

6015

2009-2010 Regular Sessions

I N S E N A T E

June 19, 2009

Introduced by COMMITTEE ON RULES -- (at request of the Governor) -- read twice and ordered printed, and when printed to be committed to the Committee on Rules

AN ACT to amend the public health law and the education law, in relation to prohibiting certain payments to prescribers and requiring the disclosure of other payments; prohibiting the presentation of information at continuing professional education programs that is false or misleading and requiring disclosure of certain potential conflicts of interest in connection with such programs

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

1 Section 1. Declaration of legislative findings and intent. The legis-
2 lature makes the following findings with respect to improper influences
3 exerted on prescribing decisions:
4 1. The pharmaceutical, biological product and medical device indus-
5 tries spend billions of dollars annually to attempt to influence pres-
6 cribers' decisions about which drugs or other treatment to prescribe to
7 their patients, including more than half of all formal continuing
8 medical education programs. Legislation is necessary to prohibit drug
9 and device manufacturers from making payments to prescribers in an
10 attempt to influence their prescribing decisions and further to require
11 prescribers and manufacturers to disclose the things of value that are
12 legitimately transferred from drug and device manufacturers to prescri-
13 bers.
14 2. There is compelling evidence that the vast majority of physicians
15 accept some type of gift or payment from pharmaceutical and medical
16 device manufacturers, and often such gifts and payments, even when of
17 little value, influence physicians to prescribe treatments that are more
18 expensive and no more effective or safe, and are sometimes less effec-
19 tive and more dangerous, than other available treatments.

EXPLANATION--Matter in *ITALICS* (underscored) is new; matter in brackets [] is old law to be omitted.

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1 3. Legislation is necessary to prohibit presenters at continuing
2 professional education programs from providing false or misleading
3 information to prescribers and to require all potential conflicts of
4 interest be disclosed to attendees of such programs.

5 S 2. The public health law is amended by adding a new section 279 to
6 read as follows:

7 S 279. PROHIBITED ACTS AND DISCLOSURE REQUIREMENTS RELATING TO DRUG
8 MANUFACTURERS' PROVISION OF THINGS OF VALUE TO PRESCRIBERS. 1. DEFINI-
9 TIONS. AS USED IN THIS SECTION:

10 (A) "DRUG" MEANS: (I) ARTICLES RECOGNIZED IN THE OFFICIAL UNITED
11 STATES PHARMACOPOEIA, OFFICIAL HOMEOPATHIC PHARMACOPOEIA OF THE UNITED
12 STATES, OR OFFICIAL NATIONAL FORMULARY;

13 (II) ARTICLES INTENDED FOR USE IN THE DIAGNOSIS, CURE, MITIGATION,
14 TREATMENT OR PREVENTION OF DISEASE IN HUMANS;

15 (III) ARTICLES (OTHER THAN FOOD) INTENDED TO AFFECT THE STRUCTURE OR
16 ANY FUNCTION OF THE BODY OF HUMANS;

17 (IV) ARTICLES INTENDED FOR USE AS A COMPONENT OF ANY ARTICLE SPECIFIED
18 IN SUBPARAGRAPH (I), (II) OR (III) OF THIS PARAGRAPH BUT DOES NOT
19 INCLUDE DEVICES OR THEIR COMPONENTS, PARTS OR ACCESSORIES;

20 (B) "DEVICE" MEANS ANY INSTRUMENT, APPARATUS, OR CONTRIVANCE, INCLUD-
21 ING COMPONENTS, PARTS OR ACCESSORIES, INTENDED:

22 (I) FOR USE IN THE DIAGNOSIS, CURE, MITIGATION, TREATMENT, OR
23 PREVENTION OF DISEASE IN HUMANS; OR

24 (II) TO AFFECT THE STRUCTURE OR ANY FUNCTION OF THE BODY OF HUMANS.

25 (C) "MANUFACTURER" MEANS (I) A PERSON OR ENTITY THAT FABRICATES,
26 MAKES, COMPOUNDS, MIXES, PREPARES, PRODUCES, BOTTLES OR PACKS DRUGS OR
27 DEVICES FOR THE PURPOSE OF DISTRIBUTING OR SELLING TO PHARMACIES, HEALTH
28 CARE PROVIDERS OR OTHER CHANNELS OF DISTRIBUTION, OR (II) A PERSON OR
29 ENTITY THAT, PURSUANT TO AN AGREEMENT WITH A PERSON OR ENTITY DESCRIBED
30 IN SUBPARAGRAPH (I) OF THIS PARAGRAPH, MARKETS A DRUG OR DEVICE UNDER A
31 DIFFERENT NAME OR LABELER CODE.

