Amend **CSHB 2145**, Senate committee printing, as follows:

(1) Insert the following new SECTIONS, appropriately numbered:

SECTION ____. Subtitle H, Title 8, Insurance Code, is amended by adding Chapter 1626 to read as follows:

CHAPTER 1626. DRUG INTERCHANGE PROGRAMS WITH CERTAIN GOVERNMENT HEALTH BENEFIT PLANS

Sec. 1626.001. DEFINITIONS. In this chapter:

(1) "Actual cost savings" means, with respect to a proposed drug interchange, the actual amount in dollars a client plan and patient, respectively, will save in net drug costs annually if a drug interchange occurs at the expected dosage, assuming the patient will use the drug for 12 months.

(2) "Board" means the Texas State Board of Pharmacy.

(3) "Class E pharmacy" has the meaning assigned by Section 560.051(f), Occupations Code.

(4) "Clear and conspicuous," as regards a disclosure under this chapter, means a disclosure made in such a size, color, contrast, and location that:

(A) is readily noticeable, readable, and understandable;

(B) is presented in proximity to all information necessary to prevent it from being misleading or deceptive;

(C) is presented in a manner that the information is readily noticeable, readable, and understandable and not obscured in any manner; and

(D) if a print disclosure, appears in a type size, contrast, and location sufficient for a patient or practitioner to read and comprehend the disclosure.

(5) "Client plan" means a health benefit plan provided under Chapter 1551, 1575, 1579, or 1601 for which a Class E pharmacy, under contract, provides or administers pharmacy benefits.

(6) "Currently prescribed drug" means a drug prescribed for a patient that is the subject of a drug interchange solicitation by a Class E pharmacy.

(7) "Drug interchange" means any change from one

prescription drug to another that is requested by a Class E pharmacy. The term does not include a drug interchange:

(A) initiated under a drug utilization review;

(B) initiated for patient safety reasons;

(C) required due to market unavailability of the currently prescribed drug;

(D) from a brand drug to a generically or pharmaceutically equivalent drug, as defined by Section 562.001, Occupations Code; or

(E) required because the currently prescribed drug is not covered by the formulary or plan applicable to the patient.

(8) "Drug interchange-related health care costs" means a patient's copayments or deductibles for tests, doctor visits, and other health care services that are incurred in accordance with a treating physician's instructions, and are incurred as a result of:

(A) a drug interchange for the purpose of assessing the continuum of the previous therapy for up to six months following the drug interchange; or

(B) a drug interchange solicitation for the purpose of assessing whether to undertake a proposed drug interchange.

(9) "Drug interchange solicitation" means a communication by a Class E pharmacy to request a drug interchange.

(10) "Generically equivalent" has the meaning assigned by Section 562.001, Occupations Code.

(11) "Manufacturer additional payments" means all manufacturer payments other than manufacturer formulary payments.

(12) "Manufacturer formulary payments" means payments that:

(A) a Class E pharmacy receives from a manufacturer in return for formulary placement or access; or

(B) are characterized as "formulary" or "base" rebates under agreements by the Class E pharmacy with pharmaceutical manufacturers.

(13) "Manufacturer payments" means all compensation a

Class E pharmacy receives from a pharmaceutical manufacturer, including rebates, regardless of how categorized, market share incentives, commissions, mail service purchase discounts, administrative or management fees, and any fees received for sales of utilization data to a pharmaceutical manufacturer. The term does not include purchase discounts based on invoiced purchase terms.

(14) "Minimum cost savings" means the minimum dollar amount a client plan and patient, respectively, will save annually if a drug interchange occurred at the expected dosage.

(15) "Net drug cost" means the price a Class E pharmacy charges a client plan or patient for a prescription drug whether that drug is delivered through a retail pharmacy or mail order. The term may include all discounts, rebates, credits, or other payments that lower the cost of the drug, to the extent those payments are provided to the client plan, and may be reduced by manufacturer payments to the extent those payments are provided to the client plan, but may not be reduced by manufacturer payments that are paid to and retained by the Class E pharmacy.

(16) "Patient" means a person whose prescription drug benefit is administered by a Class E pharmacy.

(17) "Practitioner" has the meaning assigned by Section 551.003(34), Occupations Code.

(18) "Proposed drug" means a drug that a Class E pharmacy in its drug interchange solicitation proposes to substitute for a currently prescribed drug.

