Approved	2-21-89	
FF	Date	

MINUTES OF THE SENATE	COMMITTEE ON	PUBLI	C HEALTH	AND WEL	FARE	
The meeting was called to order by	SENATOR	ROY M.	EHRLICH Chairperso	n		at
a.m./xxx on	February 14		, 19_8	<u> </u>	526-S	of the Capitol.
All members were present except:						

Committee staff present:

Emalene Correll, Legislative Research Clarene Wilms, Committee Secretary

Conferees appearing before the committee:

Helen DeWitt, Right to Life of Kansas, Hays, Kansas Senator Jack Steineger Tom Hitchcock, Executive Secretary, State Board of Pharmacy

The chairman called the meeting to order and called for any requests for committee bills.

Helen Dewitt asked a bill be requested by the committee which would provide that a child born as a result of an attempted abortion is a child in need of care under the Kansas code for care of children. ($\underline{\text{Attachment 1}}$)

Senator Reilly moved, with a second by Senator Strick, to accept the bill as a committee bill. The motion carried.

The minutes of February 6, 7, 8 and 9, 1989 were presented for approval or correction. Senator Reilly moved to accept the minutes as presented. Senator Strick seconded the motion and the motion carried.

Senator Jack Steineger told the committee that $\underline{SB-136}$ had been introduced at the request of several Kansas senior citizen groups who said that by virtue of Kansas law, their doctors were unable to write a prescription which would remain valid for a period longer than six months. It was felt that this procedure was time consuming and costly, particularly when these type of prescriptions having to do with arthritis and other simpler type of drugs. This would permit a specific prescription to be written for more than five refills and would permit it to be refilled after a six months period.

Tom Hitchcock appeared in opposition to <u>SB-136</u> stating that both state and federal regulations, as shown in <u>Attachment 2</u>, have exactly the same restrictions, that being that Schedule III or IV prescriptions cannot be refilled more than 5 times in a period of 6 months from the date of the original prescription. <u>Senate Bill 136</u> would have no effect on federal regulations as the pharmacist is required to comply with both statutes, whichever is more restrictive. He further replied that motrin and other inflammatory drugs used in treating arthritis were not included in the III and IV scheduled drugs. Mr. Hitchcock stated that changing this act would have no affect whatsoever, that the pharmacist would still be responsible.

The chairman called for the wishes of the committee concerning $\underline{\text{SB-136}}$. No comments or motions were forthcoming.

The meeting adjourned at 10:20 a.m. and will convene at 10:00 a.m. Wednesday, February 15, 1989, in room 526-S.

SENATE PUBLIC HEALTH AND WELFARE COMMITTEE DATE February 14,1489

(PLEASE PRINT)	'
NAME AND ADDRESS	ORGANIZATION
Bob Willyams 31308W104 46604	Ks. Prannaists Assoc.
Tom Intereock Topeka	Bd. of Pharmacy
GARY Robhins	Ks Opt, asset
Allen DeWitt	Right to Life 7 K5.
Chy Wheelen	KMS
- HRENM	KAOU
gin Clare	KCDAA
KOTH & LANDIS	CHRISTIAN SUENCE COMMITTON FOR KAINS
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SENATE BILL	NO.
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AN ACT concerning children; providing that a child born as a result of an attempted abortion is a child in need of care under the Kansas code for care of children.

Be it enacted by the Legislature of the State of Kansas:

Section 1. (a) A child born as a result of an attempted abortion who exhibits any sign of a live birth as defined in K.S.A. 65-2401 and amendments thereto shall be considered a child in need of care under the Kansas code for care of children.

- (b) The secretary of social and rehabilitation services shall adopt rules and regulations to carry out the provisions of this section.
- Sec. 2. This act shall take effect and be in force from and after its publication in the Kansas register.

SP4/4W 2-14-89 HHachment 1

Kansas State Board of Pharmacy

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STATE OF KANSAS



MIKE HAYDEN GOVERNOR MEMBERS

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BARBARA A. RENICK, GARDEN CITY
EXECUTIVE SECRETARY
TOM C. HITCHCOCK

SENATE BILL 136

BOARD ATTORNEY

JOHN C. WHITAKER

SENATE PUBLIC HEALTH AND WELFARE COMMITTEE

Mr. Chairman, members of the Committee, my name is Tom Hitchcock and I am the Executive Secretary for the Kansas State Board of Pharmacy. I appear before you today on behalf of the Board to speak in opposition to Senate Bill 136.