32 (D) "PRESCRIBER" MEANS A PHYSICIAN, DENTIST, PHYSICIAN ASSISTANT,
33 SPECIALIST'S ASSISTANT, NURSE PRACTITIONER, MIDWIFE, OPTOMETRIST AND
34 OTHER LICENSED HEALTH CARE PROVIDER AUTHORIZED UNDER TITLE EIGHT OF THE
35 EDUCATION LAW TO PRESCRIBE DRUGS OR DEVICES.

36 (E) "HEALTH CARE PROVIDER" MEANS (I) A PRESCRIBER WHO PRACTICES IN
37 THIS STATE IN AN INDIVIDUAL PRACTICE, GROUP PRACTICE, PARTNERSHIP,
38 PROFESSIONAL CORPORATION OR OTHER AUTHORIZED FORM OF ASSOCIATION, OR IN
39 A HOSPITAL OR OTHER HEALTH CARE INSTITUTION ISSUED AN OPERATING CERTIF-
40 ICATE PURSUANT TO THIS CHAPTER OR THE MENTAL HYGIENE LAW; (II) SUCH
41 PRESCRIBER'S INDIVIDUAL PRACTICE, GROUP PRACTICE, PARTNERSHIP, PROFES-
42 SIONAL CORPORATION OR OTHER AUTHORIZED FORM OF ASSOCIATION; AND (III) AN
43 EMPLOYEE OF A PERSON OR ENTITY DESCRIBED IN SUBPARAGRAPH (I) OR (II) OF
44 THIS PARAGRAPH.

45 (F) "DOCTOR-IN-TRAINING" MEANS A PERSON ACTIVELY ENGAGED IN THE STATE
46 IN POST-BACCALAUREATE EDUCATION OR PROFESSIONAL TRAINING DESIGNED TO
47 PREPARE PERSONS TO BE ELIGIBLE TO BE LICENSED AS A DOCTOR OF MEDICINE OR
48 DOCTOR OF OSTEOPATHY AND IS NOT AUTHORIZED TO PRESCRIBE DRUGS OR
49 DEVICES.

50 (G) "PAYMENT" MEANS ANYTHING WITH AN ECONOMIC VALUE, INCLUDING BUT NOT
51 LIMITED TO MONEY, GOODS AND SERVICES.

52 (H) "BENEFIT" MEANS ONE OR MORE THINGS WITH AN AGGREGATED FAIR MARKET
53 VALUE FOR THE YEAR EQUAL TO OR GREATER THAN FIFTY DOLLARS, THAT WOULD BE
54 A PAYMENT, AS DEFINED IN PARAGRAPH (G) OF THIS SUBDIVISION, EXCEPT THAT
55 IT COMES WITHIN THE EXCEPTION SET OUT IN PARAGRAPH (B) OR (D) OF SUBDI-
56 VISION THREE OF THIS SECTION.

1 (I) "FAIR MARKET VALUE" MEANS THE VALUE IN ARMS LENGTH TRANSACTIONS,
2 CONSISTENT WITH THE GENERAL MARKET VALUE.

3 (J) "FINANCIAL RELATIONSHIP" MEANS AN OWNERSHIP INTEREST, INVESTMENT
4 INTEREST OR COMPENSATION ARRANGEMENT. AN OWNERSHIP INTEREST OR INVEST-
5 MENT INTEREST MAY BE THROUGH EQUITY, DEBT OR OTHER MEANS; BUT SHALL NOT
6 INCLUDE OWNERSHIP OF INVESTMENT SECURITIES, INCLUDING SHARES OR BONDS,
7 DEBENTURES, NOTES OR OTHER DEBT INSTRUMENTS, WHICH WERE PURCHASED ON
8 TERMS GENERALLY AVAILABLE TO THE PUBLIC AND WHICH ARE IN A CORPORATION
9 THAT IS LISTED FOR TRADING ON THE NEW YORK STOCK EXCHANGE OR ON THE
10 AMERICAN STOCK EXCHANGE, OR IS A NATIONAL MARKET SYSTEM SECURITY TRADED
11 UNDER AN AUTOMATED INTERDEALER QUOTATION SYSTEM OPERATED BY THE NATIONAL
12 ASSOCIATION OF SECURITIES DEALERS, AND HAD, AT THE END OF THE CORPO-
13 RATION'S MOST RECENT FISCAL YEAR, TOTAL ASSETS EXCEEDING ONE HUNDRED
14 MILLION DOLLARS.

