

GIFTS TO HEALTH CARE PRACTITIONERS

56 2 Sec. 68. NEW SECTION. 155C.1 PURPOSES.

56 3 The purposes of this chapter are to improve the public
56 4 health and the quality of prescribing and medical decision
56 5 making; promote consumer access to information relating to
56 6 medical care and gifts; reduce the inappropriate influence of
56 7 gifts and payments on provider medical decisions; limit annual
56 8 increases in the cost of health care; and assist the state in
56 9 its role as a purchaser of health care services and an
56 10 administrator of health care programs by enabling the state to
56 11 determine the effect of gifts on the cost, utilization, and
56 12 delivery of health care services.

56 13 Sec. 69. NEW SECTION. 155C.2 DEFINITIONS.

56 14 As used in this chapter, unless the context otherwise
56 15 requires:

56 16 1. "Biologic" means a biological product as defined in 42
56 17 U.S.C. } 262.

56 18 2. "Bona fide clinical trial" means any research project
56 19 that prospectively assigns human subjects to intervention and
56 20 comparison groups to study the cause and effect relationship
56 21 between a medical intervention and a health outcome.

56 22 3. "Department" means the department of administrative
56 23 services.

56 24 4. "Gift" means a payment, fee, food, entertainment,
56 25 travel, honorarium, subscription, advance, service, subsidy,
56 26 economic benefit, or anything of value provided, unless
56 27 consideration of equal or greater value is received, and
56 28 includes anything of value provided to a health care
56 29 practitioner for less than market value. "Gift" does not
56 30 include product samples or negotiated rebates or discounts.

56 31 5. "Health care practitioner" means a health care
56 32 professional who is licensed to prescribe prescription drugs,
56 33 biologics, or medical devices, or a partnership or corporation
56 34 consisting of such health care professionals, or an officer,
56 35 employee, agent, or contractor of such a health care
57 1 professional acting in the course of employment, agency, or
57 2 contract related to or supportive of the provision of health
57 3 care by the health care professional.

57 4 6. "Manufacturer" means a person engaged in the
57 5 manufacturing, preparing, propagating, compounding,
57 6 processing, packaging, repackaging, distributing, or labeling
57 7 of prescription drugs, biologics, or medical devices.

57 8 7. "Medical device" means device as defined in section
57 9 155A.3.

57 10 8. "Prescription drug" means prescription drug as defined
57 11 in section 155A.3.

57 12 9. "Significant educational, scientific, or policy-making
57 13 conference or seminar" means an educational, scientific, or
57 14 policy-making conference or seminar that meets both of the
57 15 following requirements:

57 16 a. Is accredited by the accreditation council for
57 17 continuing medical education or a comparable organization.

57 18 b. Offers continuing medical education credit, features
57 19 multiple presenters on scientific research, or is authorized
57 20 by the sponsoring association to recommend or make policy.

57 21 10. "State health care program" means a program for which
57 22 the state purchases prescription drugs, biologics, or medical

57 23 devices, including but not limited to the medical assistance
57 24 program, or a state employee, corrections, or retirement
57 25 system program.

57 26 11. "Wholesaler" means wholesaler as defined in section
57 27 155A.3.

57 28 Sec. 70. NEW SECTION. 155C.3 GIFTS TO HEALTH CARE
57 29 PRACTITIONERS PROHIBITED.

57 30 1. A manufacturer or wholesaler, or a manufacturer's or
57 31 wholesaler's agent, who participates in a state health care
57 32 program shall not offer or give any gift to a health care
57 33 practitioner.

57 34 2. Notwithstanding subsection 1, the following gifts are
57 35 not prohibited but shall be disclosed pursuant to section
58 1 155C.4:

58 2 a. Payment to the sponsor of a significant educational,
58 3 scientific, or policy-making conference or seminar if the
58 4 payment is not made directly to a health care practitioner;
58 5 the payment is used solely for bona fide educational purposes;
58 6 and all conference or seminar activities are objective, free
58 7 from industry influence, and do not promote specific products.