K.S.A. 65-4123 (attachment #1) and the federal regulation 1306.22 (attachment #2), as underlined in subsection (c) and (a), respectively, have exactly the same restrictions. These denote that a Kansas licensed pharmacist cannot refill a duly authorized refillable Schedule III or IV prescription more than 5 times in a period of 6 months from the date of the original prescription dating.

The change in SB 136 to extend these requirements would have no effect on the federal regulation. The pharmacist is required to comply with Kansas statute or federal regulation, whichever is more restrictive.

The federal Drug Enforcement Administration (DEA), like most other federal agencies, would prefer that state agencies handle their own compliance problems. This becomes more complex for the Board and the profession with additional changes and differences in requirements.

The Board, therefore, respectfully requests that SB 136 not be approved, leaving K.S.A. 65-4123 in concert with the federal regulation.

Thank you.

S PHUW 2-14-89 HHachment 2

Attachment

65-4123. Prescriptions. (a) Except as otherwise provided in K.S.A. 65-4117 and amendments thereto or in this subsection (a), no schedule I controlled substance may be dispensed. The board by rules and regulations may designate in accordance with the provisions of this subsection (a) a schedule I controlled substance as a schedule I designated prescription

substance. A schedule I controlled substance designated as a schedule I designated prescription substance may be dispensed only upon the written prescription of a practitioner. Prior to designating a schedule I controlled substance as a schedule I designated prescription substance, the board shall find: (1) That the schedule I controlled substance has an accepted medical use in treatment in the United States; (2) that the public health will benefit by the designation of the substance as a schedule I designated prescription substance; and (3) that the substance may be sold lawfully under federal law pursuant to a prescription. No prescription for a schedule I designated prescription substance may be refilled.

(b) Except when dispensed by a practitioner, other than a pharmacy, to an ultimate user, no controlled substance in schedule II may be dispensed without the written prescription of a practitioner. In emergency situations, as defined by rules and regulations of the board, schedule II drugs may be dispensed upon oral prescription of a practitioner reduced promptly to writing and filed by the pharmacy. No prescription for a schedule II substance may be refilled.

(c) Except when dispensed by a practitioner, other than a pharmacy, to an ultimate user, a controlled substance included in schedule III or IV which is a prescription drug shall not be dispensed without a written or oral prescription of a practitioner. The prescription shall not be filled or refilled more than six months after the date thereof or be refilled more than five times.

(d) A controlled substance shall not be distributed or dispensed other than for a medical purpose. Prescriptions shall be retained in conformity with the requirements of K.S.A. 65-4121 and amendments thereto.

History: L. 1972, ch. 234, § 23; L. 1972, ch. 235, § 1; L. 1986, ch. 242, § 2; July 1.

tachmented USP Gen onces and Chapters 2289

Controlled Substances Listed in Schedules III and IV

§ 1306.21 Requirement of prescription.

(a) A pharmacist may dispense directly a controlled substance listed in Schedule III or IV, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to either a written prescription signed by a prescribing individual practitioner or an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist containing all information required in § 1306.05, except for the signature of the prescribing individual practitioner.

(b) An individual practitioner may administer or dispense directly a controlled substance listed in Schedule III or IV in the course of his professional practice without a prescription, subject to § 1306.07.

(c) An institutional practitioner may administer or dispense directly (but not prescribe) a controlled substance listed in Schedule III or IV pursuant to a written prescription signed by a prescribing individual practitioner, or pursuant to an oral prescription made by a prescribing individual practitioner and promptly reduced to writing by the pharmacist (containing all information required in § 1306.05 except for the signature of the prescribing individual practitioner), or pursuant to an order for medication made by an individual practitioner which is dispensed for immediate administration to the ultimate user, subject to § 1306.07.

§ 1306.22 Refilling of prescriptions.