15 (K) "DISCOUNT" MEANS A REDUCTION IN THE AMOUNT A HEALTH CARE PROVIDER,
16 ACTING AS A BUYER OR PAYER, IS CHARGED FOR AN ITEM OR SERVICE, WHERE THE
17 REDUCTION IS OFFERED BY OR ON BEHALF OF A MANUFACTURER, AND INCLUDES ALL
18 SUCH REDUCTIONS WHENEVER THEY ARE GIVEN, INCLUDING BEFORE OR AFTER THE
19 TIME OF SALE, PROVIDED THAT SUCH REDUCTIONS GIVEN TO A HEALTH CARE
20 PROVIDER HAVE A FAIR MARKET VALUE AGGREGATED FOR THE CALENDAR YEAR EQUAL
21 TO OR GREATER THAN FIFTY DOLLARS. FOR THE PURPOSE OF THIS PARAGRAPH,
22 "REDUCTION" MEANS A DECREASE FROM THE AMOUNT THAT WOULD BE CHARGED BASED
23 ON AN ARMS-LENGTH TRANSACTION OR THAT IS REPRESENTED TO THE PRESCRIBER
24 AS CONSTITUTING SUCH A DECREASE.

25 2. PROHIBITED ACTS. (A) A MANUFACTURER SHALL NOT, DIRECTLY OR INDI-
26 RECTLY, GIVE OR OFFER TO GIVE ONE OR MORE PAYMENTS WITH AN AGGREGATED
27 FAIR MARKET VALUE IN EXCESS OF FIFTY DOLLARS DURING A CALENDAR YEAR, TO
28 ANY HEALTH CARE PROVIDER OR DOCTOR-IN-TRAINING.

29 (B) A HEALTH CARE PROVIDER OR A DOCTOR-IN-TRAINING SHALL NOT, DIRECTLY
30 OR INDIRECTLY, REQUEST OR RECEIVE FROM ANY MANUFACTURER ONE OR MORE
31 PAYMENTS WITH AN AGGREGATED FAIR MARKET VALUE IN EXCESS OF FIFTY DOLLARS
32 DURING A CALENDAR YEAR.

33 3. EXCEPTIONS. THE FOLLOWING PAYMENTS SHALL NOT BE PROHIBITED UNDER
34 SUBDIVISION TWO OF THIS SECTION AND SHALL BE DISCLOSED, AS APPLICABLE,
35 PURSUANT TO SUBDIVISION FOUR OF THIS SECTION:

36 (A) SAMPLES OF PRESCRIPTION DRUGS THAT THE MANUFACTURER'S EMPLOYEE
37 PROVIDES DIRECTLY TO A PRESCRIBER WHO PROVIDES OR ADMINISTERS SUCH
38 SAMPLE TO A PATIENT WITHOUT CHARGE;

39 (B) ANY PAYMENT TO SUPPORT A SPECIFIED AND BONA FIDE RESEARCH, CLIN-
40 ICAL OR EDUCATIONAL ACTIVITY IN CONNECTION WITH WHICH THE RECIPIENT (I)
41 PRIOR TO RECEIPT OF ANY SUCH PAYMENT, HAS SUBMITTED TO THE MANUFACTURER
42 A PROPOSAL THAT DESCRIBES THE PURPOSE AND METHODS TO BE USED IN CARRYING
43 OUT THE ACTIVITY, THE OUTCOMES OF THE ACTIVITY THAT WILL BE MEASURED AND
44 THE METHODS TO BE USED TO MEASURE SUCH OUTCOMES, A PROCEDURE FOR
45 ACCOUNTING FOR SUCH PAYMENT AND A DEADLINE FOR SUBMITTING TO THE
46 MANUFACTURER A FINAL REPORT CONCERNING THE ACTIVITY; (II) HAS SUBMITTED
47 TO THE MANUFACTURER THE FINAL REPORT, WITH ALL REQUIRED INFORMATION AS
48 DESCRIBED IN ITS PROPOSAL AS SET FORTH IN SUBPARAGRAPH (I) OF THIS PARA-
49 GRAPH, WITHIN THE DEADLINE SET OUT IN SUCH PROPOSAL OR AS EXTENDED IN
50 WRITING BY THE MANUFACTURER; AND (III) MAKES SUCH FINAL REPORT AVAIL-
51 ABLE TO THE DEPARTMENT AND HEALTH CARE PROVIDERS UPON REQUEST;

