Senate Bill No. 11

(By Senators Foster and D. Facemire)

_____

[Introduced January 12, 2011; referred to the Committee on Health and Human Resources; and then to the Committee on the Judiciary.]

_____

A BILL to amend the Code of West Virginia, 1931, as amended, by adding thereto a new section, designated §30-5-12a, relating to prescription and pharmacy data privacy; stating legislative intent; prohibiting disclosure of certain data; requiring legislative rules; creating administrative penalties assessed by the West Virginia Pharmaceutical Cost Management Council and assessed by the Attorney General; and providing for enforcement.

Be it enacted by the Legislature of West Virginia:

That the Code of West Virginia, 1931, as amended, be amended by adding thereto a new section, designated §30-5-12a, to read as follows:

ARTICLE 5. PHARMACISTS, PHARMACY TECHNICIANS, PHARMACY INTERNS AND PHARMACIES.

§30-5-12a. Prescription Record Privacy Act.

(a) *Findings.* -- The Legislature hereby finds:

(1) That the spiraling cost of brand-name prescription drugs is a great concern to the State of West Virginia;

(2) That the commercial use of prescription data mining by pharmaceutical representatives, which allows them to specifically target physicians and shape their sales pitches accordingly, induces physicians to prescribe more expensive brand-name drugs in the place of equally effective, low-cost generic or alternative drugs, greatly increasing the cost of health care for private consumers as well as for state health care programs without increased health benefits;

(3) That pharmaceutical representatives spend large sums of money offering physicians all expenses paid speaking engagements, lucrative consulting opportunities and office luncheons, as well as free drug samples, pens, notepads, and other gifts of greater or lesser value;

(4) That, when time is not limiting, pharmaceutical representatives also spend large sums of money offering physicians all expenses paid speaking engagements, lucrative consulting opportunities and office luncheons;

(5) That such gifts and honoraria erode consumer confidence in the medical profession and are viewed by the public as just as

negatively influential to physician conduct as similar gifts are negatively influential, and therefore restricted, to public official conduct;

(6) That the American Medical Association's (A.M.A.) physician data restriction program has been ineffective at best or has been subject to a conflict of interest in view of the fact that the association receives over $40 million annually from selling physician profiles to data mining companies;

(7) That there is an inherent conflict between marketing agendas and truly evidence-based, individual care policies;

(8) That there are educational, nonprofit and law enforcement uses of this type of data, which are beneficial; and

(9) That the State of West Virginia has a duty to promote responsible health care practices among physicians and to promote the general welfare of its citizens, as well as, a fiscal responsibility to taxpayers in administering state health care programs.

(b) *Legislative intent.* --

It is the intent of the Legislature to safeguard the confidentiality of prescribing information, protect the integrity of the physician-patient relationship, maintain the integrity and public trust in the medical profession, restrain the undue influence of pharmaceutical representatives on a physician's

prescribing habits and further the state interest in improving the quality and lowering the cost of health care.

The Legislature intends to regulate the use of prescription data for marketing purposes but allow the use in noncommercial areas.

© *Definitions*. -- As used in this section:

(1) "Bona fide clinical trial" means any research project that prospectively assigns human subjects to intervention and comparison groups to study the cause and effect relationship between a medical intervention and a health outcome, has received approval from an appropriate Institutional Review Board and has been registered at clinicaltrials.gov prior to commencement.

(2) "Individual identifying information" means information which directly or indirectly identifies a prescriber or a patient in this state, where the information is derived from or relates to a prescription for any prescribed product.

(3) "Marketing" means any activity by a company making or selling prescribed products, or such company’s agent, intended to influence prescribing or purchasing choices of its products including, but not limited to:

(A) Advertising, publicizing, promoting or sharing information about a product;

(B) Identifying individuals to receive a message promoting use

of a particular product, including, but not limited to, an advertisement, brochure or contact by a sales representative, or identifying individuals to receive any form of gift, product sample, consultancy or any other item, service, compensation or employment of value;

(C) Planning the substance of a sales representative visit or communication or the substance of an advertisement or other promotional message or document; or

(D) Evaluating or compensating sales representatives.