- (a) No prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than 6 months after the date on which such prescription was issued and no such prescription authorized to be refilled may be refilled more than five times. Each refilling of a prescription shall be entered on the back of the prescription or on another appropriate document. If entered on another document, such as a medication record, the document must be uniformly maintained and readily retrievable. The following information must be retrievable by the prescription number consisting of the name and dosage form of the controlled substance, the date filled or refilled, the quantity dispensed, initials of the dispensing pharmacist for each refill, and the total number of refills for that prescription. If the pharmacist merely initials and dates the back of the prescription it shall be deemed that the full face amount of the prescription has been dispensed. The prescribing practitioner may authorize additional refills of Schedule III or IV controlled substances on the original prescription through an oral refill authorization transmitted to the pharmacist provided the following conditions are met:
- (1) The total quantity authorized, including the amount of the original prescription, does not exceed five refills nor extend beyond six months from the date of issue of the original prescription.
- (2) The pharmacist obtaining the oral authorization records on the reverse of the original prescription the date, quantity of refill, number of additional refills authorized, and initials the prescription showing who received the authorization from the prescribing practitioner who issued the original prescription.
- (3) The quantity of each additional refill authorized is equal to or less than the quantity authorized for the initial filling of the original prescription.
- (4) The prescribing practitioner must execute a new and separate prescription for any additional quantities beyond the five refill, sixmonth limitation.
- (b) As an alternative to the procedures provided by subsection (a), an automated data processing system may be used for the storage and retrieval of refill information for prescription orders for controlled sub-stances in Schedules III and IV, subject to the following conditions:
- (1) Any such proposed computerized system must provide on-line retrieval (via CRT display or hard-copy printout) of original prescription order information for those prescription orders which are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number, date of issuance of the original prescription order by the practitioner, full name and address of the patient, name, address, and DEA registration number of the practitioner, and the name, strength, dosage form, quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.
- (2) Any such proposed computerized system must also provide online retrieval (via CRT display or hard-copy printout) of the current refill history for Schedule III or IV controlled substance prescription orders (those authorized for refill during the past six months). This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for that prescription
- (3) Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for a Schedule III or IV controlled substance is correct must be

provided by the individual pharmacist who makes use of such a system. If such a system provides a hard-copy printout of each day's controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated is correct and then sign this document in the same manner as he would sign a check or legal document (e.g., J. H. Smith, or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data must be provided to each pharmacy using such a computerized system within 72 hours of the date on which the refill was dispensed. It must be verified and signed by each pharmacist who is involved with such dispensing. In lieu of such a printout, the pharmacy shall maintain a bound log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him and is correct as shown. Such a book or file must be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing the appropriately authorized refill.

(4) Any such computerized system shall have the capability of producing a printout of any refill data which the user pharmacy is responsible for maintaining under the Act and its implementing regulations. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic name or both). Such a printout must indicate name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist, and the number of the original prescription order. In any computerized system employed by a user pharmacy the central recordkeeping location must be capable of sending the printout to the pharmacy within 48 hours, and if a DEA Special Agent or Compliance Investigator requests a copy of such printout from the user pharmacy, it must, if requested to do so by the Agent or Investigator, verify the printout transmittal capability of its system by documentation (e.g., postmark).

(5) In the event that a pharmacy which employs such a computerized system experiences system down-time, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of Schedule III and IV controlled substance prescription orders. This auxiliary procedure must insure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data are retained for online data entry as soon as the computer system is available for use again.

(c) When filing refill information for original prescription orders for Schedule III or IV controlled substances, a pharmacy may use only one of the two systems described in paragraph (a) or (b) of this section.

§ 1306.23 Partial filling of prescriptions.

The partial filling of a prescription for a controlled substance listed in Schedule III or IV is permissible, provided that:

- (a) Each partial filling is recorded in the same manner as a refilling,
- (b) The total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and
- (c) No dispensing occurs after 6 months after the date on which the prescription was issued.

§ 1306.24 Labeling of substances.

- (a) The pharmacist filling a prescription for a controlled substance listed in Schedule III or IV shall affix to the package a label showing the pharmacy name and address, the serial number and date of initial filling, the name of the patient, the name of the practitioner issuing the prescription, and directions for use and cautionary statements, if any, contained in such prescription as required by law.
- (b) The requirements of paragraph (a) of this section do not apply when a controlled substance listed in Schedule III or IV is prescribed for administration to an ultimate user who is institutionalized: Provided,
- (1) Not more than a 34-day supply or 100 dosage units, whichever is less, of the controlled substance listed in Schedule III or IV is dispensed at one time;
- (2) The controlled substance listed in Schedule III or IV is not in the possession of the ultimate user prior to administration;
- (3) The institution maintains appropriate safeguards and records the proper administration, control, dispensing, and storage of the controlled substance listed in Schedule III or IV; and
- (4) The system employed by the pharmacist in filling a prescription is adequate to identify the supplier, the product and the patient, and to set forth the directions for use and cautionary statements, if any, contained in the prescription or required by law.

§ 1306.25 Filing prescriptions.

All prescriptions for controlled substances listed in Schedules III and IV shall be kept in accordance with § 1304.04(h) of this chapter.