52 (C) A REDUCTION IN THE COST TO THE HEALTH CARE PROVIDER OF ONE OR MORE
53 OF THE MANUFACTURER'S DRUGS OR DEVICES;

54 (D) REIMBURSEMENT FOR TRAVEL, LODGING AND PERSONAL EXPENSES OR REMUN-
55 ERATION PROVIDED TO A PRESCRIBER OR SUCH REIMBURSEMENT PROVIDED TO A
56 DOCTOR-IN-TRAINING, THE AMOUNT OF WHICH REMUNERATION OR REIMBURSEMENT IS

1 NOT DEPENDENT, DIRECTLY OR INDIRECTLY, ON THE AMOUNT OR VOLUME OF THE
2 MANUFACTURER'S DRUGS OR DEVICES ANY PERSON OR ENTITY PRESCRIBES, IF:

3 (I) WITH RESPECT TO PRESCRIBERS, THE REMUNERATION OR REIMBURSEMENT IS
4 PROVIDED IN CONNECTION WITH BONA FIDE TEACHING, SCIENTIFIC RESEARCH,
5 WRITING OR CONSULTING SERVICES THE PRESCRIBER ACTUALLY PROVIDES, THE
6 NATURE AND PROVISION OF WHICH CAN BE VERIFIED BY DOCUMENTS THE MANUFAC-
7 Turer MAINTAINS FOR NOT LESS THAN THREE YEARS, PROVIDED THAT (A) THE
8 AMOUNT OF BOTH THE REMUNERATION AND REIMBURSEMENT IS CONSISTENT WITH THE
9 FAIR MARKET VALUE OF THE SERVICES THE PRESCRIBER PROVIDES TO OR ON
10 BEHALF OF THE MANUFACTURER, (B) WITH RESPECT TO TEACHING ACTIVITIES, THE
11 PRESCRIBER IS PART OF THE FACULTY FOR AN EDUCATIONAL PROGRAM AND
12 PROVIDES ATTENDEES WITH SIGNIFICANT SCIENTIFIC OR CLINICAL INFORMATION,
13 AND (C) WITH RESPECT TO WRITING, THE PRESCRIBER IS IDENTIFIED AS AN
14 AUTHOR ONLY WHEN HE OR SHE HAS HAD UNRESTRICTED ACCESS TO ALL DATA
15 PERTAINING TO THE SUBJECT OF THE MANUSCRIPT, HAS GIVEN FINAL APPROVAL OF
16 THE MANUSCRIPT, HAS PARTICIPATED SUFFICIENTLY IN THE WORK TO TAKE PUBLIC
17 RESPONSIBILITY FOR AT LEAST PART OF THE CONTENT, AND HAS MADE SUBSTAN-
18 TIAL CONTRIBUTIONS TO THE INTELLECTUAL CONTENT OF THE WRITTEN WORK IN
19 EITHER CONCEPTION AND DESIGN OR ACQUISITION OF DATA AND IN EITHER DRAFT-
20 ING OR CRITICAL REVISION OF THE MANUSCRIPT FOR IMPORTANT INTELLECTUAL
21 CONTENT; AND

22 (II) WITH RESPECT TO DOCTORS-IN-TRAINING, THE REIMBURSEMENT IS
23 PROVIDED IN CONNECTION WITH ATTENDANCE AT A BONA FIDE MEDICAL CONFER-
24 ENCE, THE PRINCIPAL PURPOSE OF WHICH IS TO IMPART SCIENTIFIC OR CLINICAL
25 INFORMATION, PROVIDED THAT (A) THE AMOUNT OF ANY REIMBURSEMENT IS
26 CONSISTENT WITH THE FAIR MARKET VALUE OF THE TRAVEL, LODGING AND
27 PERSONAL EXPENSES BEING REIMBURSED, AND (B) THE MANUFACTURER TRANSFERS
28 ALL SUCH FUNDS TO THE DOCTOR'S-IN-TRAINING MEDICAL SCHOOL OR PROFES-
29 SIONAL EMPLOYER, THE MEDICAL SCHOOL OR PROFESSIONAL EMPLOYER SELECTS THE
30 DOCTORS-IN-TRAINING WHOSE ATTENDANCE THE MANUFACTURER WILL FUND AND THE
31 MEDICAL CONFERENCES THEY WILL ATTEND, AND THE SCHOOL, EMPLOYER AND
32 MANUFACTURER DO NOT, DIRECTLY OR INDIRECTLY, INFORM THE DOCTOR-IN-TRAIN-
33 ING OF THE SOURCE OF SUCH FUNDS; AND

34 (E) ANYTHING OF ECONOMIC VALUE GIVEN BY A PERSON WITH A FINANCIAL
35 RELATIONSHIP WITH A MANUFACTURER WHO IS RELATED BY BLOOD, MARRIAGE OR
36 ADOPTION WITHIN THREE DEGREES OF CONSANGUINITY TO THE RECIPIENT PRESCRI-
37 BER.