(4) "Person" means a business, individual, corporation, union, association, firm, partnership, committee or other organization or group of persons.

(5) “Pharmacy” means an individual or entity licensed by the Board of Pharmacy to dispense prescribed products.

(6) “Prescribed product” means a biological product as defined in 42 U.S.C. §262, as amended by section three hundred fifty one of the Public Health Service Act of 1944 and a device or drug as defined in 21 U.S.C. §321, as amended by section two hundred one of the Food, Drug and Cosmetic Act of 1938.

(7) “Regulated record” means information or documentation from a prescription written by a prescriber doing business in this state or a prescription dispensed in this state.

(8) “State health care program” means a program for which the

state purchases prescribed products, including, but limited to, a state pharmaceutical assistance program, a program for state employees and their dependants, individuals under the supervision of the Division of Corrections or state retirees and their dependants, with the exception of the state medical assistance program, Medicaid.

(d) *Privacy provisions.* --

(1) A person may not knowingly disclose or use regulated records in this state that include prescription information containing individual identifying information for marketing a prescribed product.

(2) A regulated record containing individual identifying information may be transferred to another entity, including to another branch or subsidiary of the same firm, only if it carries satisfactory assurance that the recipient will safeguard the records from being disclosed or used in the state for a marketing purpose prohibited under this section.

(3) Regulated records containing individual identifying information may be disclosed, sold, transferred, exchanged or used for nonmarketing purposes.

(4) This section does not prohibit conduct involving the collection, use, transfer or sale of regulated records for marketing purposes if:

(A) Data is aggregated;

(B) Data does not contain individual identifying information; and

(C) No reasonable person would believe that the data can be used to obtain individual identifying information.

(5) A person may disclose regulated records to the identified individual as long as the information does not include protected information pertaining to any other person.

(6) This section may not be construed to regulate the content, time, place or manner of any discussion between prescribers and their patients or between a prescriber and a representative of a prescription drug manufacturer.

(7) Regulated records held by an agency administering a state health care program may only be disclosed in accordance with the provisions of this section.

(8) The Department of Health and Human Resources as the administrator of the state medical assistance program under 42 C.F.R. §§430-456, and the Medicaid waiver approved by the centers for Medicare and Medicaid services shall disclose regulated records only as provided ~~for~~ under 42 C.F.R. §431 and the federal Privacy Act of 1974. The department shall ensure that any agent or third-party contractors are informed of the limitations on disclosure and use of the data, the department shall promulgate legislative rules,

in accordance with the provision of article three, chapter twenty-nine-a of this code, to ensure compliance with this section and with the applicable federal laws and regulations.

(e) *Rulemaking*. -- The West Virginia Pharmaceutical Cost Management Council shall promulgate legislative and emergency rules in accordance with the provisions of chapter twenty-nine-a of this code setting standards for complying with the provisions of this section and enforcing the provisions of this section.

(f) *Enforcement and penalties.* --

(1) Any person found guilty of noncompliance with the provisions of this section or the provisions provided in the legislative rules adopted pursuant to this section shall be subject to an administrative penalty of not less than $10,000 nor more than $50,000 per violation, as assessed by the West Virginia Pharmaceutical Cost Management Council. Each disclosure of a regulated record constitutes a separate violation. The Attorney General shall enforce payment of penalties under this section.

(2) A violation of this section shall also constitute an unfair or deceptive act in trade or commerce and an unfair method of competition and may be enforced under section one hundred four, article six, chapter forty-six-a of this code.

(3) All state and federal laws and regulations relating to patient privacy and medical record confidentiality shall apply and

1 are not precluded by the provisions of this section.

NOTE: The purpose of this bill is to restrict the use of prescription data for marketing purposes and establish administrative penalties for misuse of prescription data.

This section is new; therefore, strike-throughs and underscoring have been omitted.