A BILL TO BE ENTITLED 1 AN ACT 2 relating to regulation of dispensing brand name and generic 3 prescriptions. BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS: 4 5 SECTION 1. Section 562.007, Occupations Code, is amended to 6 read as follows: 7 Sec. 562.007. REFILLS. A properly authorized prescription refill shall follow the original dispensing instruction unless 8 otherwise indicated by the practitioner or the practitioner's 9 agent. A prescription may not be refilled with a generic equivalent 10 if the original prescription form or dispensing directive required 11 12 a specifically prescribed brand as medically necessary. SECTION 2. Section 562.008, Occupations Code, is amended to 13 14 read as follows: Sec. 562.008. GENERIC EQUIVALENT AUTHORIZED. (a) If a 15 practitioner certifies on the prescription form that a specific 16 prescribed brand is medically necessary, the pharmacist shall 17 dispense the drug as written by the practitioner. The pharmacist 18 may substitute a generically equivalent drug only if the 19 practitioner certifies on the written prescription form that 20 21 substitution is permitted. A [The] certification must be made as required by the dispensing directive adopted under Section 562.015. 22 23 This subchapter does not permit a pharmacist to substitute a 24 generically equivalent drug unless the substitution is made as

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By: Wentworth

1 provided by this subchapter.

2 (b) Except as otherwise provided by this subchapter, a 3 pharmacist who receives a prescription for a drug for which there is 4 one or more generic equivalents may dispense any of the generic 5 equivalents <u>if otherwise permitted by the prescription or</u> 6 <u>dispensing directive</u>.

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SECTION 3. Section 562.009(a), Occupations Code, is amended to read as follows:

9 (a) A pharmacist who selects a generically equivalent drug 10 as authorized by this subchapter shall:

(1) personally, or through the pharmacist's agent or employee, and before delivery of a generically equivalent drug inform the patient or the patient's agent that a less expensive generically equivalent drug has been substituted for the brand prescribed and that the patient or the patient's agent is entitled to refuse that substitution; or

17 (2) display, in a prominent place that is in clear
18 public view where prescription drugs are dispensed, a sign in block
19 letters not less than one inch in height that reads, in both English
20 and Spanish:

"TEXAS LAW ALLOWS A LESS EXPENSIVE GENERICALLY
EQUIVALENT DRUG TO BE SUBSTITUTED FOR CERTAIN BRAND
NAME DRUGS <u>ONLY IF</u> [UNLESS] YOUR PHYSICIAN <u>AUTHORIZES</u>
<u>SUBSTITUTION</u> [DIRECTS OTHERWISE]. YOU HAVE A RIGHT TO
REFUSE SUCH SUBSTITUTION. CONSULT YOUR PHYSICIAN OR
PHARMACIST CONCERNING THE AVAILABILITY OF A SAFE, LESS
EXPENSIVE DRUG FOR YOUR USE."

1 SECTION 4. Section 562.015, Occupations Code, is amended to 2 read as follows:

Sec. 562.015. DISPENSING DIRECTIVE; 3 COMPLIANCE WITH 4 FEDERAL LAW. (a) The board shall adopt rules to provide a 5 dispensing directive to instruct pharmacists on the manner in which to dispense a drug according to the contents of a written 6 7 prescription or an electronically transmitted prescription. The 8 rules adopted under this section must:

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(1) require the physician to sign on a line marked:

[the use of the phrase] "brand necessary" [or 10 (A) "brand medically necessary"] on a prescription form to prohibit the 11 12 substitution of a generically equivalent drug for a brand name 13 drug; or

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(B) "substitution permitted" on a prescription 15 form to permit the substitution of a generically equivalent drug 16 for a brand name drug;

(2) be in a format that protects confidentiality as 17 required by the Health Insurance Portability and Accountability Act 18 of 1996 (29 U.S.C. Section 1181 et seq.) and its subsequent 19 amendments; 20

comply with federal and state law, including 21 (3) rules, with regard to formatting and security requirements; 22

(4) be developed to coordinate with 42 C.F.R. Section 23 24 447.331(c); and

(5) require that an electronically transmitted 25 prescription include "brand necessary" or "brand medically 26 necessary" to prohibit the substitution of a generically equivalent 27

1 drug for a brand name drug [include an exemption for electronic
2 prescriptions as provided by Subsection (b)].

3 (b) [The board shall provide an exemption from the directive 4 adopted under this section for prescriptions transmitted 5 electronically.] The board may regulate the use of electronic 6 prescriptions in the manner provided by federal law, including 7 rules.

8 SECTION 5. Not later than January 1, 2006, the Texas State 9 Board of Pharmacy shall adopt rules as required by Section 562.015, 10 Occupations Code, as amended by this Act.

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SECTION 6. This Act takes effect September 1, 2005.