

S. 6608

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S E N A T E - A S S E M B L Y

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S 279. Interactions between pharmaceutical companies and health care
45 professionals. 1. This section sets forth a code of conduct for all
46 pharmaceutical companies that sell or market prescription drugs, biolog-
47 ics or medical devices in the state and for all health care profes-
48 sionals practicing in this state to whom such drugs, biologics or
49 devices are sold or marketed. These provisions are intended to benefit
50 patients, enhance the practice of medicine, and ensure that the
51 relationship between pharmaceutical companies and health care profes-
52 sionals does not interfere with the independent judgment of such profes-
53 sionals in making prescribing decisions.
54 2. As used in this section:
55 (a) "biologic" means a virus, therapeutic serum, toxin, antitoxin,
56 vaccine, blood, blood component or derivative, allergenic product, immu-

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1 noglobulin product, or analogous product, as defined by the public
2 health service act, applicable to the prevention, treatment, or cure of
3 a disease or condition of human beings and regulated as a drug under the
4 federal food, drug, and cosmetic act.

5 (b) "bona fide consulting services" means an arrangement with one or
6 more health care professionals for the provision of consulting services
7 by such professional or professionals, where the arrangement is charac-
8 terized by the following factors:

9 (i) a written contract specifies the nature of the consulting services
10 to be provided and the basis for payment of those services;

11 (ii) a legitimate need for the services has been clearly identified in
12 advance of requesting the services and entering into the prospective
13 consulting arrangement;

14 (iii) the criteria for selecting consultants are directly related to
15 the identified purpose and the persons responsible for selecting the
16 consultants have the expertise necessary to evaluate whether the partic-
17 ular health care professionals meet those criteria;

18 (iv) the number of health care professionals retained is not greater
19 than the number reasonably necessary to achieve the identified purpose;

20 (v) the retaining company maintains records concerning and makes
21 appropriate use of the services provided by consultants; and

22 (vi) the venue and circumstances of any meeting with consultants are
23 conducive to the consulting services and activities related to the
24 services are the primary focus of the meeting.

25 (c) "conference or meeting" means any gathering:

26 (i) where responsibility for and control over the selection of
27 content, faculty, educational methods, materials, and venue belongs to
28 the event's organizers;

29 (ii) which is held in a venue that is appropriate and conducive to
30 informational communication and training about medical information;

31 (iii) which is primarily dedicated, in both time and effort, to
32 promoting objective scientific and educational activities and discourse;

33 (iv) which includes one or more educational presentations; and

34 (v) which has as the main incentive for bringing attendees together to
35 further their knowledge on the topic or topics being presented.

36 (d) "continuing medical education" means course work or training
37 provided in the state to health care professionals licensed health care
38 providers authorized by law to prescribe drugs, biologics or devices,
39 which pertains to the practice of their profession and for which contin-
40 uing medical education or continuing professional education credits may
41 be awarded.

42 (e) "drugs" means:

43 (i) articles recognized in the official united states pharmacopoeia,
44 official homeopathic pharmacopoeia of the united states, or official
45 national formulary;

46 (ii) articles intended for use in the diagnosis, cure, mitigation,
47 treatment or prevention of disease in humans;

48 (iii) articles (other than food) intended to affect the structure or
49 any function of the body of humans;

50 (iv) articles intended for use as a component of any article specified
51 in subparagraph (i), (ii), or (iii) of this paragraph, not including
52 medical devices or their components, parts or accessories.

53 (f) "financial support" means anything with an economic value, includ-
54 ing but not limited to money, goods and services, or a promise or agree-
55 ment to provide such financial support in the future, regardless of the
56 form of such financial support, which may include but is not limited to

1 payment, compensation, reimbursement, rebate, discount, fee reduction,
2 grant, scholarship or gift.

3 (g) "health care professional" means a physician, dentist, physician
4 assistant, specialist's assistant, nurse practitioner, midwife, optome-
5 trist or other person who is licensed, registered or certified pursuant
6 to title eight of the education law and is authorized under such title
7 to prescribe drugs or medical devices.