38 4. DISCLOSURE. (A) ANNUAL DISCLOSURE. ANNUALLY, AT A TIME AND IN A
39 MANNER TO BE DETERMINED BY THE DEPARTMENT, EACH HEALTH CARE PROVIDER OR
40 DOCTOR-IN-TRAINING AND EACH MANUFACTURER DOING BUSINESS WITH ANY SUCH
41 HEALTH CARE PROVIDER OR DOCTOR-IN-TRAINING SHALL PROVIDE TO THE DEPART-
42 MENT A REPORT THAT CONTAINS THE INFORMATION REQUIRED BY PARAGRAPHS (B),
43 (C), AND (D) OF THIS SUBDIVISION WHERE (I) SUCH HEALTH CARE PROVIDER OR
44 DOCTOR-IN-TRAINING OFFERED, GAVE OR RECEIVED A BENEFIT; (II) SUCH
45 MANUFACTURER GAVE A DISCOUNT TO A HEALTH CARE PROVIDER; OR (III) A
46 FINANCIAL RELATIONSHIP EXISTED BETWEEN SUCH A MANUFACTURER AND SUCH A
47 PROVIDER OR DOCTOR-IN-TRAINING. ACCESS TO SUCH REPORTS SHALL NOT BE
48 DENIED, THE REPORTS SHALL NOT BE WITHHELD, AND IDENTIFYING INFORMATION
49 SHALL NOT BE DELETED FROM SUCH REPORTS PURSUANT TO SECTION EIGHTY-SEVEN
50 OR EIGHTY-NINE OF THE PUBLIC OFFICERS LAW.

51 (B) DISCLOSURE OF BENEFITS. EACH REPORT REQUIRED BY PARAGRAPH (A) OF
52 THIS SUBDIVISION PERTAINING TO A BENEFIT TRANSFERRED DURING THE REPORT-
53 ING PERIOD SHALL DESCRIBE THE NATURE AND FAIR MARKET VALUE OF THE BENE-
54 FIT THAT WAS OFFERED OR TRANSFERRED; THE NATURE OF ANY GOOD OR SERVICE
55 THAT WAS PROVIDED TO THE MANUFACTURER OR ANY OTHER PERSON OR ENTITY IN

CONNECTION WITH THE PROVISION OF THE BENEFIT; AND SUCH OTHER INFORMATION AS SHALL BE REQUIRED BY THE DEPARTMENT BY REGULATION.

(C) DISCLOSURE OF DISCOUNTS. THE REPORTS REQUIRED BY PARAGRAPH (A) OF THIS SUBDIVISION SHALL NOT REQUIRE A MANUFACTURER TO DISCLOSE DISCOUNT INFORMATION SEPARATELY FOR EACH TRANSACTION. THE DEPARTMENT SHALL BY REGULATION SPECIFY THE MANNER IN WHICH THE VALUE OF THE DISCOUNT SHALL BE REPORTED, INCLUDING A THRESHOLD FOR THE VALUE OF DISCOUNTS THAT MUST BE REPORTED. THE MANUFACTURER SHALL REPORT ALL DISCOUNTS THAT OCCURRED DURING THE REPORTING PERIOD, INCLUDING THOSE DISCOUNTS THE VALUE OF WHICH WAS REALIZED BY THE PURCHASER DURING THE REPORTING PERIOD BUT PERTAIN TO SALES THAT OCCURRED AT A DIFFERENT TIME.

(D) DISCLOSURE OF FINANCIAL RELATIONSHIPS. EACH REPORT A MANUFACTURER, HEALTH CARE PROVIDER OR DOCTOR-IN-TRAINING IS REQUIRED TO MAKE BY PARAGRAPH (A) OF THIS SUBDIVISION PERTAINING TO FINANCIAL RELATIONSHIPS SHALL CONTAIN SUCH INFORMATION AS IS REQUIRED BY THE DEPARTMENT BY REGULATION, WHICH SHALL SPECIFY THE MANNER IN WHICH THE VALUE OF FINANCIAL RELATIONSHIPS SHALL BE REPORTED, INCLUDING THE THRESHOLD VALUE OF FINANCIAL RELATIONSHIPS THAT MUST BE REPORTED.