(19) "Total product revenue" means a Class E pharmacy's net revenue that consists principally of sales of prescription drugs to clients.

Sec. 1626.002. PROHIBITED ACTS. (a) Unless otherwise specifically directed by a client plan with respect to a proposed drug interchange, a Class E pharmacy may not make a drug interchange solicitation under which:

(1) the net drug cost of the proposed drug exceeds that of the currently prescribed drug;

(2) the currently prescribed drug has a generically equivalent drug and the proposed drug does not have a generically

equivalent drug, unless the proposed drug has a lower net drug cost than all generically equivalent drugs of the currently prescribed drug; or

(3) the patent protection for the currently prescribed drug is scheduled to expire within six months of the drug interchange solicitation, or the reasonable effect of the proposed drug interchange is to avoid substitution for, or generic competition against, the currently prescribed drug, other than a drug interchange that has the effect of decreasing net drug costs.

(b) A Class E pharmacy may not make any drug interchange that fails to disclose to practitioners and patients, clearly and conspicuously, minimum cost savings or actual cost savings, as well as the difference, if any, in copayments to be made by the patient, or, if there is no effect, the absence of effect on copayments. In making a disclosure, a Class E pharmacy may reasonably rely on information provided by the client plan with respect to eligibility and copayments without regard to applicable deductibles and maximum plan benefits.

(c) A Class E pharmacy may not make any drug interchange solicitation to a patient who, within two years preceding the solicitation, and with respect to the same therapeutic class of drug products involved in the proposed drug interchange, has:

(1) interchanged the patient's drug following a drug interchange solicitation from the Class E pharmacy; or

(2) interchanged the patient's drug following a Class E pharmacy drug interchange solicitation but had the interchange reversed, unless all of the proposed drugs in the current drug interchange solicitation were not among the proposed drugs included in the prior drug interchange solicitation.

Sec. 1626.003. PAYMENT OF DRUG INTERCHANGE RELATED COSTS: DISCLOSURE REQUIREMENTS. (a) A Class E pharmacy shall pay all out-of-pocket costs for drug interchange-related health care costs incurred by a patient by reimbursing the patient for those costs not later than the 30th day after receipt by the pharmacy of a claim form for those costs.

(b) Each Class E pharmacy shall enact and follow a procedure for reimbursing patients for out-of-pocket costs described by

Subsection (a) under which the Class E pharmacy shall:

(1) permit patients, practitioners, or treating physicians to request the reimbursement by telephone or in writing; and

(2) on receipt of the request, provide a single-page claim form with instructions to request reimbursement.

(c) For reimbursement requests initiated by patients, the Class E pharmacy may require that the patient's reimbursement claim provide information showing that the patient incurred drug interchange-related health care costs. The patient may satisfy the requirement by providing the physician's or practitioner's notation at a designated place on the claim form or the physician's written order, or through other evidence that shows payment of costs, including costs for copayments or deductibles for tests or doctor visits incurred as a result of a drug interchange. The Class E pharmacy may not directly or indirectly prevent or discourage patients or physicians from requesting or receiving reimbursement for drug interchange-related health care costs.

(d) The Class E pharmacy's written communications to both practitioners and patients concerning drug interchanges must clearly and conspicuously disclose the pharmacy's policy, consistent with this section, with respect to drug interchange-related health care costs. Telephone communications by the pharmacy with practitioners and patients concerning drug interchanges must communicate the existence of the pharmacy's policies with respect to drug interchange-related health care costs. Communications under this subsection with practitioners, patients, and client plans may not misrepresent, directly or indirectly, the pharmacy's policy with respect to drug interchange-related health care costs.

(e) If drug interchange-related health care costs paid to a patient with respect to any particular interchange exceed $500, the Class E pharmacy, while complying with the timely reimbursement requirement under Subsection (a), may choose to have a third party chosen by the pharmacy review the costs paid. If a determination is made that the costs were not related to an interchange, this section may not be construed as preventing the pharmacy from pursuing any

legal remedies the pharmacy may have against the patient and any other involved party.

