

DATA MINING

65 16 Sec. 53. NEW SECTION. 155D.1 PURPOSES.

65 17 The purposes of this chapter are the following:

65 18 1. To safeguard the confidentiality of prescribing  
65 19 information, protect the integrity of the doctor-patient  
65 20 relationship, maintain the integrity and public trust in the  
65 21 medical profession, combat vexatious and harassing sales  
65 22 practices, restrain undue influence exerted by pharmaceutical  
65 23 industry marketing representatives over prescribing decisions,  
65 24 and further the state interest in improving the quality and  
65 25 lowering the cost of health care.

65 26 2. To ensure the confidentiality of data held by a state  
65 27 agency which could be used directly or indirectly to identify  
65 28 a patient or a health care professional licensed to prescribe  
65 29 drugs, biologics, or medical devices.

65 30 3. To ensure compliance with federal Medicaid law and  
65 31 regulations prohibiting the disclosure and use of Medicaid  
65 32 data except to administer the Medicaid program, and to ensure  
65 33 that data held by the department of human services or its  
65 34 agents that could directly or indirectly identify patients or  
65 35 health care professionals licensed to prescribe products be  
66 1 kept confidential.

66 2 4. To regulate the monitoring of prescribing practices  
66 3 solely for commercial marketing purposes by entities selling  
66 4 prescribed products, and not to regulate monitoring for other  
66 5 uses, such as quality control, research unrelated to  
66 6 marketing, or use by governments or other entities not in the  
66 7 business of selling health care products.

66 8 Sec. 54. NEW SECTION. 155D.2 DEFINITIONS.

66 9 As used in this chapter, unless the context otherwise  
66 10 requires:

66 11 1. "Biologic" means a biological product as defined in 42  
66 12 U.S.C. } 262.

66 13 2. "Bona fide clinical trial" means a research project  
66 14 that prospectively assigns human subjects to intervention and  
66 15 comparison groups to study the cause and effect relationship  
66 16 between a medical intervention and a health outcome.

66 17 3. "Individual identifying information" means information  
66 18 which directly or indirectly identifies a prescriber or a  
66 19 patient, and the information is derived from or relates to a  
66 20 prescription for any prescribed product.

66 21 4. "Marketing" means an activity by a company or an agent  
66 22 of the company making or selling prescribed products intended  
66 23 to influence prescribing or purchasing choices of the  
66 24 company's prescribed products, including but not limited to  
66 25 any of the following:

66 26 a. Advertising, publicizing, promoting, or sharing  
66 27 information about a prescribed product.

66 28 b. Identifying individuals to receive a message promoting  
66 29 use of a particular prescribed product, including but not  
66 30 limited to an advertisement, brochure, or contact by a sales  
66 31 representative.

66 32 c. Planning the substance of a sales representative visit  
66 33 or communication or the substance of an advertisement or other  
66 34 promotional message or document.

66 35 d. Evaluating or compensating sales representatives.

67 1 e. Identifying individuals to receive any form of gift,

67 2 product sample, consultancy, or any other item, service,  
67 3 compensation, or employment of value.

67 4 f. Advertising or promoting prescribed products directly  
67 5 to patients.

67 6 5. "Medicaid program" means the medical assistance program  
67 7 administered as specified under chapter 249A.

67 8 6. "Pharmacy" means pharmacy as defined in section 155A.3.

67 9 7. "Prescription drug" means prescription drug as defined  
67 10 in section 155A.3.

67 11 8. "Prescribed product" means a biologic, prescription  
67 12 drug, or a medical device.

67 13 9. "Prescriber" means a health care practitioner who is  
67 14 licensed to prescribe prescription drugs, biologics, or  
67 15 medical devices in this state.

67 16 10. "Regulated record" means information or documentation  
67 17 from a prescription written by a prescriber doing business in  
67 18 this state or a prescription dispensed in this state.

67 19 11. "State health care program" means a program for which  
67 20 the state purchases prescribed products, including but not  
67 21 limited to a state employee, corrections, or retirement system  
67 22 program, but does not include the medical assistance program.

67 23 Sec. 55. NEW SECTION. 155D.3 PRIVACY PROVISIONS.

67 24 1. a. A person, including a state health care program,  
67 25 shall not knowingly disclose or use regulated records that  
67 26 include individual identifying information for the marketing  
67 27 of a prescribed product.

67 28 b. The department of human services shall ensure that the  
67 29 department, its employees, and agents, comply with the  
67 30 limitations on redisclosure or use of medical assistance  
67 31 program prescription information as provided for under state  
67 32 and federal law and applicable federal regulations, and shall  
67 33 have policies and procedures to ensure compliance with such  
67 34 state and federal laws and federal regulations.