5. VIOLATIONS. THE COMMISSIONER MAY ASSESS A CIVIL PENALTY FOR VIOLATIONS OF THIS SECTION IN AN AMOUNT THAT IS, FOR A MANUFACTURER'S VIOLATION OF PARAGRAPH (A) OF SUBDIVISION TWO OF THIS SECTION OR SUBDIVISION FOUR OF THIS SECTION, NOT LESS THAN FIVE THOUSAND DOLLARS AND NOT MORE THAN FIFTY THOUSAND DOLLARS PER VIOLATION, AND FOR A HEALTH CARE PROVIDER'S VIOLATION OF PARAGRAPH (B) OF SUBDIVISION TWO OF THIS SECTION OR SUBDIVISION FOUR OF THIS SECTION, NOT LESS THAN FIVE THOUSAND DOLLARS AND NOT MORE THAN TEN THOUSAND DOLLARS PER VIOLATION.

S 3. Section 6509 of the education law is amended by adding a new subdivision 15 to read as follows:

(15) A VIOLATION OF SECTION TWO HUNDRED SEVENTY-NINE OF THE PUBLIC HEALTH LAW.

S 4. Section 6530 of the education law is amended by adding a new subdivision 50 to read as follows:

50. A VIOLATION OF SECTION TWO HUNDRED SEVENTY-NINE OF THE PUBLIC HEALTH LAW.

S 5. Article 29-D of the public health law is amended by adding a new title 4 to read as follows:

TITLE 4

CONTINUING PROFESSIONAL EDUCATION

SECTION 2999-G. DEFINITIONS.

2999-H. REQUIREMENTS FOR CONDUCTING A CONTINUING PROFESSIONAL EDUCATION PROGRAM.

2999-I. VIOLATIONS.

S 2999-G. DEFINITIONS. FOR THE PURPOSE OF THIS TITLE:

1. "CONTINUING PROFESSIONAL EDUCATION PROGRAM" MEANS COURSE WORK OR TRAINING PROVIDED TO PHYSICIANS, DENTISTS, PHYSICIAN ASSISTANTS, SPECIALIST ASSISTANTS, NURSE PRACTITIONERS, MIDWIVES, OPTOMETRISTS OR OTHER LICENSED HEALTH CARE PROVIDERS AUTHORIZED BY LAW TO PRESCRIBE DRUGS OR DEVICES, WHICH PERTAINS TO THE PRACTICE OF THEIR PROFESSION AND FOR WHICH CONTINUING MEDICAL EDUCATION OR CONTINUING PROFESSIONAL EDUCATION CREDITS MAY BE AWARDED.

2. "PROVIDER" MEANS THE PERSON OR ENTITY THAT REPRESENTS TO MEMBERS OF THE RELEVANT PROFESSION THAT IT IS THE ORGANIZER OF A CONTINUING PROFESSIONAL EDUCATION PROGRAM. A CONTINUING PROFESSIONAL EDUCATION PROGRAM CAN HAVE MORE THAN ONE PROVIDER, BUT EVERY SUCH PROGRAM MUST HAVE AT LEAST ONE PROVIDER. MANUFACTURERS AND DISTRIBUTORS ARE NOT PROVIDERS.

1 3. "MANUFACTURER" MEANS (I) A PERSON OR ENTITY THAT FABRICATES, MAKES,
2 COMPOUNDS, MIXES, PREPARES, PRODUCES, BOTTLES OR PACKS DRUGS OR DEVICES
3 FOR THE PURPOSE OF DISTRIBUTING OR SELLING TO PHARMACIES, HEALTH CARE
4 PROVIDERS OR OTHER CHANNELS OF DISTRIBUTION, OR (II) A PERSON OR ENTITY
5 THAT, PURSUANT TO AN AGREEMENT WITH A PERSON OR ENTITY DESCRIBED IN
6 SUBPARAGRAPH (I) OF THIS PARAGRAPH, MARKETS A DRUG OR DEVICE UNDER A
7 DIFFERENT NAME OR LABELER CODE.

8 4. "DISTRIBUTOR" MEANS A PERSON OR ENTITY THAT DELIVERS, OTHER THAN BY
9 DISPENSING, A DRUG PRODUCT TO ANY PERSON.

