

SENATE NO. 1283

AN ACT TO REFORM THE RELATIONSHIP BETWEEN HEALTH CARE PROVIDERS AND SUPPLIERS OF HEALTH CARE SERVICES, PRODUCTS, EQUIPMENT AND MEDICATION: COMMISSION ON MEDICAL ETHICS AND HEALTH CARE PROFESSIONAL CONDUCT ESTABLISHED

*Be it enacted by the Senate and House of Representatives in General Court assembled,
And by the authority of the same, as follows:*

1 SECTION 1. The General Laws, as most recently appearing in the 2000 Official Edition are hereby
2 amended by inserting after chapter 268B, the following new chapter,

3 Chapter 268C Disclosure of Relationships by Certain Health Care Professional and Employees.

4 Section 1. Definitions.

5 As used in this chapter, unless the context requires otherwise,

6 (a) "amount", a category of value, rather than an exact dollar figure, as follows: greater than one
7 thousand dollars but not more than five thousand dollars; greater than five thousand dollars but not
8 more than ten thousand dollars; greater than ten thousand dollars but not more than twenty thousand
9 dollars; greater than twenty thousand dollars but not more than forty thousand dollars; greater than
10 forty thousand dollars but not more than sixty thousand dollars; greater than sixty thousand dollars
11 but not more than one hundred thousand dollars; greater than one hundred thousand dollars;

12 (b) "business" means any corporation, partnership, sole proprietorship, firm, franchise, association,
13 organization, holding company, joint stock company, receivership, business or real estate trust, or
14 any other legal entity organized for profit or charitable purposes that engages in manufacture, sale,
15 marketing, distribution of pharmaceutical products, medical equipment, medical publishing or other
16 business in the health care field;

17 (c) "business with which he is associated" means any business in which the reporting person or a
18 member of his immediate family is a general partner, proprietor, officer or other employee,
19 including one who is self-employed, or serves as a director, trustee or in any similar managerial
20 capacity; and any business more than one percent of any class of the outstanding equity of which is
21 beneficially owned in the aggregate by the reporting person and members of his immediate family;

22 (d) "Industry-sponsored" means any activity or program funded in whole or in part by a business as
23 defined in this section;

24 (e) "Commission," shall mean the Commission on Medical Ethics and Health Professional Conduct
25 established pursuant to section 1 of this act.

26 (f) "Financial Relationships," shall mean any consulting or pseudo-consulting relationships,
27 agreements to allow direct access to patients, patient's records, or observation of procedures with or
28 without the informed consent of the patient, participating in any continuing medical education
29 program as faculty if the individual has a financial interest in course content or which is sponsored
30 by industry unless there is independent selection of faculty and course content without input from
31 the industry; any royalty and licensing agreements, stock ownership or options to purchase below
32 the prevailing market price, positions on corporate boards, or participation in marketing efforts

33 directly or described as research, or any restructuring of income transfer in any way designed to
34 circumvent, intentionally or otherwise, the definition of financial relationship for the purpose of
35 avoiding the reporting requirements of this act.

36 (g) "Gift," shall mean any item greater than one hundred dollars in value, any travel costs including
37 hotel, meals, recreational fees or charges, any honoraria, paid participation in any industry-
38 sponsored speaker's bureau or advisory board, free or reduced cost participation in any industry-
39 sponsored symposia, or any restructuring of income transfer in any way designed to circumvent,
40 intentionally or otherwise, the definition of gift for the purpose of avoiding the reporting
41 requirements of this act.

42 (h) "Health care professional," means any person licensed under the provisions of sections 2, 9E,
43 24, 37, 74, 74A, 80C, or 80E;

44 (i) "immediate family" means a spouse and any dependent children residing in the reporting
45 person's household;

46 (k) "Industry agent" means any person who for compensation or reward does any act to influence
47 the clinical decisions or professional conduct of any health care profession, or to influence the
48 decision of any patient or medical research subject of a reporting individual where such decision
49 may not be based on current evidence-based medicine. The term shall include persons who, as any
50 part of their regular and usual employment and not simply incidental thereto, attempt to influence
51 clinical decisions or professional conduct of a health care professional, whether or not any
52 compensation in addition to the salary for such employment is received for such services;

53 (m) ""person" means a business, individual, corporation, union, association, firm, partnership,
54 committee, or other organization or group of persons.

