MISSISSIPPI LEGISLATURE REGULAR SESSION 2009

By: Representatives Lane, Evans (91st), Scott

To: Public Health and Human Services; Judiciary A

HOUSE BILL NO. 811

AN ACT TO REQUIRE PHARMACEUTICAL MANUFACTURING COMPANIES TO DISCLOSE ANNUALLY TO THE STATE DEPARTMENT OF HEALTH THE VALUE, NATURE AND PURPOSE OF ANY GIFT, FEE, PAYMENT, SUBSIDY OR OTHER ECONOMIC BENEFIT PROVIDED IN CONNECTION WITH PROMOTIONAL OR OTHER MARKETING ACTIVITIES BY THE COMPANY TO ANY PHYSICIAN OR NURSE PRACTITIONER OR ANY MEMBER OF THE IMMEDIATE FAMILY OF THE PHYSICIAN OR NURSE PRACTITIONER, INCLUDING THE NAMES OF THE RECIPIENTS; TO PROVIDE FOR CERTAIN EXEMPTIONS FROM THE DISCLOSURE REQUIREMENT; TO AUTHORIZE THE DEPARTMENT TO BRING LEGAL ACTIONS TO ENFORCE COMPLIANCE WITH THE REQUIRED DISCLOSURE, AND TO IMPOSE CIVIL PENALTIES FOR VIOLATIONS; TO REQUIRE PHYSICIANS AND NURSE PRACTITIONERS WHO ARE RECEIVING GIFTS, FEES, PAYMENTS, SUBSIDIES OR OTHER ECONOMIC BENEFITS FROM PHARMACEUTICAL MANUFACTURING COMPANIES FOR PRESCRIBING SPECIFIC DRUGS TO THEIR PATIENTS TO INFORM EACH PATIENT FOR WHOM THEY PRESCRIBE SUCH A DRUG THAT THEY ARE RECEIVING BENEFITS FROM A PHARMACEUTICAL COMPANY FOR PRESCRIBING THAT DRUG; TO AMEND SECTIONS 73-15-29 AND 73-25-29, MISSISSIPPI CODE OF 1972, TO AUTHORIZE THE LICENSING BOARDS OF NURSE PRACTITIONERS AND PHYSICIANS TO DISCIPLINE THEIR LICENSEES WHO REPEATEDLY FAIL TO MAKE THE DISCLOSURE TO PATIENTS AS REQUIRED IN THE PRECEDING PROVISION; AND FOR RELATED PURPOSES.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF MISSISSIPPI:

SECTION 1. (1) As used in this act:

(a) "Approved clinical trial" means a clinical trial that has been approved by the United States Food and Drug Administration (FDA) or has been approved by a duly constituted Institutional Review Board (IRB) after reviewing and evaluating it in accordance with the human subject protection standards set forth at 21 CFR Part 50, 45 CFR Part 46, or an equivalent set of standards of another federal agency.

(b) "Bona fide clinical trial" means an approved clinical trial that constitutes "research" as that term is defined in 45 CFR Section 46.102 when the results of the research can be published freely by the investigator and reasonably can be

considered to be of interest to scientists or medical practitioners working in the particular field of inquiry.

(c) "Clinical trial" means any study assessing the safety or efficacy of drugs administered alone or in combination with other drugs or other therapies, or assessing the relative safety or efficacy of drugs in comparison with other drugs or other therapies.

(d) "Pharmaceutical manufacturing company" means any entity that is engaged in the production, preparation, propagation, compounding, conversion, or processing of prescription drugs, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling, or distribution of prescription drugs. The term does not include a pharmacist or wholesale drug distributor licensed or registered under Section 73-21-71 et seq.

(e) "Pharmaceutical marketer" means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional activities, or other marketing of prescription drugs to any physician or nurse practitioner in the state. This term does not include a wholesale drug distributor registered under Section 73-21-71 et seq. or the distributor's representative who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug.

