharmacy, or any entity contracting with the Board, would be privileged and confidential; not subject to subpoena or discovery in civil proceedings; could be used only for investigatory or evidentiary purposes related to violations of state or federal law and regulatory activities; would not be a public record; and would not be subject to the Kansas Open Records Act. The Board would be required to maintain procedures to ensure the privacy and confidentiality of patients and to ensure information is disclosed only to authorized persons, including:

- Persons authorized to prescribe or dispense scheduled substances and drugs of concern for the purpose of providing medical or pharmaceutical care for their patients;

- Individuals who request their own prescription monitoring information;

- Designated representatives from the professional licensing, certification, or regulatory agencies charged with administrative oversight of those persons engaged in prescribing or dispensing scheduled substances and drugs of concern;

- Local, state, and federal law enforcement or prosecutorial officials engaged in the administration, investigation, or enforcement of the laws governing scheduled substances and drugs of concern;

- Designated representatives from the Kansas Health Policy Authority regarding authorized Medicaid program recipients;

- Persons authorized by a grand jury subpoena, inquisition subpoena, or court order in a criminal action;

- Personnel of the Prescription Monitoring Program Advisory Committee for the purpose of operating the Program;

- Personnel of the Board of Pharmacy for the purposes of administration and enforcement of the Prescription Monitoring Program Act and the Uniform Controlled Substances Act; and

- Public or private entities for statistical, research, or educational purposes.

The Board of Pharmacy would be required to promulgate rules and regulations specifying the nationally recognized telecommunications format to be used for the submission of information and the transmission methods and frequency of dispenser submissions. The Board could issue waivers for dispensers unable to submit prescription information by electronic means, allowing them to submit information in paper form or by other means. The Board of Pharmacy would be prohibited from imposing any charge for the establishment or maintenance of the Prescription Monitoring Program database on registered wholesale distributors, pharmacists, dispensers, or other persons authorized to prescribe or dispense scheduled substances and drugs of concern. The Board also would be prohibited from charging fees for the transmission of information from the database except for individuals who request their prescription monitoring information.

Persons violating the following provisions of the Prescription Monitoring Program Act would be guilty of a severity level 10, nonperson felony:

- Dispensers who knowingly fail to submit prescription monitoring information or who knowingly submit incorrect information;

- Persons authorized to have prescription monitoring information who knowingly disclose such information in violation of the Act; and

- Persons authorized to have prescription monitoring information who knowingly use such information in violation of the Act.

Practitioners and dispensers would not be in violation of the Act if they disclosed or used information solely in the course of care of the patient who is the subject of the information. Additionally, persons authorized to prescribe or dispense scheduled substances or drugs of concern would not be required to obtain information about a patient from the Prescription Monitoring Program prior to prescribing or dispensing scheduled substances and drugs of concern. The practitioners and dispensers also would not be liable to any person in a civil action because they did, or did not, seek or obtain information from the Prescription Monitoring Program prior to prescribing or dispensing scheduled substances or drugs of concern to a patient.

Finally, in consultation with and upon recommendation of the Prescription Monitoring Program Advisory Committee, the Board of Pharmacy would be required to review the effectiveness of the Prescription Monitoring Program and submit an annual report to the Senate Committee on Public Health and Welfare and the House Committee on Health and Human Services.

Prescription Monitoring Program Advisory Committee. The bill would create a Prescription Monitoring Program Advisory Committee, subject to Board of Pharmacy oversight, to be responsible for the operation of the Prescription Monitoring Program. The Advisory Committee would consist of

at least the following nine members appointed by the Board of Pharmacy for three-year terms:

- Two licensed physicians, one nominated by the Kansas Medical Society and one nominated by the Kansas Association of Osteopathic Medicine;

- Two licensed pharmacists nominated by the Kansas Pharmacists Association;

- One person representing the Kansas Bureau of Investigation nominated by the Attorney General;

- One person representing the University of Kansas School of Medicine nominated by the Dean of the School of Medicine;

- One person representing the University of Kansas School of Pharmacy nominated by the Dean of the School of Pharmacy;

- One licensed dentist nominated by the Kansas Dental Association; and

- One person representing the Kansas Hospital Association nominated by the Hospital Association.

The Board of Pharmacy could appoint other persons authorized to prescribe or dispense scheduled substances and drugs of concern, recognized experts, and representatives from law enforcement. Members of the Advisory Committee would serve without compensation.

The Advisory Committee would be required to work with each entity charged with administrative oversight of persons engaged in prescribing or dispensing scheduled substances and drugs of concern to develop a continuing education program about the purposes and uses of the Prescription Monitoring Program. It also would be required to work with the Kansas Bar Association and the Kansas Bureau of Investigation

to develop continuing education programs for attorneys and law enforcement officers.