8 (h) "hospital setting" means:

9 (i) a hospital, as that term is used under article twenty-eight of
10 this chapter;

11 (ii) academic medical center; or

12 (iii) pharmaceutical or medical device specialized training facility,
13 where the facility, as certified to the department by the pharmaceutical
14 or medical device manufacturing company, is specifically designed to
15 approximate the conditions of a surgical suite, or the conditions of a
16 working clinical laboratory or to provide medical training on large and
17 technical medical devices, such as surgical equipment, implants, and
18 imaging and clinical laboratory equipment.

19 (i) "medical device" means instruments, apparatus, and contrivances,
20 including their components, parts and accessories, which are:

21 (i) recognized in the official national formulary or the united states
22 pharmacopeia or any supplement thereto;

23 (ii) intended for use in the diagnosis of disease or other conditions
24 or in the cure, mitigation, treatment or prevention of disease, in
25 persons or animals; or

26 (iii) intended to affect the structure or function of the body of a
27 person or animal, and which does not achieve its primary intended
28 purposes through chemical action within or on such body and which is not
29 dependent upon being metabolized for the achievement of its primary
30 intended purposes.

31 (j) "pharmaceutical company" means:

32 (i) an entity that is engaged in the production, preparation, propa-
33 gation, compounding, conversion, or processing of prescription drugs,
34 biologics, or medical devices, either directly or indirectly, by
35 extraction from substances of natural origin or independently by means
36 of chemical synthesis or by a combination of extraction and chemical
37 synthesis;

38 (ii) an entity engaged in the packaging, repackaging, labeling, rela-
39 beling, or distribution of drugs; or

40 (iii) a person who engages in pharmaceutical detailing, promotional
41 activities, or other marketing of prescription drugs, biologics or
42 medical devices to health care professionals in this state on behalf of
43 an entity described in subparagraphs (i) or (ii) of this paragraph,
44 including but not limited to field sales representatives.

45 "pharmaceutical company" does not include a licensed pharmacist to the
46 extent he or she dispenses or prepares for dispensing a prescription
47 drug, biologic or medical device.

48 (k) "presenter" means a health care professional who conducts, teaches
49 or participates, other than solely as an attendee, in any aspect of a
50 continuing medical education program.

51 (l) "provider" means a person or entity that represents to attendees
52 or potential attendees that it is the organizer, or an organizer, of a
53 continuing medical education event.

54 (m) "speaker" means any health care professional engaged by a pharma-
55 ceutical company to participate in external promotional programs that

1 provide medical or scientific information to other health care profes-
2 sionals on behalf of the company.

3 (n) "sponsor" means a pharmaceutical company, or a person or entity
4 acting on behalf of a pharmaceutical company, that provides financial
5 support to a provider in connection with one or more continuing medical
6 education programs.

7 (o) "substantial value" means the value of an item or service which
8 reasonably appears to an objective person to be one hundred dollars or
9 more.

10 3. (a) no pharmaceutical company shall offer or provide to a health
11 care professional, and no health care professional shall accept:

12 (i) any financial support, including but not limited to any grant,
13 scholarship, subsidy, support, consulting contract, speaker contract or
14 educational or practice-related items to reward the professional for
15 having prescribed particular drugs, biologics or medical devices in the
16 past, or to induce the professional to prescribe or continue prescribing
17 particular drugs, biologics or medical devices in the future;

18 (ii) any tangible or intangible good or service in a manner or on
19 conditions that would interfere with the independence of the health care
20 professional's prescribing practices; or

21 (iii) any payment in cash or cash equivalents, either directly or
22 indirectly, except as compensation for bona fide consulting services or
23 speaker services pursuant to subdivision nine or ten of this section.