(2) (a) Annually on or before December 1 of each year, every pharmaceutical manufacturing company shall disclose to the State Department of Health the value, nature, and purpose of any gift, fee, payment, subsidy or other economic benefit provided in connection with detailing, promotional, or other marketing activities by the company, directly or through its pharmaceutical marketers, to any physician or nurse practitioner in the state or

any member of the immediate family of a physician or nurse practitioner in the state, and shall include the names of the recipients of the gifts, fees, payments, subsidies and other economic benefits. The disclosure shall be made on a form and in a manner prescribed by the department, and shall require the pharmaceutical manufacturing companies to report the value, nature, and purpose of all gifts, fees, payments, subsidies and other economic benefits provided according to specific categories. The department shall report annually on the disclosures made under this section to the Legislature and the Governor not later than April 1 of each year.

(b) The disclosure required by paragraph (a) shall include any gift, fee, payment, subsidy, or other economic benefit provided to any physician or nurse practitioner in the state or any member of the immediate family of a physician or nurse practitioner in the state, under a contractual arrangement or other agreement between the pharmaceutical manufacturing company and the physician or nurse practitioner by which the company will provide a gift, fee, payment, subsidy, or other economic benefit to the physician or nurse practitioner for prescribing a specific drug to his or her patients.

(c) Annually on October 1, each pharmaceutical manufacturing company subject to the provisions of this section also shall disclose to the department the name and address of the individual responsible for the company's compliance with the provisions of this section, or if this information has been previously reported, any changes to the name or address of the individual responsible for the company's compliance with the provisions of this section.

(d) The department shall keep confidential all trade secret information, as defined in Section 75-26-3, provided by pharmaceutical manufacturing companies in the required disclosure. The disclosure form shall permit the company to identify any

information that it claims is a trade secret. If the department receives a request for any information designated as a trade secret, the department may release that information only as provided under Section 25-61-1 et seq.

(e) The following shall be exempt from disclosure:

(i) Free samples of prescription drugs intended to be distributed to patients;

(ii) Prescription drug rebates and discounts;

(iii) The payment of reasonable compensation and reimbursement of expenses in connection with bona fide clinical trials; and

(iv) Food and beverages for immediate consumption provided by a pharmaceutical manufacturing company or pharmaceutical marketer up to a value of Ten Dollars ($10.00) in the aggregate during any calendar year.

(3) If any pharmaceutical manufacturing company fails to make the disclosure required by this section, the department may bring an action in any court of competent jurisdiction for injunctive relief, costs and attorneys fees to enforce compliance with the required disclosure, and to impose a civil penalty of not more than Ten Thousand Dollars ($10,000.00) per violation. Each unlawful failure to disclose shall constitute a separate violation.

SECTION 2. If a pharmaceutical manufacturing company provides any gift, fee, payment, subsidy, or other economic benefit to a physician or nurse practitioner or any member of the immediate family of a physician or nurse practitioner in the state, under a contractual arrangement or other agreement between the pharmaceutical manufacturing company and the physician or nurse practitioner by which the company will provide a gift, fee, payment, subsidy, or other economic benefit to the physician or nurse practitioner for prescribing a specific drug to his or her patients, the physician or nurse practitioner shall inform each

patient for whom he or she prescribes that drug that he or she is receiving a gift, fee, payment, subsidy, or other economic benefit from a pharmaceutical manufacturing company for prescribing that drug to the patient.

SECTION 3. Section 73-15-29, Mississippi Code of 1972, is amended as follows:

73-15-29. (1) The board shall have power to revoke, suspend or refuse to renew any license issued by the board, or to revoke or suspend any privilege to practice, or to deny an application for a license, or to fine, place on probation and/or discipline a licensee, in any manner specified in this article, upon proof that such person:

(a) Has committed fraud or deceit in securing or attempting to secure such license;

(b) Has been convicted of felony, or a crime involving moral turpitude or has had accepted by a court a plea of nolo contendere to a felony or a crime involving moral turpitude (a certified copy of the judgment of the court of competent jurisdiction of such conviction or pleas shall be prima facie evidence of such conviction);