Methamphetamine Precursor Scheduling Task Force. The Methamphetamine Precursor Scheduling Task Force would be established to study the possibility and practicability of making methamphetamine precursors Schedule III or IV drugs and the impact of that change on consumer access and cost. The Task Force would consist of the following nine members:

- The Attorney General, or the Attorney General's designee;
- One member appointed by the Kansas Health Policy Authority;
- One member appointed by the Director of the Kansas Bureau of Investigation;
- One member appointed by the State Board of Pharmacy; and
- One member appointed by the Board of Healing Arts.

The four remaining members would be appointed by the Board of Pharmacy as follows:

- One member nominated by the Kansas Medical Society;
- One member nominated by the Kansas Association of Osteopathic Medicine;
- One member nominated by the Kansas Pharmacists Association; and
- One member appointed by the Kansas Task Force of the Pharmaceutical Research and Manufacturing Association representing the pharmaceutical industry.

The nominations and appointments to the Methamphetamine Precursor Scheduling Task Force would be required to be made within 30 days after the effective date of the bill, publication in the statute book. The Board of Pharmacy would be required to convene the initial meeting of the Task Force within 60 days of the effective date. All Task Force members would serve without compensation. The Task Force would be required to report its findings and conclusions to the Legislature on or before January 12, 2009, and the Task Force would sunset on January 13, 2009.

Veterinary Prescription Monitoring Program Task Force. The Veterinary Prescription Monitoring Program Task Force would be established to study and determine whether to require licensed veterinarians to report to the Prescription Monitoring Program established by the bill. The study would be required to include appropriate methods and procedures of reporting by veterinarians and necessary database field information. The Task Force would consist of the following three members:

- One member appointed by the Prescription Monitoring Program Advisory Committee;

- One member appointed by the Kansas Board of Veterinary Examiners; and

- One member nominated by the Kansas Veterinary Medical Association and appointed by the Kansas Board of Veterinary Examiners.

Appointments to the Task Force would be required within 120 days after the effective date of the bill and the initial meeting of the Task Force would be required to convene within 180 days after the effective date. All Task Force members would serve without compensation. The Task Force would report its findings and progress to the Prescription Monitoring Program Advisory Committee at least annually or when requested by the Advisory Committee and the Task Force also

would be required to report its progress to the Senate Committee on Public Health and Welfare and the House Committee on Health and Human Services, if requested. The Task Force would report its conclusions and recommendations to the two legislative committees within five years after the effective date of the bill. Based on the recommendation of the Task Force, the Prescription Monitoring Program Act would be amended to include veterinarians as practitioners.

Continuous Quality Improvement Program. The bill would create a new statute that would require each pharmacy in Kansas to establish a continuous quality improvement program which is referenced in the bill as a CQI program. A CQI program would have to be in place no later than July 1, 2009. The purpose of the new program would be to assess errors in dispensing or furnishing prescription medications in order that the pharmacy may take appropriate action to prevent a recurrence of any errors.

Pursuant to the provisions of the substitute bill, reports, memoranda, proceedings, findings, or other records generated as part of a CQI program would be considered confidential and privileged peer review documents and not subject to discovery, subpoena, or other means of legal compulsion for their release and not admissible in any civil or administrative action other than an administrative proceeding initiated by the Board of Pharmacy. Nothing in the new statute is to be construed to prevent a patient from accessing such patient's prescription records, nor should the confidentiality provision be construed to affect the discoverability of records that are not generated or maintained solely as a part of a CQI program. No person in attendance at any meeting generated as part of a CQI program could be compelled to testify in any civil, criminal, or administrative action as to discussions or decisions occurring as part of a CQI program, except in an administrative action initiated by the Board of Pharmacy. All reports and records generated as a part of a CQI program would be available for inspection by the Board of Pharmacy within a time period set by the Board through rules and regulations.

The new statute that would be created by the substitute bill would require the Board of Pharmacy, in conducting a disciplinary proceeding, to close that portion of the hearing in which any report, record, or testimony falling under the confidentiality provisions of the bill is to be disclosed and to exclude any person from the closed hearing except those listed in the bill. Further, the Board would be required to make any portions of the administrative record in which privileged matters are disclosed subject to a protective order prohibiting further disclosure and such records would not be subject to subpoena, discovery, or other means of legal compulsion. No person in attendance at a closed part of a disciplinary proceeding could be required to testify at a subsequent civil, criminal, or administrative proceeding.