24 (b) nothing in this section shall be construed to prohibit:

25 (i) the provision of price concessions by a pharmaceutical company to
26 a health care professional, such as rebates or discounts, of the type
27 that are commonly offered in the normal course of business, for legiti-
28 mate business reasons and to the extent such concessions comply with
29 applicable laws and regulations;

30 (ii) the provision of prescription drugs by a pharmaceutical company
31 to a health care professional without charge solely and exclusively for
32 the purpose of permitting the professional to distribute such drugs to
33 his or her patients without charge, to the extent such provision and
34 distribution comply with applicable laws and regulations including the
35 prescription drug marketing act; or

36 (iii) the investment of a pharmaceutical company in a business venture
37 in the pharmaceutical or biotechnology field in which a health care
38 professional is a principal, or other joint arrangement between a phar-
39 maceutical company or health care professional in such a venture,
40 provided that the relationship between the company and the professional
41 chiefly relates to such venture and is not intended to influence the
42 professional's prescribing decisions.

43 4. No pharmaceutical company shall provide any promotional materials
44 to a health care professional unless such materials:

45 (a) are accurate and not misleading;

46 (b) make claims about a product only when properly substantiated;

47 (c) accurately reflect the balance between risks and benefits;

48 (d) are consistent with all other requirements of the united states
49 food and drug administration governing such communications; and

50 (e) do not violate the provisions of article twenty-two-a of the
51 general business law.

52 nothing in this section shall be construed to limit the application of
53 any provision of article twenty-two-a of the general business law or of
54 subdivision twelve of section sixty-three of the executive law, or any
55 other applicable federal or state law or regulation.

1 5. (a) no pharmaceutical company may offer or provide meals to health
2 care professionals, and no health care professional may accept or permit
3 his or her staff members to accept such meals from a pharmaceutical
4 company, unless such meals:
5 (i) are provided in connection with structured, oral informational
6 presentations that provide scientific or educational value and meet the
7 criteria set forth in subdivision four of this section;
8 (ii) are served only for consumption during such presentation and are
9 not offered or served for consumption at another time or place or
10 outside the presence of the pharmaceutical company;
11 (iii) are, if offered or provided by a field sales representative or
12 their immediate managers, provided only in the professional's office or
13 in a hospital setting;
14 (iv) are offered or provided only to health care professionals and
15 members of their staff attending presentations, and are not offered or
16 provided to spouses or other guests of a health care professional;
17 (v) are modest as judged by local standards;
18 (vi) are not provided as part of an entertainment or recreational
19 event;
20 (vii) are provided in a manner and location conducive to informational
21 communication; and
22 (viii) are provided to a particular health care professional or
23 members of such professional's staff on no more than an occasional
24 basis.
25 (b) notwithstanding the provisions of paragraph (a) of this subdivi-
26 sion, meals may be provided to and accepted by health care professionals
27 who interact with personnel employed by a pharmaceutical company, other
28 than field sales representatives or their immediate managers, or who are
29 engaged in bona fide consulting services or speaker services pursuant to
30 subdivision nine or ten of this section, outside of the professional's
31 office or a hospital setting, provided that such meals:
32 (i) are incidental to a substantive interaction with the health care
33 professional;
34 (ii) are not provided as part of an entertainment or recreational
35 event;
36 (iii) are held in venues that are appropriate and conducive to infor-
37 mational communication and training about medical information;
38 (iv) are modest as judged by local standards; and
39 (v) are provided on no more than an occasional basis.
40 6. (a) no pharmaceutical company shall offer or provide to any health
41 care professional, and no health care professional shall accept from a
42 pharmaceutical company, any entertainment or recreational items or bene-
43 fits, including but not limited to tickets to the theater or sporting
44 events, sporting equipment, or leisure or vacation trips, regardless of:
45 (i) the value of the items or benefits;
46 (ii) whether the company engages the health care professional as a
47 speaker or consultant; or
48 (iii) whether the entertainment or recreation is secondary to an
49 educational purpose.
50 (b) nothing contained in paragraph (a) of this subdivision shall be
51 construed to prohibit a pharmaceutical company from providing to a
52 health care professional, or to prohibit a health care professional from
53 accepting, entertainment or recreational benefits if the health care
54 professional is employed by the pharmaceutical company on a full-time,
55 salaried basis.

1 7. (a) no pharmaceutical company shall be a provider of any continuing
2 medical education program within the state.