Sec. 1626.004. SOLICITATION PROCESS; DISCLOSURE OF PRICING INFORMATION. (a) A Class E pharmacy may not interchange, or obtain an interchange promise for, the prescription drug of any patient without first obtaining the express verifiable authorization of the practitioner who prescribed the currently prescribed drug. Each drug interchange solicitation to a practitioner must:

(1) identify the name and title of the person making the drug interchange solicitation;

(2) state that the Class E pharmacy is soliciting a drug interchange;

(3) identify the minimum cost savings or actual cost savings to be achieved by interchanging to the proposed drug from the currently prescribed drug;

(4) describe under what circumstances the currently prescribed drug will continue to be covered by the client plan, if that is the case;

(5) describe the difference in the applicable copayment, if any, or the absence of any effect on the applicable copayment;

(6) if the pharmacy receives manufacturer payments from a drug manufacturer as a result of the proposed drug interchange or the interchange solicitation that is not reflected in the net drug cost because the manufacturer payments do not inure to the pharmacy's client plan, disclose that the pharmacy receives those payments or potential payments;

(7) disclose the existence of the pharmacy's policy with respect to drug interchange-related health care costs, as described by Section 1626.003; and

(8) disclose any material differences between the currently prescribed drug and the proposed drug regarding side effects or potential effects on patient health and safety.

(b) A Class E pharmacy may not interchange a patient's drug without express verifiable authorization from the practitioner as communicated directly by the practitioner, either in writing or verbally, or by a person who affirms in writing or verbally that the

interchange has been authorized by the practitioner. If the authorization is by a person other than the practitioner and verbal, the Class E pharmacy shall request that person's name and title or position. The Class E pharmacy shall maintain records documenting, with respect to each drug interchange, how the express verifiable authorization was obtained, including the name of the person providing the authorization, whether the authorization was written or verbal, and, if verbal and by a person other than the practitioner, that person's title or position, if provided.

(c) On receipt of authorization under Subsection (b), the Class E pharmacy shall send a written communication to the practitioner confirming the interchange. If the interchange solicitation under Subsection (a) was not in writing, the written confirmation must include the information required by Subsection (a). Regardless of whether the interchange solicitation was in writing, the written confirmation must:

(1) identify the minimum cost savings or actual cost savings resulting from the interchange;

(2) clearly and conspicuously disclose the pharmacy's policy with respect to drug interchange-related health care costs, in accordance with Section 1626.003; and

(3) provide a toll-free telephone number for the prescribing practitioner.

Sec. 1626.005. PATIENT DRUG INTERCHANGE NOTICE. (a) With respect to home delivery prescriptions, not later than the earlier of 24 hours after receipt of an authorization of a drug interchange by the practitioner or dispensing the proposed drug, the Class E pharmacy shall send the patient a written notice and make a telephonic communication advising the patient of the practitioner's approval of the drug interchange.

(b) Following receipt of authorization for a non-home delivery prescription, the pharmacy shall send the patient a written notice that clearly and conspicuously:

(1) states that the pharmacy requested a drug interchange by contacting the patient's practitioner;

(2) states that, following the pharmacy's interchange solicitation, the practitioner approved the drug interchange;

(3) identifies the proposed drug and the currently prescribed drug;

(4) identifies the minimum cost savings or actual cost savings;

(5) describes under what circumstances the currently prescribed drug will continue to be covered by the client plan, if that is the case;

(6) describes any difference in the applicable copayment or the absence of any effect on the applicable copayment;

(7) if the pharmacy receives compensation from a drug manufacturer as a result of the proposed drug interchange or the drug interchange solicitation that is not reflected in the net drug cost because it is compensation that does not inure to the pharmacy's client plan, discloses the fact of that compensation or potential compensation;

(8) discloses the pharmacy's policy with respect to drug interchange-related health care costs, in accordance with Section 1626.003; and

(9) advises the patient that the patient may decline the drug interchange, in which case the patient will receive the currently prescribed drug if the currently prescribed drug remains on the client plan's formulary and the patient is willing to pay any difference in the applicable copayment.

(c) The telephonic communication described by Subsection (a) must:

(1) state that the Class E pharmacy requested a drug interchange by contacting the patient's practitioner;

(2) state that, following the pharmacy's interchange solicitation, the practitioner approved the drug interchange;

(3) advise the patient that further written information about the drug interchange will arrive in the mail; and

(4) provide the pharmacy's toll-free telephone number so that the patient may speak to a customer service representative about the interchange.

(d) A disclosure under Subsection (b) or (c) may not represent that the practitioner initiated the drug interchange.