10 5. "DRUG" MEANS: (I) ARTICLES RECOGNIZED IN THE OFFICIAL UNITED
11 STATES PHARMACOPOEIA, OFFICIAL HOMEOPATHIC PHARMACOPOEIA OF THE UNITED
12 STATES, OR OFFICIAL NATIONAL FORMULARY;

13 (II) ARTICLES INTENDED FOR USE IN THE DIAGNOSIS, CURE, MITIGATION,
14 TREATMENT OR PREVENTION OF DISEASE IN HUMANS;

15 (III) ARTICLES (OTHER THAN FOOD) INTENDED TO AFFECT THE STRUCTURE OR
16 ANY FUNCTION OF THE BODY OF HUMANS;

17 (IV) ARTICLES INTENDED FOR USE AS A COMPONENT OF ANY ARTICLE SPECIFIED
18 IN SUBPARAGRAPH (I), (II) OR (III) OF THIS PARAGRAPH BUT DOES NOT
19 INCLUDE DEVICES OR THEIR COMPONENTS, PARTS OR ACCESSORIES;

20 6. "DEVICE" MEANS ANY INSTRUMENT, APPARATUS, OR CONTRIVANCE, INCLUDING
21 COMPONENTS, PARTS OR ACCESSORIES, INTENDED:

22 (I) FOR USE IN THE DIAGNOSIS, CURE, MITIGATION, TREATMENT, OR
23 PREVENTION OF DISEASE IN HUMANS; OR

24 (II) TO AFFECT THE STRUCTURE OR ANY FUNCTION OF THE BODY OF HUMANS.

25 7. "PRESENTER" IS A NATURAL PERSON WHO CONDUCTS, TEACHES AND PARTIC-
26 IPATES, OTHER THAN SOLELY AS AN ATTENDEE, IN ANY ASPECT OF A CONTINUING
27 PROFESSIONAL EDUCATION PROGRAM, REGARDLESS OF WHETHER SUCH PROGRAM IS
28 PROVIDED IN PERSON OR BY ELECTRONIC OR OTHER MEANS.

29 8. "FINANCIAL RELATIONSHIP" MEANS AN OWNERSHIP INTEREST, INVESTMENT
30 INTEREST OR COMPENSATION ARRANGEMENT. AN OWNERSHIP INTEREST OR INVEST-
31 MENT INTEREST MAY BE THROUGH EQUITY, DEBT OR OTHER MEANS; BUT SHALL NOT
32 INCLUDE OWNERSHIP OF INVESTMENT SECURITIES, INCLUDING SHARES OR BONDS,
33 DEBENTURES, NOTES OR OTHER DEBT INSTRUMENTS, WHICH WERE PURCHASED ON
34 TERMS GENERALLY AVAILABLE TO THE PUBLIC AND WHICH ARE IN A CORPORATION
35 THAT IS LISTED FOR TRADING ON THE NEW YORK STOCK EXCHANGE OR ON THE
36 AMERICAN STOCK EXCHANGE, OR IS A NATIONAL MARKET SYSTEM SECURITY TRADED
37 UNDER AN AUTOMATED INTERDEALER QUOTATION SYSTEM OPERATED BY THE NATIONAL
38 ASSOCIATION OF SECURITIES DEALERS, AND HAD, AT THE END OF THE CORPO-
39 RATION'S MOST RECENT FISCAL YEAR, TOTAL ASSETS EXCEEDING ONE HUNDRED
40 MILLION DOLLARS.

41 9. "CONTINUING PROFESSIONAL EDUCATION MATERIAL" MEANS ANY INFORMATION
42 CONCERNING ANY ASPECT OF THE PRACTICE OF A PROFESSION REFERENCED IN
43 SUBDIVISION ONE OF THIS SECTION WHICH IS COMMUNICATED BY ORAL, WRITTEN,
44 GRAPHIC, AUDIO, VISUAL, ELECTRONIC OR OTHER MEANS DURING A CONTINUING
45 PROFESSIONAL EDUCATION PROGRAM AND IS NOT BEING DISSEMINATED BY OR ON
46 BEHALF OF A MANUFACTURER OR DISTRIBUTOR CONCERNING ONE OR MORE OF ITS
47 PRODUCTS.