3 (b) no pharmaceutical company shall be a sponsor of any continuing
4 medical education program within the state unless the company has
5 adopted and is in compliance with policies by which the company:

6 (i) has separated its continuing medical education grant-making func-
7 tions from its sales and marketing departments and does not permit its
8 sales and marketing departments to have any involvement in its continu-
9 ing medical education grant-making activities;

10 (ii) has developed and utilizes objective criteria for making continu-
11 ing medical education grant decisions to ensure that the program funded
12 by the company is a bona fide educational program and that the financial
13 support is not an inducement to prescribe or recommend a particular
14 medicine or course of treatment; and

15 (iii) agrees to respect the independent judgment of the continuing
16 medical education provider and to follow standards for commercial
17 support established by the accreditation council for continuing medical
18 education or an equivalent national entity that accredits continuing
19 medical education and is independent of any sponsor or organization of
20 sponsors.

21 (c) no pharmaceutical company shall, in connection with any continuing
22 medical education program within the state:

23 (i) provide any advice or guidance to the continuing medical education
24 provider, even if asked by the provider, regarding the content or facul-
25 ty for a particular continuing medical education program funded by the
26 company; or

27 (ii) provide any verbal or written information to a health care
28 professional who is expected to serve as a presenter at such continuing
29 medical education program regarding any drug, biologic or device manu-
30 factured, distributed or marketed by or on behalf of the company unless
31 such information is consistent with the criteria set forth in subdivi-
32 sion four of this section.

33 (d) no pharmaceutical company may directly or indirectly offer or
34 provide, and no health care professional shall accept, any financial
35 support in connection with the professional's attendance or presentation
36 at a continuing medical education program, including but not limited to
37 financial support intended to compensate the professional for his or her
38 time spent attending or presenting at the continuing medical education
39 program or to reimburse the professional for the costs of travel, lodg-
40 ing, or other personal expenses incurred for attendance or presentation
41 at the continuing medical education program.

42 (e) the provider of a continuing medical education program at its own
43 discretion may apply financial support received from a pharmaceutical
44 company for such program to reduce the overall continuing medical educa-
45 tion registration fee for all attendees. In such case, notwithstanding
46 paragraph (d) of this subdivision, health care professionals may accept
47 the benefit of the reduced fee.

48 (f) a pharmaceutical company shall not provide meals directly at
49 continuing medical education programs, except that a continuing medical
50 education provider at its own discretion may apply the financial support
51 provided by a company for a continuing medical education program to
52 provide modest meals for all participants. In such case, notwithstand-
53 ing paragraph (d) of this subdivision, health care professionals may
54 accept such meals.

55 (g) notwithstanding paragraph (d) of this subdivision, a pharmaceu-
56 tical company may provide financial support for the costs of travel,

1 lodging, or other personal expenses to a health care professional
2 attending or presenting at a continuing medical education program who is
3 a full-time salaried employee of the pharmaceutical company, or who is
4 engaged by the company as a speaker or consultant pursuant to a bona
5 fide agreement and such financial support is provided pursuant to such
6 agreement.

7 (h) no health care professional practicing in the state shall attend
8 or present at any continuing medical education program sponsored by any
9 pharmaceutical company unless advised by the program provider that such
10 pharmaceutical company has provided assurance that it has adopted the
11 policies articulated in paragraph (b) of this subdivision and is in
12 compliance with such policies and with the requirements of paragraph (c)
13 of this subdivision.

14 (i) no health care professional who practices in the state and serves
15 as a presenter at a continuing medical education program shall:

16 (i) present or make available any materials at such continuing medical
17 education program unless such materials are, to the best of the profes-
18 sional's knowledge based on reasonable inquiry, consistent with the
19 criteria set forth in subdivision four of this section;

20 (ii) represent to attendees of such continuing medical education
21 program that he or she authored any materials discussed, distributed or
22 otherwise presented during his or her presentation at such continuing
23 medical education program unless he or she made substantial contrib-
24 utions to the intellectual content of such materials; or

25 (iii) fail to disclose during his or her presentation the existence
26 and nature of any financial support he or she has received from or
27 expects to receive from a sponsor of such continuing medical education
28 program or from a pharmaceutical company that manufacturers, distributes
29 or markets any drug, biologic or medical device discussed in such pres-
30 entation or commonly prescribed for a disease, injury or condition
31 discussed in such presentation, except that disclosure need not be made
32 of any fee reduction pursuant to paragraph (g) of this subdivision or
33 the acceptance of a meal pursuant to paragraph (f) of this subdivision.