55 (r) ""reporting person" means any person required to file a statement of financial interest pursuant
56 to the provisions of section five.

57 Section 2. Commission on Medical Ethics and Health Professional Conduct.

58 (a) There is established a Commission on Medical Ethics and Health Professional Conduct
59 composed of five members. At no time shall more than three members be from the same political
60 party.

61 (b) Two members of the commission shall be appointed by the governor, one of whom shall be
62 selected from a list of three candidates submitted by the Massachusetts Medical Society and one of
63 who shall be selected for a list of three members submitted by the Massachusetts Bar Association,
64 one member shall be appointed by the Board of Registration in Medicine, member shall be
65 appointed by the commissioner of the department of public health and one member shall be
66 appointed by the attorney general. At no time shall both of the members to be appointed by the
67 governor be from the same political party.

68 (c) Members of the commission shall serve for terms of five years, but may continue to hold office
69 until a successor has been appointed and qualified.

70 (d) No person shall be appointed to more than one full five year term on the commission.

71 (e) Not less than thirty days prior to making any appointment to the commission, the appointing
72 official or nominating organization shall give public notice that a vacancy on the commission exists.

73 (f) No member or employee of the commission shall:

74 (1) hold or be a candidate for any other public office while a member or employee or for one year
75 thereafter;

76 (2) hold office in any medical or health care association;

77 (3) participate in any business as defined in section one of this act.

78 (g) Members of the commission may be removed by joint agreement of the governor and attorney
79 general, for substantial neglect of duty, inability to discharge the powers and duties of office,
80 violation of subsection (f) of this section, gross misconduct, or conviction of a felony.

81 (h) Any vacancy occurring on the commission shall be filled within ninety days by the original
82 appointing authority. A person appointed to fill a vacancy occurring other than by expiration of a
83 term of office shall be appointed for the unexpired term of the member he succeeds, and shall be
84 eligible for appointment to one full five year term.

85 (i) The commission shall elect a chairman and vice chairman. The vice chairman shall act as
86 chairman in the absence of the chairman or in the event of a vacancy in that position.

87 (j) Three members of the commission shall constitute a quorum and three affirmative votes shall be
88 required for any action or recommendation of the commission; the chairman or any three members
89 of the commission may call a meeting; advance notice of all meetings shall be given to each
90 member of the commission and to any other person who requests such notice;

91 (k) Members of the commission shall be compensated for work performed for the commission at
92 such rate as the secretary of administration and finance shall determine, and shall be reimbursed for
93 their expenses.

94 (l) The commission shall annually report to the general court and the governor concerning the
95 action it has taken; the names and salaries and duties of all individuals in its employ and the money
96 it has collected and disbursed; and shall make such further reports on matters within its jurisdiction
97 as may appear necessary;

98 (m) The commission shall employ an executive director, a general counsel, and, subject to
99 appropriation, such other staff, including but not limited to clerks, accountants, and investigators, as
100 are necessary to carry out its duties pursuant to this chapter and chapter two hundred and sixty-eight
101 A. The staff shall serve at the pleasure of the commission and shall not be subject to the provisions
102 of chapter thirty-one or section nine A of chapter thirty. The executive director shall be responsible
103 for the administrative operation of the commission and shall perform such other tasks as the
104 commission shall determine. The general counsel shall be the chief legal officer of the commission.
105 The commission may employ, subject to appropriation, the services of experts and consultants
106 necessary to carry out its duties. The commissioner of the department of revenue, the state auditor,
107 the comptroller, the attorney general may make, and the several health professional boards of
108 registration shall make, available to the commission personnel and other assistance as the
109 commission may request.