Sec. 1626.006. REJECTED INTERCHANGES. (a) Unless a

currently prescribed drug is no longer on the client plan's formulary or the patient is unwilling to pay any higher applicable copayment or other costs, a Class E pharmacy shall cancel and reverse a drug interchange on written or verbal instructions from a practitioner or patient. The Class E pharmacy shall maintain a toll-free telephone number during business hours to handle telephone calls from patients and practitioners in response to the pharmacy's interchange confirmations, and the customer service standards for those telephone numbers must be equivalent to the pharmacy's other customer service standards.

(b) On cancellation, if the Class E pharmacy has not yet dispensed the proposed drug, the pharmacy on approval of the practitioner shall dispense the currently prescribed drug. If the pharmacy has already dispensed the proposed drug, the pharmacy shall obtain a prescription for and dispense the currently prescribed drug, and may charge the patient only one copayment and shipping and handling fees. Unless otherwise provided by contract with a client plan, the pharmacy shall also bear the expense of shipping the proposed drug back to the pharmacy, either by offset or by reversing and crediting the initial copayment.

(c) Each Class E pharmacy shall provide notice to each client plan that the client plan may request information regarding the costs to the plan resulting from a patient's rejection of a proposed drug interchange. If a patient will exhaust the patient's supply of the currently prescribed drug before a replacement shipment will arrive to the patient, the pharmacy shall arrange for dispensing of an appropriate quantity of replacement medications at a participating network pharmacy at no additional cost to the patient. If a patient reverses an interchange and the Class E pharmacy is unable to obtain approval from the practitioner or a physician covering for the practitioner for the currently prescribed drug, the pharmacy shall take reasonable steps to provide the currently prescribed drug or the proposed drug before the patient exhausts the patient's existing supply.

Sec. 1626.007. ROLE OF ADVISORY COMMITTEE. (a) If a Class E pharmacy uses an advisory committee of health care professionals to assist the pharmacy in establishing drug formularies and

determining clinical criteria used by the pharmacy as a basis for the pharmacy's drug interchange program, the pharmacy may not misrepresent the role of the advisory committee in initiating, reviewing, approving, or endorsing a proposed drug interchange or interchange solicitation. If the pharmacy mentions the advisory committee in any interchange solicitation or communication related to drug interchanges, the pharmacy shall clearly and conspicuously disclose:

(1) the role of the advisory committee in the pharmacy's interchange proposal;

(2) that the interchange being proposed was not initiated by the advisory committee and not initiated due to medical care considerations; and

(3) that the advisory committee did not consider cost issues, if such is the case.

(b) With respect to the operation of the advisory committee, the Class E pharmacy shall provide to each client plan at the plan's expense, unless the client plan contract provides otherwise, on request:

(1) copies of all information provided to the advisory committee; and

(2) copies of all minutes of the advisory committee that include:

(A) the list of attendees at the advisory committee meeting;

(B) the record of all votes to approve or disapprove a drug for a formulary, recommend a therapeutically equivalent drug interchange, or take other action;

(C) a summary of any discussion of material differences between a currently prescribed drug and a proposed drug with respect to side effects or potential effects on patient health and safety; and

(D) a summary of all discussions on each agenda point.

(c) In addition to the requirements under Subsections (a) and (b), the Class E pharmacy shall advise each client plan that the plan may send a representative, at the plan's expense, to attend any

advisory committee meeting.

(d) If an advisory committee approves a drug interchange with conditions, the Class E pharmacy shall provide a complete description of those conditions to the practitioner at the time of the interchange solicitation.

Sec. 1626.008. MONITORING OF HEALTH EFFECTS OF DRUG INTERCHANGE. Each Class E pharmacy shall monitor the effects of drug interchanges requested by the pharmacy on the health of patients, and shall report to its advisory committee, if any, not less than quarterly, the results of that monitoring. The monitoring must include a system designed to identify patient and practitioner communications with the pharmacy that concern the efficacy or health effects of a drug interchange, and maintain the information received from those communications in a manner that allows the pharmacy to collect and generate reports on patient and practitioner communications concerning drug interchanges. The pharmacy shall report the results of the monitoring to its advisory committee, if any, not less than quarterly, and the committee shall reasonably consider the results of the monitoring.