34 8. (a) no pharmaceutical company shall directly or indirectly offer or
35 provide any financial support to a health care professional in
36 connection with the professional's attendance at or participation in a
37 conference or meeting, including but not limited to compensation for the
38 professional's time spent attending or participating in the conference
39 or meeting or reimbursement of the costs incurred by the professional
40 for travel, lodging, or other personal expenses in connection with the
41 attendance at or participation in the conference or meeting.

42 (b) no pharmaceutical company shall provide financial support for a
43 conference or meeting if it has any responsibility for and control over
44 the selection of content, faculty, educational methods, materials, or
45 venue of the conference or guidelines, except for conferences or meet-
46 ings sponsored by the company.

47 (c) notwithstanding paragraph (a) or (b) of this subdivision, a phar-
48 maceutical company may provide financial support to the sponsor of a
49 conference or meeting, which may be used by the sponsor to reduce the
50 overall conference registration fee for all attendees.

51 (d) a pharmaceutical company may provide modest meals or receptions
52 during company-sponsored meetings to health care professionals with whom
53 they have bona fide consulting or speaker arrangements, but may not
54 provide recreational or entertainment events in conjunction with such
55 meetings.

1 9. No pharmaceutical company shall provide financial support to a
2 health care professional pursuant to a consulting agreement, and no
3 health care professional shall accept such financial support, unless:
4 (a) the consulting arrangement is a bona fide consulting agreement;
5 and
6 (b) such financial support constitutes reasonable compensation for the
7 professional's consulting services and reasonable reimbursement for
8 reasonable travel, lodging, and meal expenses incurred as part of
9 providing such services, and is based on fair market value.

10 10. (a) no pharmaceutical company shall provide financial support to a
11 health care professional as a speaker pursuant to a speaker agreement,
12 and no health care professional shall accept such financial support,
13 unless:
14 (i) the speaker arrangement meets the criteria of a bona fide consult-
15 ing agreement;
16 (ii) such financial support constitutes reasonable compensation for
17 the professional's speaker services and reasonable reimbursements for
18 reasonable travel, lodging and meal expenses incurred as part of provid-
19 ing such services, and is based on fair market value; and
20 (iii) the professional possesses the general medical expertise and
21 reputation, knowledge and experience regarding a particular therapeutic
22 area, and communications skills such as would reasonably be expected of
23 a speaker in the relevant field.

24 (b) no pharmaceutical company shall retain a health care professional
25 as a speaker unless the company:
26 (i) caps the total amount of annual compensation it will pay to an
27 individual health care professional in connection with all speaking
28 arrangements at a reasonable amount;
29 (ii) provides for periodic monitoring of speaker programs for compli-
30 ance with united states food and drug administration regulatory require-
31 ments for communications on behalf of the company about its medicines;
32 (iii) ensures that each professional receives extensive training on
33 the company's drug products or other specific topic to be presented and
34 on compliance with united states food and drug administration regulatory
35 requirements for communications;
36 (iv) reasonably believes that the training will result in the partic-
37 ipants providing a valuable service to the company; and
38 (v) speaker training sessions are held in venues that are appropriate
39 and conducive to informational communication and training about medical
40 information.

41 (c) a pharmaceutical company shall not provide meals to health care
42 professionals at speaker programs unless such meals are modest, offered
43 to all attendees and occur in a venue and manner conducive to informa-
44 tional communication.

45 (d) a pharmaceutical company shall ensure that each speaker and his or
46 her materials clearly identify the company that is sponsoring the pres-
47 entation, the fact that the speaker is presenting on behalf of the
48 company, and that the speaker is presenting information that is consist-
49 ent with united states food and drug administration guidelines.

50 11. (a) no pharmaceutical company shall retain as a speaker or
51 consultant any health care professional who is a member of a committee
52 that sets formularies or develops clinical guidelines unless the company
53 requires that the professional disclose to such committee the existence
54 and nature of his or her relationship with the company, for as long as
55 such relationship lasts and for at least two years after such relation-
56 ship is terminated.