110 Section 3. Duties of the Commission

111 The commission shall:

112 (a) prescribe and publish, pursuant to the provisions of chapter thirty A, rules and regulations to
113 carry out the purposes of this chapter, including rules governing the conduct of proceedings
114 hereunder;

115 (b) prepare and publish, after giving the public an opportunity to comment, forms for the statements
116 and reports required to be filed by this chapter and make such forms available to any and all persons
117 required to file statements and reports pursuant to the provisions of this chapter;

118 (c) prepare and publish, pursuant to the provisions of chapter thirty A, methods of accounting and
119 reporting to be used by persons required to file statements and reports by this chapter;

120 (d) make statements and reports filed with the commission available for public inspection and
121 copying during regular office hours upon the written request of any individual who provides
122 identification acceptable to the commission, including his affiliation, if any, at a charge not to
123 exceed the actual administrative and material costs required in reproducing said statements and
124 reports; provided, however, that the commission shall be authorized, in its discretion, to exempt
125 from public disclosure those portions of a statement of financial interest filed pursuant to section
126 five which contain the home address of the filer; and provided, further, that the commission shall
127 forward a copy of said request to the person whose statement has been examined;

128 (e) compile and maintain an index of all reports and statements filed with the commission to
129 facilitate public access to such reports and statements;

130 (f) inspect all statements of financial interests filed with the commission in order to ascertain
131 whether any reporting person has failed to file such a statement or has filed a deficient statement. If,
132 upon inspection, it is ascertained that a reporting person has failed to file a statement of financial

133 interests, or if it is ascertained that any such statement filed with the commission fails to conform
134 with the requirements of section five of this chapter, then the commission shall, in writing, notify
135 the delinquent; such notice shall state in detail the deficiency and the penalties for failure to file a
136 statement of financial interests;

137 (g) upon written request from a person who is or may be subject to the provisions of this chapter or
138 chapter two hundred and sixty-eight A, render advisory opinions on the requirements of said
139 chapters. An opinion rendered by the commission, until and unless amended or revoked, shall be a
140 defense in a criminal action brought under chapter two hundred and sixty-eight A and shall be
141 binding on the commission in any subsequent proceedings concerning the person who requested the
142 opinion and who acted in good faith, unless material facts were omitted or misstated by the person
143 in the request for an opinion. Such requests shall be confidential; provided, however, that the
144 commission may publish such opinions, but the name of the requesting person and any other
145 identifying information shall not be included in such publication unless the requesting person
146 consents to such inclusion;

147 (h) preserve all statements and reports filed with the commission for a period of six years from the
148 date of receipt;

149 (i) act as the primary civil enforcement agency for violations of all sections of this chapter.

150 (j) on or before February first of each year the executive director of the commission shall request a
151 list of all persons licensed under the provisions of sections 2, 9E, 24, 37, 74, 74A, 80C, or 80E for
152 their respective licensing boards.

153 Section 4. Investigations by the commission.

154 (a) Upon receipt of a sworn complaint signed under pains and penalties of perjury, or upon receipt
155 of evidence which is deemed sufficient by the commission, the commission shall initiate a
156 preliminary inquiry into any alleged violation of this chapter. All commission proceedings and
157 records relating to a preliminary inquiry or initial staff review to determine whether to initiate an
158 inquiry shall be confidential, except that the general counsel may turn over to the attorney general,
159 the United States Attorney or a district attorney of competent jurisdiction evidence which may be
160 used in a criminal proceeding. The general counsel shall notify any person who is the subject of the
161 preliminary inquiry of the existence of such inquiry and the general nature of the alleged violation
162 within thirty days of the commencement of the inquiry.