Pursuant to the statute that would be created by the bill, the Board of Pharmacy could review any matters that are confidential or privileged under a CQI program, testimony, or reports in conducting a disciplinary proceeding, but the Board would be required to prove its findings with independently obtained testimony or records presented in an open Board meeting.

The bill would allow the Board of Pharmacy to establish requirements relating to the functions and record keeping of a pharmacy CQI program.

Nonresident Pharmacy Provisions. The bill would amend an existing statute to add new authority for the Board of Pharmacy to assess a civil fine against any nonresident pharmacy in an amount not exceeding $5,000 for each violation when a nonresident pharmacy fails to supply information requested by the Board or to respond to an inquiry after being noticed by certified mail.

Conference Committee Action

The Conference Committee agreed to amend the bill, as passed by the House, to eliminate provisions that would have

created the Methamphetamine Precursor Recording Act (SB 503, amended into the bill by the House Committee of the Whole). In addition, the Conference Committee incorporated all of the provisions of Sub. for SB 549, as amended by the House Committee on Health and Human Services, which would require each pharmacy in Kansas to establish a continuous quality improvement program and allow the Board of Pharmacy to assess civil fines against nonresident pharmacies under certain circumstances.

Background

The 2007 Legislature enacted SB 302 which established a Controlled Substance Monitoring Task Force to develop a plan for the creation and implementation of a controlled substance prescription monitoring program and an electronic purchase log capable, in real time, of checking compliance with all state, federal and local laws concerning the sale of ephedrine and pseudoephedrine. The Task Force was required to report its findings and conclusions to the Legislature on or before January 14, 2008. SB 491 encompasses, in part, the work of the Controlled Substance Monitoring Task Force.

The Senate Committee on Public Health and Welfare recommended the introduction of a substitute bill. Proponents appearing before the Committee or providing written testimony on the original bill included Senator Vicki Schmidt and representatives of the Kansas Board of Pharmacy, State Board of Healing Arts, Kansas Association of Osteopathic Medicine, Kansas Academy of Physician Assistants, Kansas Bureau of Investigation, Cypress Recovery, Inc., and the parent of a prescription drug addicted child. Proponents supporting the bill but requesting amendments included the Kansas Board of Veterinary Examiners, Kansas Veterinary Medical Association, Kansas Medical Society, National Association of Chain Drug Stores, Kansas Pharmacy Coalition, and a practicing veterinarian. One representative of the Kansas Veterinary Medical Association was neutral on the bill but requested an amendment.

There were no opponents to the bill.

The House Committee on Health and Human Services made amendments to clarify that members of the Prescription Monitoring Advisory Committee would serve without compensation, to clarify that persons nominated by private entities to serve on a task force created by the bill are subject to appointment by a state agency, and to clarify that the Methamphetamine Precursor Scheduling Task Force would be subject to sunset in January 2009. The Committee also made technical amendments.

The House Committee of the Whole amended the bill to include the contents of SB 503 (the Methamphetamine Precursor Recording Act) in its entirety.

The Conference Committee removed the provisions of SB 503 and incorporated the contents of Sub. for SB 549, which requires each pharmacy to establish a continuous quality improvement program, and which allows the Board of Pharmacy to assess civil fines against nonresident pharmacies.

Sub. for SB 549 was presented as the work product of conferees who were asked to work together to come up with a compromise version of the bill. The pharmacy groups expressed support for the substitute bill.

Proponents appearing or providing written testimony in support of the substitute bill during hearings in the House Health and Human Services Committee included Senator Vicki Schmidt, the Board of Pharmacy, The Kansas Pharmacy Coalition, the Kansas Pharmacists Association and the National Association of Drug Stores.

A representative of the Kansas Association of Justice spoke in opposition to the substitute bill.

The House Committee on Health and Human Services made two amendments related to disciplinary hearings: they added members of the Board of Pharmacy to the list of parties

who cannot be excluded from closed disciplinary proceedings where privileged matters may be disclosed, and they clarified that the board may review any matters that are confidential and privileged under a CQI program during a disciplinary hearing. The Committee also made a technical amendment.

The fiscal note prepared by the Division of the Budget for the original version of the Sub. for SB 491 states that the Board of Pharmacy estimates passage of the bill would require between $350,000 and $500,000 in start-up costs. The Board of Pharmacy also indicated that it would apply for a one-year grant from the United States Department of Justice. Expenses of the Board are financed from the Board of Pharmacy Fee Fund. Any fiscal effect resulting from enactment of the bill is not included in *The FY 2009 Governor's Budget Report*. The original fiscal note for Sub. for SB 549 may not be relevant.

Prescription Monitoring; methamphetamine; pharmacy nonresident