

DATA MINING

60 14 Sec. 75. NEW SECTION. 155D.1 PURPOSES.

60 15 The purposes of this chapter are the following:

60 16 1. To safeguard the confidentiality of prescribing
60 17 information, protect the integrity of the doctor-patient
60 18 relationship, maintain the integrity and public trust in the
60 19 medical profession, combat vexatious and harassing sales
60 20 practices, restrain undue influence exerted by pharmaceutical
60 21 industry marketing representatives over prescribing decisions,
60 22 and further the state interest in improving the quality and
60 23 lowering the cost of health care.

60 24 2. To ensure the confidentiality of data held by a state
60 25 agency which could be used directly or indirectly to identify
60 26 a patient or a health care professional licensed to prescribe
60 27 drugs, biologics, or medical devices.

60 28 3. To ensure compliance with federal Medicaid law and
60 29 regulations prohibiting the disclosure and use of Medicaid
60 30 data except to administer the Medicaid program, and to ensure
60 31 that data held by the department of human services or its
60 32 agents that could directly or indirectly identify patients or
60 33 health care professionals licensed to prescribe products be
60 34 kept confidential.

60 35 4. To regulate the monitoring of prescribing practices
61 1 solely for commercial marketing purposes by entities selling
61 2 prescribed products, and not to regulate monitoring for other
61 3 uses, such as quality control, research unrelated to
61 4 marketing, or use by governments or other entities not in the
61 5 business of selling health care products.

61 6 Sec. 76. NEW SECTION. 155D.2 DEFINITIONS.

61 7 As used in this chapter, unless the context otherwise
61 8 requires:

61 9 1. "Biologic" means a biological product as defined in 42
61 10 U.S.C. } 262.

61 11 2. "Bona fide clinical trial" means a research project
61 12 that prospectively assigns human subjects to intervention and
61 13 comparison groups to study the cause and effect relationship
61 14 between a medical intervention and a health outcome.

61 15 3. "Individual identifying information" means information
61 16 which directly or indirectly identifies a prescriber or a
61 17 patient, and the information is derived from or relates to a
61 18 prescription for any prescribed product.

61 19 4. "Marketing" means an activity by a company or an agent
61 20 of the company making or selling prescribed products intended
61 21 to influence prescribing or purchasing choices of the
61 22 company's prescribed products, including but not limited to
61 23 any of the following:

61 24 a. Advertising, publicizing, promoting, or sharing
61 25 information about a prescribed product.

61 26 b. Identifying individuals to receive a message promoting
61 27 use of a particular prescribed product, including but not
61 28 limited to an advertisement, brochure, or contact by a sales
61 29 representative.

61 30 c. Planning the substance of a sales representative visit
61 31 or communication or the substance of an advertisement or other
61 32 promotional message or document.

61 33 d. Evaluating or compensating sales representatives.

61 34 e. Identifying individuals to receive any form of gift,

61 35 product sample, consultancy, or any other item, service,
62 1 compensation, or employment of value.

62 2 f. Advertising or promoting prescribed products directly
62 3 to patients.

62 4 5. "Medicaid program" means the medical assistance program
62 5 administered as specified under chapter 249A.

62 6 6. "Pharmacy" means pharmacy as defined in section 155A.3.

62 7 7. "Prescription drug" means prescription drug as defined
62 8 in section 155A.3.

62 9 8. "Prescribed product" means a biologic, prescription
62 10 drug, or a medical device.

62 11 9. "Prescriber" means a health care practitioner who is
62 12 licensed to prescribe prescription drugs, biologics, or
62 13 medical devices in this state.

62 14 10. "Regulated record" means information or documentation
62 15 from a prescription written by a prescriber doing business in
62 16 this state or a prescription dispensed in this state.

62 17 11. "State health care program" means a program for which
62 18 the state purchases prescribed products, including but not
62 19 limited to a state employee, corrections, or retirement system
62 20 program, but does not include the medical assistance program.

62 21 Sec. 77. NEW SECTION. 155D.3 PRIVACY PROVISIONS.

62 22 1. a. A person, including a state health care program,
62 23 shall not knowingly disclose or use regulated records that
62 24 include individual identifying information for the marketing
62 25 of a prescribed product.

62 26 b. The department of human services shall ensure that the
62 27 department, its employees, and agents, comply with the
62 28 limitations on redisclosure or use of medical assistance
62 29 program prescription information as provided for under state
62 30 and federal law and applicable federal regulations, and shall
62 31 have policies and procedures to ensure compliance with such
62 32 state and federal laws and federal regulations.

62 33 2. a. Regulated records containing individual identifying
62 34 information may be disclosed, sold, transferred, exchanged, or
62 35 used only for nonmarketing purposes including but not limited
63 1 to:

63 2 (1) Activities related to filling a valid prescription,
63 3 including but not limited to the dispensing of a prescribed
63 4 product to a patient or to the patient's authorized
63 5 representative; the transmission of regulated record
63 6 information between an authorized prescriber and a pharmacy;
63 7 the transfer of regulated record information between
63 8 pharmacies; the transfer of regulated records that may occur
63 9 if pharmacy ownership is changed or transferred; and pharmacy
63 10 reimbursement.