Sec. 1626.009. DISCLOSURE TO CLIENT PLANS OF COMPENSATION FROM DRUG MANUFACTURERS. (a) With respect to each client plan that has contracted to receive any manufacturer payments from a Class E pharmacy, for each pharmacy fiscal year during which the client plan receives a manufacturer payment, the pharmacy shall provide a report for each fiscal quarter and fiscal year. A payment report must provide the information required under Subsection (b). If the precise reported figure is not known by the pharmacy at the time of the report, the pharmacy shall provide its current best estimate of the reported information, and shall provide an update to the reported information to reflect any revision.

(b) The report must include:

(1) the dollar amount of total product revenue for the reporting period, with respect to the Class E pharmacy's entire client base;

(2) the dollar amount of total drug expenditures for each client plan;

(3) the dollar amount of all manufacturer payments

earned by the pharmacy for the reporting period;

(4) the percentage of all manufacturer payments earned by the pharmacy for the reporting period that were manufacturer formulary payments; and

(5) the percentage of all manufacturer payments received by the pharmacy during the reporting period that were manufacturer additional payments.

(c) A manufacturer payment report must present the required information in a clear and conspicuous manner that serves to inform client plans of all manufacturer payments earned by the Class E pharmacy, including client plans that share in manufacturer formulary payments but not manufacturer additional payments.

(d) The Class E pharmacy shall disclose to each client plan or prospective client plan, in advance of executing an initial or renewal contract with the plan:

(1) that the pharmacy solicits and receives manufacturer payments and may pass through those payments to client plans or may retain those payments, depending on contract terms;

(2) the information required under Subsection (b) concerning the most recent fiscal year for which the information is publicly available at the time of the communication under this subsection; and

(3) that the pharmacy must report, quarterly and annually, on manufacturer payments, as required by this section.

Sec. 1626.010. PHARMACY ETHICS. (a) Each Class E pharmacy contracting to provide pharmacy benefits for a client plan shall adopt the code of ethics of the American Pharmacists Association or an analogous code of ethics recognized by the board for its employed pharmacists. The pharmacy shall accept the association's principles of practice for pharmaceutical care or analogous principles recognized by the board as a framework for ongoing evolution of its pharmacy practice. The pharmacy shall provide these documents to all staff pharmacists with any explanations as necessary to make clear to staff pharmacists that the Class E pharmacy is striving to achieve the objectives established by the profession.

(b) The Class E pharmacy shall make available to its

employed pharmacists, client plans, and patients copies of those codes of ethics or professional standards, which may be made available in electronic form or on an Internet website.

(c) The Class E pharmacy shall require its pharmacists to comply with all state law requirements governing pharmacists.

(d) The Class E pharmacy shall permit its pharmacists to give good faith professional opinions.

(e) The Class E pharmacy shall require that its pharmacists form an independent professional judgment that a drug interchange would be in a patient's best interest before soliciting a drug interchange.

Sec. 1626.011. ADDITIONAL PRICE TRANSPARENCY REMEDIES. (a) A Class E pharmacy contracting to provide pharmacy benefits for a client plan may not refuse to respond to a request for a proposal or a request for a bid from a client plan on the grounds that the proposal does not use the average wholesale price or prohibits the use of the average wholesale price in pricing terms, and the pharmacy, if asked, shall communicate to each plan that pricing methods other than use of the average wholesale price are available.

(b) The pharmacy may not describe relative prices of drugs by use of symbols or other indirect means without disclosing the price range those symbols represent.

SECTION ____. Section 562.013, Occupations Code, is amended to read as follows:

Sec. 562.013. APPLICABILITY OF SUBCHAPTER. (a) Unless a drug is determined to be generically equivalent to the brand prescribed, drug selection as authorized by this subchapter does not apply to:

(1) an enteric-coated tablet;

(2) a controlled release product;

(3) an injectable suspension, other than an antibiotic;

(4) a suppository containing active ingredients for which systemic absorption is necessary for therapeutic activity; or

(5) a different delivery system for aerosol or nebulizer drugs.

(b) This subchapter applies to a drug interchange program described by Chapter 1626, Insurance Code, except to the extent of any conflict with that chapter. In the event of a conflict between Chapter 1626, Insurance Code, and this subchapter, Chapter 1626, Insurance Code, controls.

SECTION ____. This Act applies to a health benefit plan provided under Subtitle H, Title 8, Insurance Code, beginning with the 2005-2006 plan year.

(2) Strike SECTION 5 (page 2, lines 2-3, senate committee printing).

(3) Renumber the SECTIONS of the bill accordingly.