(c) Has negligently or willfully acted in a manner inconsistent with the health or safety of the persons under the licensee's care;

(d) Has had a license or privilege to practice as a registered nurse or a licensed practical nurse suspended or revoked in any jurisdiction, has voluntarily surrendered such license or privilege to practice in any jurisdiction, has been placed on probation as a registered nurse or licensed practical nurse in any jurisdiction or has been placed under a disciplinary order(s) in any manner as a registered nurse or licensed practical nurse in any jurisdiction, (a certified copy of the order of suspension, revocation, probation or disciplinary action shall be prima facie evidence of such action);

(e) Has negligently or willfully practiced nursing in a manner that fails to meet generally accepted standards of such nursing practice;

(f) Has negligently or willfully violated any order, rule or regulation of the board pertaining to nursing practice or licensure;

(g) Has falsified or in a repeatedly negligent manner made incorrect entries or failed to make essential entries on records;

(h) Is addicted to or dependent on alcohol or other habit-forming drugs or is a habitual user of narcotics, barbiturates, amphetamines, hallucinogens, or other drugs having similar effect, or has misappropriated any medication;

(i) Has a physical, mental or emotional condition that renders the licensee unable to perform nursing services or duties with reasonable skill and safety;

(j) Has engaged in any other conduct, whether of the same or of a different character from that specified in this article, that would constitute a crime as defined in Title 97 of the Mississippi Code of 1972, as now or hereafter amended, and that relates to such person's employment as a registered nurse or licensed practical nurse;

(k) Engages in conduct likely to deceive, defraud or harm the public;

(l) Engages in any unprofessional conduct as identified by the board in its rules; *** * ***

(m) Has repeatedly failed to make the required disclosure to patients as provided in Section 2 of this act; or

(n) Has violated any provision of this article.

(2) When the board finds any person unqualified because of any of the grounds set forth in subsection (1) of this section, it may enter an order imposing one or more of the following penalties:

(a) Denying application for a license or other authorization to practice nursing or practical nursing;

(b) Administering a reprimand;

(c) Suspending or restricting the license or other authorization to practice as a registered nurse or licensed practical nurse for up to two (2) years without review;

(d) Revoking the license or other authorization to practice nursing or practical nursing;

(e) Requiring the disciplinee to submit to care, counseling or treatment by persons and/or agencies approved or designated by the board as a condition for initial, continued or renewed licensure or other authorization to practice nursing or practical nursing;

(f) Requiring the disciplinee to participate in a program of education prescribed by the board as a condition for initial, continued or renewed licensure or other authorization to practice;

(g) Requiring the disciplinee to practice under the supervision of a registered nurse for a specified period of time; or

(h) Imposing a fine not to exceed Five Hundred Dollars ($500.00).

(3) In addition to the grounds specified in subsection (1) of this section, the board shall be authorized to suspend the license or privilege to practice of any licensee for being out of compliance with an order for support, as defined in Section 93-11-153. The procedure for suspension of a license or privilege to practice for being out of compliance with an order for support, and the procedure for the reissuance or reinstatement of a license or privilege to practice suspended for that purpose, and the payment of any fees for the reissuance or reinstatement of a license or privilege to practice suspended for that purpose, shall be governed by Section 93-11-157 or 93-11-163, as the case may be.

If there is any conflict between any provision of Section 93-11-157 or 93-11-163 and any provision of this article, the provisions of Section 93-11-157 or 93-11-163, as the case may be, shall control.

(4) If the public health, safety or welfare imperatively requires emergency action and the board incorporates a finding to that effect in an order, the board may order summary suspension of a license pending proceedings for revocation or other action. These proceedings shall be promptly instituted and determined by the board.

SECTION 4. Section 73-25-29, Mississippi Code of 1972, is amended as follows:

73-25-29. The grounds for the nonissuance, suspension, revocation or restriction of a license or the denial of reinstatement or renewal of a license are:

(1) Habitual personal use of narcotic drugs, or any other drug having addiction-forming or addiction-sustaining liability.

(2) Habitual use of intoxicating liquors, or any beverage, to an extent which affects professional competency.