63 11 (2) Law enforcement purposes as otherwise authorized or
63 12 required by statute or court order.

63 13 (3) Research including but not limited to bona fide
63 14 clinical trials, postmarketing surveillance research, product
63 15 safety studies, population-based public health research, and
63 16 research regarding the effects of health care practitioner
63 17 prescribing practices, and statistical reports if individual
63 18 identifying information is not published, redisclosed, or used
63 19 to identify or contact individuals.

63 20 (4) Product safety evaluations, product recalls and
63 21 specific risk management plans, as identified or requested by

63 22 the federal food and drug administration, or its successor
63 23 agency.

63 24 (5) Pharmacy reimbursement, formulary compliance, case
63 25 management related to the diagnosis, treatment, or management
63 26 of illness for a specific patient, including but not limited
63 27 to care management educational communications provided to a
63 28 patient about the patient's health condition, adherence to a
63 29 prescribed course of therapy, or other information about the
63 30 product being dispensed, treatment options, or clinical
63 31 trials.

63 32 (6) Utilization review by the state, by a health care
63 33 provider, or by the patient's insurance provider for health
63 34 care services, including but not limited to determining
63 35 compliance with the terms of coverage or medical necessity.

64 1 (7) The collection and analysis of product utilization
64 2 data for health care quality improvement purposes, including
64 3 but not limited to development of evidence-based treatment
64 4 guidelines or health care performance effectiveness and
64 5 efficiency measures, promoting compliance with evidence-based
64 6 treatment guidelines or health care performance measures, and
64 7 providing prescribers with information that details their
64 8 practices relative to their peers to encourage prescribing
64 9 consistent with evidence-based practice.

64 10 (8) The collection and dissemination of product
64 11 utilization data to promote transparency in evaluating
64 12 performance related to the health care quality improvement
64 13 measures.

64 14 (9) The transfer of product utilization data to and
64 15 through secure electronic health record or personal health
64 16 record systems.

64 17 (10) Use by any government agency or government agency
64 18 sponsored program in carrying out its functions, or by any
64 19 private person acting on behalf of a federal, state, or local
64 20 agency in carrying out its functions.

64 21 (11) Use in connection with any civil, criminal,
64 22 administrative, or arbitral proceeding in any federal, state,
64 23 or local court or agency or before any self-regulatory body,
64 24 including but not limited to the service of process,
64 25 investigation in anticipation of litigation, and the execution
64 26 or enforcement of judgments and orders, or pursuant to an
64 27 order of a federal, state, or local court.

64 28 b. An authorized recipient of regulated records containing
64 29 individual identifying information may resell, reuse, or
64 30 redisclose the information only as permitted under paragraph
64 31 "a".

64 32 c. An authorized recipient of regulated records that
64 33 resells, reuses, or rediscloses individual identifying
64 34 information covered by this chapter shall maintain for a
64 35 period of five years, records identifying each person or
65 1 entity that receives the information and the permitted purpose
65 2 for which the information will be used. The authorized
65 3 recipient shall make such records available to any person upon
65 4 request.

65 5 3. This section shall not be interpreted to prohibit
65 6 conduct involving the collection, use, transfer, or sale of
65 7 regulated records for marketing purposes if all of the
65 8 following conditions apply:

65 9 a. The data is aggregated.

65 10 b. The data does not contain individually identifying
65 11 information.

65 12 c. There is no reasonable basis to believe that the data
65 13 can be used to obtain individually identifying information.

65 14 4. This section shall not prevent any person from
65 15 disclosing individual identifying information to the
65 16 identified individual if the information does not include
65 17 protected information pertaining to any other person.

65 18 Sec. 78. NEW SECTION. 155D.4 CIVIL PENALTY ==
65 19 ENFORCEMENT == RULEMAKING.

65 20 1. Any person who knowingly fails to comply with the
65 21 requirements of this chapter or rules adopted pursuant to this
65 22 chapter by using or disclosing regulated records in a manner
65 23 not authorized by this chapter or rules adopted pursuant to
65 24 this chapter is subject to a civil penalty of not more than
65 25 fifty thousand dollars per violation. Each disclosure of a
65 26 regulated record constitutes a separate violation.

65 27 2. The attorney general shall enforce payment of penalties
65 28 assessed under this section.

65 29 3. The board of pharmacy shall adopt rules to administer
65 30 this chapter including the assessment of penalties under this
65 31 section.

65 32 Sec. 79. NEW SECTION. 155D.5 CONSUMER FRAUD.

65 33 A violation of this chapter is an unfair or deceptive act
65 34 in trade or commerce and an unfair method of competition under
65 35 the consumer fraud Act, section 714.16.