67 35 2. a. Regulated records containing individual identifying  
68 1 information may be disclosed, sold, transferred, exchanged, or  
68 2 used only for nonmarketing purposes including but not limited  
68 3 to:

68 4 (1) Activities related to filling a valid prescription,  
68 5 including but not limited to the dispensing of a prescribed  
68 6 product to a patient or to the patient's authorized  
68 7 representative; the transmission of regulated record  
68 8 information between an authorized prescriber and a pharmacy;  
68 9 the transfer of regulated record information between  
68 10 pharmacies; the transfer of regulated records that may occur  
68 11 if pharmacy ownership is changed or transferred and pharmacy  
68 12 reimbursement.

68 13 (2) Law enforcement purposes as otherwise authorized or  
68 14 required by statute or court order.

68 15 (3) Research including but not limited to bona fide  
68 16 clinical trials, postmarketing surveillance research, product  
68 17 safety studies, population-based public health research, and  
68 18 research regarding the effects of health care practitioner  
68 19 prescribing practices, and statistical reports if individual  
68 20 identifying information is not published, redisclosed, or used  
68 21 to identify or contact individuals.

68 22 (4) Product safety evaluations, product recalls and  
68 23 specific risk management plans, as identified or requested by

68 24 the federal food and drug administration, or its successor  
68 25 agency.

68 26 (5) Pharmacy reimbursement, formulary compliance, case  
68 27 management related to the diagnosis, treatment, or management  
68 28 of illness for a specific patient, including but not limited  
68 29 to care management educational communications provided to a  
68 30 patient about the patient's health condition, adherence to a  
68 31 prescribed course of therapy, or other information about the  
68 32 product being dispensed, treatment options, or clinical  
68 33 trials.

68 34 (6) Utilization review by the state, by a health care  
68 35 provider, or by the patient's insurance provider for health  
69 1 care services, including but not limited to determining  
69 2 compliance with the terms of coverage or medical necessity.

69 3 (7) The collection and analysis of product utilization  
69 4 data for health care quality improvement purposes, including  
69 5 but not limited to development of evidence-based treatment  
69 6 guidelines or health care performance effectiveness and  
69 7 efficiency measures, promoting compliance with evidence-based  
69 8 treatment guidelines or health care performance measures, and  
69 9 providing prescribers with information that details their  
69 10 practices relative to their peers to encourage prescribing  
69 11 consistent with evidence-based practice.

69 12 (8) The collection and dissemination of product  
69 13 utilization data to promote transparency in evaluating  
69 14 performance related to the health care quality improvement  
69 15 measures.

69 16 (9) The transfer of product utilization data to and  
69 17 through secure electronic health record or personal health  
69 18 record systems.

69 19 (10) Use by any government agency or government agency  
69 20 sponsored program in carrying out its functions, or by any  
69 21 private person acting on behalf of a federal, state, or local  
69 22 agency in carrying out its functions.

69 23 (11) Use in connection with any civil, criminal,  
69 24 administrative, or arbitral proceeding in any federal, state,  
69 25 or local court or agency or before any self-regulatory body,  
69 26 including but not limited to the service of process,  
69 27 investigation in anticipation of litigation, and the execution  
69 28 or enforcement of judgments and orders, or pursuant to an  
69 29 order of a federal, state, or local court.

69 30 b. An authorized recipient of regulated records containing  
69 31 individual identifying information may resell, reuse, or  
69 32 redisclose the information only as permitted under paragraph  
69 33 "a".

69 34 c. An authorized recipient that resells, reuses, or  
69 35 rediscloses individual identifying information covered by this  
70 1 chapter shall maintain for a period of five years, records  
70 2 identifying each person or entity that receives the  
70 3 information and the permitted purpose for which the  
70 4 information will be used. The authorized recipient shall make  
70 5 such records available to any person upon request.

70 6 3. This section shall not be interpreted to prohibit  
70 7 conduct involving the collection, use, transfer, or sale of  
70 8 regulated records for marketing purposes if all of the  
70 9 following conditions apply:

70 10 a. The data is aggregated.

70 11     b. The data does not contain individually identifying  
70 12 information.

70 13     c. There is no reasonable basis to believe that the data  
70 14 can be used to obtain individually identifying information.

70 15     4. This section shall not prevent any person from  
70 16 disclosing individual identifying information to the  
70 17 identified individual if the information does not include  
70 18 protected information pertaining to any other person.