1 (b) no health care professional shall serve both as a speaker or
2 consultant for a pharmaceutical company and as a member of a committee
3 that sets formularies or develops clinical guidelines unless he or she:

4 (i) discloses to such committee the existence and nature of his or her
5 relationship with the company, which disclosure requirement shall extend
6 for a minimum of two years beyond the termination of any speaker or
7 consultant arrangement; and

8 (ii) follows the relevant procedures set forth by the committee of
9 which they are a member, which may include recusing themselves from
10 decisions relating to the prescription drug, device or biologic for
11 which they have provided speaking or consulting services.

12 12. No pharmaceutical company shall offer or provide financial assist-
13 ance for scholarships or other educational funds to permit medical
14 students, residents, fellows, and other health care professionals in
15 training to attend educational conferences unless:

16 (a) such conferences are sponsored by the major educational, scientif-
17 ic, or policy-making meetings of national, regional, or specialty
18 medical associations; and

19 (b) the selection of individuals who will receive the assistance is
20 made by the academic or training institution.

21 13. A pharmaceutical company that obtains prescriber data from health
22 care professionals shall:

23 (a) maintain the confidential nature of prescriber data and comply
24 with all applicable laws and regulations that protect the confidentiali-
25 ty of patient information;

26 (b) develop written policies regarding the use of the data;

27 (c) educate its employees and agents about such policies;

28 (d) designate an internal contact person to handle inquiries regarding
29 the use of the data;

30 (e) identify appropriate disciplinary actions for misuse of prescriber
31 data; and

32 (f) abide by the wishes of any health care professional who requests
33 that his or her prescriber data not be made available for any sales or
34 marketing purpose.

35 14. No pharmaceutical company shall offer or provide to health care
36 professionals or members of their staff:

37 (a) any item or service intended for the personal benefit of the
38 professional or staff members, such as floral arrangements, artwork,
39 compact discs or tickets to a sporting event;

40 (b) any tangible item, even if they are practice-related items of
41 minimal value such as pens, note pads, or mugs, or are accompanied by
42 patient or physician educational materials, except for educational items
43 described in this subdivision; or

44 (c) any cash or cash equivalents, such as gift certificates, either
45 directly or indirectly, except as compensation for bona fide services
46 expressly permitted under this section.

47 15. A pharmaceutical company may offer or provide to health care
48 professionals items designed primarily for the education of patients or
49 health care professionals only if the items:

50 (a) are not of substantial value and do not have value to the health
51 care professional outside of his or her professional responsibilities,
52 such as an anatomical model for use in an examination room; and

53 (b) are not offered to a particular health care professional on more
54 than an occasional basis, even if each individual item is appropriate.

55 16. (a) no pharmaceutical company shall sell or market prescription
56 drugs, biologics or medical devices to health care professionals prac-

1 ticing in this state unless the representatives who are employed by or
2 act on behalf of the company and who visit health care professionals
3 practicing in this state are:

4 (i) trained in the applicable laws and regulations that govern the
5 representatives' interactions with health care professionals, which
6 training shall be updated as necessary;

7 (ii) trained in or otherwise knowledgeable about general science and
8 product-specific information sufficient to allow the representatives to
9 provide accurate, up-to-date information, consistent with united states
10 food and drug administration requirements and other criteria set forth
11 in subdivision four of this section;

12 (iii) periodically assessed to ensure that they comply with applicable
13 laws, regulations and relevant company policies and standards of
14 conduct; and

15 (iv) subject to appropriate action when they fail to comply with laws,
16 regulations and relevant company policies and standards of conduct.

17 17. The commissioner may assess a civil penalty:

18 (a) against a pharmaceutical company that violates any provision of
19 this section in an amount that is not less than fifteen thousand dollars
20 and not more than two hundred fifty thousand dollars per violation; and

21 (b) against a health care professional that violates any provision of
22 this section in an amount that is not less than five thousand dollars
23 and not more than ten thousand dollars per violation.