BILL ANALYSIS

Senate Research Center
76R12802 JMM-F

C.S.S.B. 1524
By: Madla
Health Services
4/22/1999
Committee Report (Substituted)

DIGEST

Currently, pharmacists may refill narrow therapeutic index (NTI) drugs only by using the same drug product by the same manufacturer for which the medication was last dispensed; if the same drug is not in stock, the pharmacist may dispense a generic version, if the pharmacist notifies the patient and the prescribing physician by phone, fax, or mail. The Food and Drug Administration specifies NTI drugs as a small group of drugs in which the difference between a beneficial therapeutic amount and potentially dangerous amount of medication is very small. C.S.S.B. 1524 would set forth provisions for the refilling of a prescription for a narrow therapeutic index drug.

PURPOSE

As proposed, C.S.S.B. 1524 sets forth provisions for the refilling of a prescription for a narrow therapeutic index drug.

RULEMAKING AUTHORITY

Rulemaking authority is granted to the Texas Board of Pharmacy in SECTION 1 (Section 40(n) (1) and (2), Article 4542a-1, V.T.C.S. (Texas Pharmacy Act)) of this bill.

SECTION BY SECTION ANALYSIS

SECTION 1. Amends Section 40, Article 4542a-1, V.T.C.S. (Texas Pharmacy Act), by amending Subsection (m) and adding Subsections (n) and (o), to authorize a prescription for a narrow therapeutic index drug to be refilled with a generically equivalent drug from another manufacturer under certain conditions. Requires, as appropriate, but at least every two years, the board, in consultation with the Texas State Board of Medical Examiners, to determine under Chapter 2001, Government Code, whether any prescription drugs meet the definition of narrow therapeutic index drug under Subsection (o) of this section. Requires the board to make determinations required by this subsection based on scientific evidence presented by independent clinical studies, peer-reviewed literature, or any other reasonable method of demonstrating scientific evidence. Authorizes the board, to assist the board in making its determination, to appoint an advisory committee consisting of a cross-section of persons having professional credentials in pharmacology, the practice of medicine, drug manufacturing, or any other profession considered appropriate to evaluate prescription drugs for the purposes of this subsection. Requires the meetings and deliberations of the board or an advisory committee appointed under this subsection to be recorded and are subject to Chapters 551 and 552, Government Code. Requires the board, upon making its determination, to adopt, by rule, a list of the drugs determined to be narrow therapeutic index drugs, or publish in the Texas Register a certain statement which includes listing each drug that was evaluated by the board, and stating that none of the evaluated drugs were determined to be narrow therapeutic index drugs. Defines “narrow therapeutic index drug.”

SECTION 2. Emergency clause.
Effective date: upon passage.

SUMMARY OF COMMITTEE CHANGES

SECTION 1.

Amends Section 40, rather than Section 40(m), Article 4542a-1, V.T.C.S., by amending Subsection (m) and adding Subsections (n) and (o), to authorize a prescription for a narrow therapeutic index drug to be refilled with a generically equivalent drug from another manufacturer under certain conditions, including a patient or a person acting for the patient is notified at the time the prescription is dispensed that a substitution of the prescribed drug product has been made; and the prescribing practitioner is notified of the drug product substitution. Requires as appropriate, but at least every two years, the board, in consultation with the Texas State Board of Medical Examiners, to determine under Chapter 2001, Government Code, whether any prescription drugs meet the definition of narrow therapeutic index drug under Subsection (o) of this section. Requires the board to make determinations required by this subsection based on scientific evidence presented by independent clinical studies, peer-reviewed literature, or any other reasonable method of demonstrating scientific evidence. Authorizes the board, to assist the board in making its determination, to appoint an advisory committee consisting of a cross-section of persons having professional credentials in pharmacology, the practice of medicine, drug manufacturing, or any other profession considered appropriate to evaluate prescription drugs for the purposes of this subsection. Requires the meetings and deliberations of the board or an advisory committee appointed under this subsection to be recorded and are subject to Chapters 551 and 552, Government Code. Requires the board, upon making its determination, to adopt, by rule, a list of the drugs determined to be narrow therapeutic index drugs, or publish in the Texas Register a certain statement which includes listing each drug that was evaluated by the board, and stating that none of the evaluated drugs were determined to be narrow therapeutic index drugs. Revises the definition of "narrow therapeutic index drug." Deletes text requiring the board, in consultation with the Texas State Board of Medical Examiners, to establish, by rule, a list of narrow therapeutic index drugs; authorize a prescription for a narrow therapeutic index drug to be refilled; and authorize a pharmacist to dispense a drug product under certain circumstances. Deletes text regarding the open meetings law, Chapter 551, Government Code, and the open records law, Chapter 552, Government Code. Deletes proposed Subdivisions (2), (2)(a) and (b), and (3).