58 8 b. Reasonable honoraria and payment of the reasonable
58 9 expenses of a health care practitioner who serves on the
58 10 faculty at a significant educational, scientific, or
58 11 policy-making conference or seminar pursuant to an explicit
58 12 contract with specific deliverables which are restricted to
58 13 scientific issues, not marketing efforts, and the content of
58 14 any presentation, including slides and written materials, are
58 15 determined by the health care practitioners.

58 16 c. Compensation for the substantial professional or
58 17 consulting services of a health care practitioner in
58 18 connection with a bona fide clinical trial pursuant to an
58 19 explicit contract with specific deliverables which are
58 20 restricted to scientific issues, not marketing efforts.

58 21 Sec. 71. NEW SECTION. 155C.4 DISCLOSURE OF EXEMPTED
58 22 GIFTS.

58 23 1. a. Annually, on or before December 1, every
58 24 manufacturer or wholesaler of prescription drugs, biologics,
58 25 or medical devices that participates in a state health care
58 26 program shall disclose to the department, the value, nature,
58 27 purpose, and recipient of any gift not prohibited in section
58 28 155C.3, which is provided by the manufacturer or wholesaler,
58 29 directly or through its agents, to any health care
58 30 practitioner or any other person in this state authorized to
58 31 prescribe, dispense, or purchase prescription drugs,
58 32 biologics, or medical devices in this state.

58 33 b. For each expenditure, the manufacturer or wholesaler
58 34 shall also identify the recipient and the recipient's address,
58 35 credentials, institutional affiliation, and state board or
59 1 drug enforcement agency numbers.

59 2 2. Each manufacturer or wholesaler subject to the
59 3 provisions of this section shall also disclose to the
59 4 department the name and address of the individual responsible
59 5 for the manufacturer's or wholesaler's compliance with this
59 6 section, or if this information has been previously reported,
59 7 any changes in the name or address of the individual
59 8 responsible for the manufacturer's or wholesaler's compliance
59 9 with this section.

59 10 3. The report shall be accompanied by payment of a fee, to
59 11 be established by rule of the department, to defray
59 12 administrative costs.

59 13 4. The department shall make all disclosed data publicly
59 14 available and easily searchable on its internet site.

59 15 Sec. 72. NEW SECTION. 155C.5 DEPARTMENTAL REPORTS.

59 16 The department shall provide an annual report to the
59 17 governor and the general assembly on or before January 15,
59 18 containing an analysis of the data submitted to the department
59 19 under section 155C.4. The report shall include all of the
59 20 following:

59 21 1. Information on gifts required to be disclosed under
59 22 section 155C.4, which shall be presented in aggregate form and
59 23 by selected types of health care practitioners or individual
59 24 health care practitioners, as prioritized each year by the
59 25 department and analyzed to determine whether prescribing
59 26 patterns by these health care practitioners reimbursed by the
59 27 state health care programs may reflect manufacturer's or
59 28 wholesaler's influence.

59 29 2. Information on violations and enforcement actions
59 30 brought pursuant to this chapter.

59 31 Sec. 73. NEW SECTION. 155C.6 PUBLIC RECORDS.

59 32 1. The information required to be submitted pursuant to
59 33 section 155C.4, and the data and reports compiled by the
59 34 department pursuant to section 155C.5, are public records.

59 35 2. Notwithstanding any other provision of law to the
60 1 contrary, the identity of health care practitioners and other
60 2 recipients of gifts, payments, and materials required to be
60 3 reported in this section do not constitute confidential
60 4 information or trade secrets.

60 5 Sec. 74. NEW SECTION. 155C.7 ENFORCEMENT == RULES.

60 6 1. The department may bring an action for injunctive
60 7 relief, costs, and attorneys fees, and to impose a civil
60 8 penalty of no more than ten thousand dollars per violation on
60 9 a manufacturer or wholesaler that fails to comply with any
60 10 provision of this chapter.

60 11 2. The department shall adopt rules as necessary to
60 12 administer this chapter.