SUBJECT: Controlled substance prescriptions and reporting requirements

COMMITTEE: Public Health — committee substitute recommended

VOTE: 5 ayes — Berlanga, Hirschi, Coleman, Delisi, Glaze

0 nays

4 absent — Davila, Janek, Maxey, Rodriguez

WITNESSES: For — Leigh Fredholm, Hospice Austin; C. Stratton Hill, M.D., Texas Medical Association/Texas Cancer Pain Initiative; Karen Kenny Reagan, Texas Pharmacy Association; Deborah M. Thorpe, Texas Nurses Association; Cherry Hershberger, Texas Hospice Organization; Arana Hagan, Texas Association for Home Care; Terry Boucher, Texas Osteopathic Medicine Association; Mark Mullinax, R.N.; David Ralston, Sharon Weinstien, M.D., Texas Pain Society; Carolyn A. Parker, Ph.D., Texas AIDS Network; Tom White, Texas Academy of Physician Assistants; Michael C. Fitzpatrick, M.D., American Cancer Society; Troy Alexander, Texas Academy of Family Physicians

Against — None

On — David Boatright, Department of Public Safety

BACKGROUND: The use of Department of Public Safety-issued, paper triplicate prescription forms is statutorily required for the dispensing of Schedule II controlled substances. Schedule II controlled substances are drugs classified by the commissioner of health or the federal government as being legal and having legitimate medical purposes but that also are potentially highly abusable. Schedule II controlled substances generally refer to strong analgesics and pain killers, such as cocaine, Darvon and Tylenol III with codeine.

DIGEST: CSHB 226 would replace requirements that practitioners use triplicate forms for the prescription of Schedule II controlled substances with provisions that would require 1) pharmacists who dispense Schedule II drugs to transmit specified information to a central repository, and 2) pharmacists to dispense Schedule II drugs only upon receipt of a written prescription of a

practitioner who provides information necessary for reporting requirements.

The bill would take effect January 1, 1998, and would not affect the retention, use or destruction of information obtained through the use of triplicate forms written before that date. Offenses committed before January 1, 1998, would be covered by the law in effect on the date the offense was committed. The bill would authorize DPS to adopt rules and take necessary action to ensure the central repository is prepared to accept information on January 1, 1998.

Required reporting

Pharmacists would have to transmit to a central repository designated by the Department of Public Safety the following information by the 15th day after the date the drug was dispensed:

- the date the controlled substance was dispensed and the date it was prescribed;
- the National Drug Code number of the controlled substance, the quantity prescribed, the instructions for use, and the intended use of the drug;
- the quantity dispensed;
- the name, address and federal drug enforcement administration number of the dispensing pharmacy and the prescribing practitioner and the name of the dispensing pharmacist;
- the name, address and age of the person for whom the controlled substance was dispensed; and
- the driver's license or other identification, if available, of the person for whom the drug was prescribed.

The information could be reported on an electronic device, by computer diskette, magnetic tape, facsimile transmission, or pharmacy universal claim form. The information would be confidential, and access would not be permitted except to:

- investigators of the boards of medical examiners, podiatry examiners, dental examiners, veterinary examiners or pharmacy;
- authorized DPS officers engaged in the investigation of suspected criminal violations; or

- persons engaged in research, educational activities or demographic studies approved by the commissioner of health, provided that the information was provided in a format that did not reveal the identities of the prescribers or recipients of Schedule II substances.

DPS requirements

The department could create the repository within the agency or contract with a vendor to provide the central repository. The repository would have to be able to provide the department with on-line access to information at all times, provide the collected information in DPS-required formats and secure the information against unauthorized access. A person would commit a third degree felony offense, punishable by two-to-10 years in prison and an optional fine of up to $10,000, for intentionally or knowingly permitting or obtaining unauthorized access to central repository information.

In most cases, information would have to be destroyed not later than one year after the information was submitted that revealed the identity of a recipient of a controlled substance, and the department would have to issue a semiannual report to the Legislative Budget Board that certified compliance with this provision.

SUPPORTERS SAY:

CSHB 226 would enact much needed modernization of controlled substance oversight, enforcement and information analysis that would improve surveillance and legitimate patient access to pain medication. Only eight other states continue to use triplicate prescription forms to monitor controlled substance use.

The use of triplicate forms is an antiquated, pre-computer system of surveillance and enforcement. The practitioner writes a prescription on a triplicate prescription form for a patient, keeps one of the forms for recordkeeping, and gives the patient the other two forms. The pharmacy takes the two forms from the patient, keeps one for its records and sends the original form to the DPS for data entry, which is often six months to two years behind schedule.

Special triplicate prescription forms also hinder legitimate access to pain medications because some patients feel stigmatized when presenting their

prescription to a pharmacist as if their prescription to treat a severe medical problem may be suspected as a possible criminal act. Practitioners are also wary of using triplicate forms, and some do not request the forms from DPS even though their patients need strong pain killing medications, because they do not want to risk potential misuse of the forms by unauthorized individuals. Without access to pain medication for legitimate medical problems, patients' quality of life suffers, and many further jeopardize their health by over consuming over-the-counter drugs to try to combat their pain.

CSHB 226 would not burden pharmacists with additional procedures or costs; most pharmacies already use electronic on-line communications and computerized recordkeeping. Smaller, independent pharmacies could continue to submit information by paper, using a claim form universally used by insurers and other providers.

CSHB 226 would spur long overdue computerization and efficiencies in DPS recordkeeping, and would protect patient and provider confidentiality while simultaneously authorizing summary reports and information on the use of controlled substances to be released for public analysis. Current law requires the collection of triplicate form information, but prohibits the release of valuable information to the public, because the DPS is not authorized to strip the data of information that would identify specific individuals or to correlate the data in any meaningful way.

Surveillance and control of controlled substance prescriptions would not be diminished. However, a floor amendment will be offered by the author that would institute a system in which practitioner prescriptions would be traceable to the prescribing practitioner by the use of nonremovable, sequentially numbered, identifying stickers that would be developed by DPS and purchased by doctors. The sticker system would provide an intermediate safeguard as Schedule II substance surveillance evolves from a paper to electronic system and would be sunsetted in 1999.

OPPONENTS SAY:

CSHB 226, by completely replacing the triplicate prescription form, would remove important public safety controls that also provide sufficient and documentable evidence for successful prosecution of drug criminals. Triplicate forms are printed by DPS and distributed to practitioners by serial numbers, which can be double checked against signatures, traced to

negligent or abusing doctors and provide hard evidence of illegal activities.

Without readily identifiable forms, pharmacy liability would also increase because of statutory prohibitions against the dispensing of controlled substances to unauthorized individuals. Patient access to pain medication would be limited because many pharmacies will be extremely cautious in filling such prescriptions.

NOTES:

The committee substitute specified that offenses committed prior to January 1, 1998 would be subject to law in effect at the time and made other nonsubstantive changes to the filed version.

Rep. Hirschi plans to offer a floor amendment that would institute a system in which practitioner prescriptions would be traceable to the prescribing practitioner by the use of nonremovable, sequentially numbered, identifying stickers that would be developed by DPS and purchased by doctors. The sticker system would provide an intermediate safeguard as Schedule II substance surveillance evolves from a paper to electronic system and would be sunsetted in 1999.

Related legislation includes HB 2319 by Van de Putte, which would replace triplicate forms with sequentially numbered non-transferable stickers that attach to a normal prescription for Schedule II prescriptions and make other changes, and HB 1070 by Van de Putte, also on today's calendar, which would eliminate specified schedule lists from the law, establish new penalty groups, and make other changes.