163 (b) If a preliminary inquiry fails to indicate reasonable cause for belief that this chapter or said
164 chapter two hundred and sixty-eight A has been violated, the commission shall immediately
165 terminate the inquiry and so notify, in writing, the complainant, if any, and the person who had been
166 the subject of the inquiry. All commission records and proceedings from any such preliminary
167 inquiry, or from any initial staff review to determine whether to initiate an inquiry, shall be
168 confidential.

169 (c) If a preliminary inquiry indicates reasonable cause for belief that this chapter has been violated,
170 the commission may, upon a majority vote, initiate an adjudicatory proceeding to determine
171 whether there has been such a violation.

172 (d) The commission may require by summons the attendance and testimony of witnesses and the
173 production of books, papers and other records relating to any matter being investigated by it
174 pursuant to this chapter or said chapter two hundred and sixty-eight A. Such summons may be
175 issued by the commission only upon a majority vote of the commission and shall be served in the

176 same manner as summonses for witnesses in civil cases, and all provisions of law relative to
177 summonses issued in such cases, including the compensation of witnesses, shall apply to
178 summonses issued by the commission. Any justice of the superior court may, upon application by
179 the commission, in his discretion issue an order requiring the attendance of witnesses summoned as
180 aforesaid and the giving of testimony or the production of books, papers and other records before
181 the commission in furtherance of any investigation pursuant to the provisions of this chapter.

182 (e) Any member of the commission may administer oaths and any member of the commission may
183 hear testimony or receive other evidence in any proceeding before the commission.

184 (f) All testimony in a commission adjudicatory proceeding shall be under oath. All parties shall
185 have the right to call and examine witnesses, to introduce exhibits, to cross-examine witnesses who
186 testify, to submit evidence, and to be represented by counsel. Before testifying, all witnesses shall
187 be given a copy of the regulations governing commission proceedings. All witnesses shall be
188 entitled to be represented by counsel.

189 (g) Any person whose name is mentioned during an adjudicatory proceeding of the commission and
190 who may be adversely affected thereby may appear personally before the commission on his own
191 behalf, with or without an attorney, to give a statement in opposition to such adverse mention or file
192 a written statement of such opposition for incorporation into the record of the proceeding.

193 (h) All adjudicatory proceedings of the commission carried out pursuant to the provisions of this
194 section shall be public, unless the members vote to go into executive session.

195 (i) Within thirty days after the end of an adjudicatory proceeding pursuant to the provisions of this
196 section, the commission shall meet in executive session for the purpose of reviewing the evidence

197 before it. Within thirty days after completion of deliberations, the commission shall publish a
198 written and electronic report of its findings and conclusions which shall be deemed public record.

199 (j) The commission, upon a finding pursuant to an adjudicatory proceeding that there has been a
200 violation of this chapter, may issue an order requiring the violator to:

201 (1) cease and desist such violation of this chapter;

202 (2) file any report, statement or other information as required by this chapter; or

203 (3) pay a civil penalty of not more than five thousand dollars for each violation of this chapter.

204 The commission may file a civil action in superior court to enforce such order.

205 (k) Any final action by the commission made pursuant to this chapter shall be subject to review in
206 superior court upon petition of any party in interest filed within thirty days after the action for
207 which review is sought. The court shall enter a judgment enforcing, modifying or setting aside the
208 order of the commission or it may remand the proceedings to the commission for such further
209 action as the court may direct. If the court modifies or sets aside the commission order or remands
210 the proceedings to the commission, the court shall determine whether such modification, set aside
211 or remand is substantial. If the court does find such modification, set aside or remand to be
212 substantial, the employee shall be entitled to be reimbursed from the treasury of the commonwealth
213 for reasonable attorneys' fees and all court costs incurred by him in the defense of the charges
214 contained in said proceedings. The amount of such reimbursement shall be awarded by the court,
215 but shall not exceed twenty thousand dollars per person, per case. Reimbursement of such costs

216 shall be applicable to state, county or municipal employees whose conduct is so regulated by the
217 provisions of this chapter.