(3) Administering, dispensing or prescribing any narcotic drug, or any other drug having addiction-forming or addiction-sustaining liability otherwise than in the course of legitimate professional practice.

(4) Conviction of violation of any federal or state law regulating the possession, distribution or use of any narcotic drug or any drug considered a controlled substance under state or federal law, a certified copy of the conviction order or judgment rendered by the trial court being prima facie evidence thereof, notwithstanding the pendency of any appeal.

(5) Procuring, or attempting to procure, or aiding in, an abortion that is not medically indicated.

(6) Conviction of a felony or misdemeanor involving moral turpitude, a certified copy of the conviction order or judgment rendered by the trial court being prima facie evidence thereof, notwithstanding the pendency of any appeal.

(7) Obtaining or attempting to obtain a license by fraud or deception.

(8) Unprofessional conduct, which includes, but is not limited to:

(a) Practicing medicine under a false or assumed name or impersonating another practitioner, living or dead.

(b) Knowingly performing any act which in any way assists an unlicensed person to practice medicine.

(c) Making or willfully causing to be made any flamboyant claims concerning the licensee's professional excellence.

(d) Being guilty of any dishonorable or unethical conduct likely to deceive, defraud or harm the public.

(e) Obtaining a fee as personal compensation or gain from a person on fraudulent representation of a disease or injury condition generally considered incurable by competent medical authority in the light of current scientific knowledge and practice can be cured or offering, undertaking, attempting or agreeing to cure or treat the same by a secret method, which he refuses to divulge to the board upon request.

(f) Use of any false, fraudulent or forged statement or document, or the use of any fraudulent, deceitful, dishonest or immoral practice in connection with any of the licensing requirements, including the signing in his professional capacity any certificate that is known to be false at the time he makes or signs such certificate.

(g) Failing to identify a physician's school of practice in all professional uses of his name by use of his earned degree or a description of his school of practice.

(9) The refusal of a licensing authority of another state or jurisdiction to issue or renew a license, permit or certificate to practice medicine in that jurisdiction or the revocation, suspension or other restriction imposed on a license, permit or certificate issued by such licensing authority which prevents or restricts practice in that jurisdiction, a certified copy of the disciplinary order or action taken by the other state or jurisdiction being prima facie evidence thereof, notwithstanding the pendency of any appeal.

(10) Surrender of a license or authorization to practice medicine in another state or jurisdiction or surrender of membership on any medical staff or in any medical or professional association or society while under disciplinary investigation by any of those authorities or bodies for acts or conduct similar to acts or conduct which would constitute grounds for action as defined in this section.

(11) Final sanctions imposed by the United States Department of Health and Human Services, Office of Inspector General or any successor federal agency or office, based upon a finding of incompetency, gross misconduct or failure to meet professionally recognized standards of health care; a certified copy of the notice of final sanction being prima facie evidence thereof. As used in this paragraph, the term "final sanction" means the written notice to a physician from the United States Department of Health and Human Services, Officer of Inspector General or any successor federal agency or office, which implements the exclusion.

(12) Failure to furnish the board, its investigators or representatives information legally requested by the board.

(13) Repeated failure to make the required disclosure to patients as provided in Section 2 of this act.

(14) Violation of any provision(s) of the Medical Practice Act or the rules and regulations of the board or of any order, stipulation or agreement with the board.

In addition to the grounds specified above, the board shall be authorized to suspend the license of any licensee for being out of compliance with an order for support, as defined in Section 93-11-153. The procedure for suspension of a license for being out of compliance with an order for support, and the procedure for the reissuance or reinstatement of a license suspended for that purpose, and the payment of any fees for the reissuance or reinstatement of a license suspended for that purpose, shall be governed by Section 93-11-157 or 93-11-163, as the case may be. If there is any conflict between any provision of Section 93-11-157 or 93-11-163 and any provision of this chapter, the provisions of Section 93-11-157 or 93-11-163, as the case may be, shall control.

SECTION 5. This act shall take effect and be in force from and after July 1, 2009.