218 Section 5. Statements of financial interests.

219 (a) Every reporting person as specified in this chapter shall file a statement of financial interest for
220 the preceding calendar year with the commission on or before the date established by the
221 commission.

222 (b) The commission shall, upon receipt of a statement of financial interests pursuant to the
223 provisions of this section, issue to the person filing such statement a receipt verifying the fact that a
224 statement of financial interests has been filed and a receipted copy of such statement.

225 (c) No reporting person shall be allowed to continue to perform his duties under the terms of his
226 professional license or to receive compensation from public funds unless he has filed a statement of
227 financial interests with the commission as required by this chapter.

228 (d) The statement of financial interests filed pursuant to the provisions of this section shall be on a
229 form prescribed by the commission and shall be signed under penalty of perjury by the reporting
230 person.

231 (e) Reporting persons shall disclose, to the best of their knowledge, the following information for
232 the preceding calendar year, or as of the last day of said year with respect to the information
233 required by clauses (1) and (2) below; such persons shall also disclose the same information with
234 respect to their immediate family provided, however, that no amount need be given for such
235 information with regard to the reporting person's immediate family:

236 1) Every person or organization licensed provisions of sections 2, 9E, 24, 37, 74, 74A, 80C, or
237 80E shall annually file a report on a form prescribed by the Commission that, at a minimum, shall
238 include:

239 (a) Name;

240 (b) Professional Address and Personal Address;

241 (c) Professional and Personal telephone and fax numbers and e-mail address;

242 (d) Profession License Number(s);

243 (e) Gift or financial relationship with any providers and suppliers of health care services, products,
244 equipment, or medication;

245 (f) Specific product that may result in a conflict with the provisions of Section 1 (a) through (c);

246 (g) Financial value of the relationship, by range of amounts; and

247 (h) Such other information as the Commission deems relevant.

248 2) Every person licensed under the provisions of sections 2, 9E, 24, 37, 74, 74A, 80C, or 80E
249 shall report any financial interest with or gift from any business pursuant to the provisions of this
250 chapter.

251 Failure of a reporting person to file a statement of financial interests within ten days after receiving
252 notice as provided in clause (f) of section three of this chapter, or the filing of an incomplete

253 statement of financial interests after receipt of such a notice, is a violation of this chapter and the
254 commission may initiate appropriate proceedings pursuant to the provisions of section four.

255 Section 6. Prohibited acts.

256 No person shall accept gifts or engage in financial relationships that, in the determination of the
257 Commission on Medical Ethics and Professional Conduct, established pursuant to this chapter:

258 (a) That may compromise a health care provider's decisions or clinical judgment relative to the
259 care of a patient or a subject involved in medical research;

260 (b) That directly affects patient care because of medical information generated by providers and
261 suppliers of health care services, products, equipment, or medication that has not been
262 independently verified through evidence-based research; or

263 (c) That result in undue commercial influence that increases the cost of care making such care
264 unaffordable to patients, individually or as a class, which could otherwise benefit from that care.

265 Section 7. Penalties for violation of confidentiality and for perjury.

266 Any person who violates the confidentiality of a commission inquiry under the provisions of
267 paragraph (a) of section four of this chapter shall be punished by a fine of not more than one
268 thousand dollars or by imprisonment for not more than one year, or both.

269 Any person who willfully affirms or swears falsely in regard to any material matter before a
270 commission proceeding under paragraph (c) of section four of this chapter, or who files a false
271 statement of financial interests under section five of this chapter shall be punished by a fine of not

272 more than one thousand dollars or by imprisonment in the state prison for not more than three years,
273 or in a house of correction for not more than two and one-half years, or both.

274 Section 8. Retribution for engaging in commission proceedings.

275 No person shall discharge an employee, or change his official rank, grade or compensation, or deny
276 him a promotion, or threaten so to do, for filing a complaint with or providing information to the
277 commission or testifying in any commission proceeding.

278 SECTION 2. This act shall take effect on January 1, 2009.