48 S 2999-H. REQUIREMENTS FOR CONDUCTING A CONTINUING PROFESSIONAL EDUCA-
49 TION PROGRAM. 1. IN CONNECTION WITH ANY CONTINUING PROFESSIONAL EDUCA-
50 TION PROGRAM CONDUCTED IN THE STATE, A PRESENTER:

51 (A) SHALL NOT KNOWINGLY PRESENT ANY CONTINUING PROFESSIONAL EDUCATION
52 MATERIALS THAT ARE FALSE OR MISLEADING;

53 (B) SHALL NOT REPRESENT, EXPLICITLY OR BY NOT DISCLOSING ANOTHER
54 AUTHOR, THAT HE OR SHE WAS THE AUTHOR OF ANY CONTINUING PROFESSIONAL
55 EDUCATION MATERIALS UNLESS THE PRESENTER HAS GIVEN FINAL APPROVAL OF
56 SUCH MATERIALS, HAS PARTICIPATED SUFFICIENTLY IN THE DEVELOPMENT OF SUCH

1 MATERIALS TO TAKE PUBLIC RESPONSIBILITY FOR THE CONTENT, AND HAS MADE
2 SUBSTANTIAL CONTRIBUTIONS TO THE INTELLECTUAL CONTENT OF SUCH MATERIALS
3 EITHER IN DRAFTING OR IN CRITICAL REVISION OF SUCH MATERIALS FOR IMPOR-
4 TANT INTELLECTUAL CONTENT;

5 (C) SHALL DISCLOSE TO THE PROVIDER ALL FINANCIAL RELATIONSHIPS HE OR
6 SHE HAS WITH ANY MANUFACTURER OR DISTRIBUTOR, INCLUDING THE NAME OF SUCH
7 ENTITIES WITH WHICH HE OR SHE HAS A FINANCIAL RELATIONSHIP, THE NATURE
8 OF THE RELATIONSHIP, AND THE FAIR MARKET VALUE OF ANYTHING OF ECONOMIC
9 VALUE THE PRESENTER RECEIVED DURING THE PRECEDING TWELVE MONTHS IN
10 CONNECTION WITH OR AS A RESULT OF SUCH RELATIONSHIP; AND

11 (D) SHALL DISCLOSE TO THE PROVIDER ANY INFORMATION OR WRITTEN, GRAPH-
12 IC, AUDIO, VISUAL OR ELECTRONIC MATERIALS OF ANY KIND THAT THE PRESENTER
13 INTENDS TO COMMUNICATE AT THE CONTINUING PROFESSIONAL EDUCATION PROGRAM
14 WHICH ARE EXEMPTED FROM THE DEFINITION OF CONTINUING PROFESSIONAL EDUCA-
15 TION MATERIALS BECAUSE THEY ARE BEING DISSEMINATED BY OR ON BEHALF OF A
16 MANUFACTURER OR DISTRIBUTOR, WHICH INFORMATION OR MATERIALS THE PRESEN-
17 TER SHALL DESCRIBE WITH SPECIFICITY.

18 2. IN CONNECTION WITH ANY CONTINUING PROFESSIONAL EDUCATION PROGRAM
19 CONDUCTED IN THE STATE, A PROVIDER:

20 (A) SHALL INFORM EVERY PRESENTER OF HIS OR HER OBLIGATIONS UNDER
21 SUBDIVISION ONE OF THIS SECTION;

22 (B) SHALL ACT PRUDENTLY TO OBTAIN FROM EACH PRESENTER THE INFORMATION
23 HE OR SHE IS REQUIRED TO DISCLOSE BY PARAGRAPHS (C) AND (D) OF SUBDIVI-
24 SION ONE OF THIS SECTION; AND

25 (C) SHALL DISCLOSE TO ALL PERSONS ATTENDING A CONTINUING PROFESSIONAL
26 EDUCATION PROGRAM:

27 (I) THE INFORMATION REQUIRED BY PARAGRAPHS (C) AND (D) OF SUBDIVISION
28 ONE OF THIS SECTION THAT EACH PRESENTER AT SUCH PROGRAM HAS DISCLOSED TO
29 THE PROVIDER; AND

30 (II) THE NATURE OF ANY SUPPORT FOR THE CONTINUING PROFESSIONAL EDUCA-
31 TION PROGRAM, WHETHER MONETARY OR IN KIND, PROVIDED BY A MANUFACTURER OR
32 DISTRIBUTOR, AND THE FAIR MARKET VALUE OF ALL SUCH SUPPORT.

33 S 2999-I. VIOLATIONS. THE COMMISSIONER MAY ASSESS A CIVIL PENALTY FOR
34 VIOLATIONS OF THIS SECTION IN AN AMOUNT THAT IS, FOR A VIOLATION OF
35 SUBDIVISION ONE OF SECTION TWENTY-NINE HUNDRED NINETY-NINE-H OF THIS
36 TITLE, NOT MORE THAN TWENTY-FIVE HUNDRED DOLLARS PER VIOLATION AND, FOR
37 A VIOLATION OF SUBDIVISION TWO OF SECTION TWENTY-NINE HUNDRED
38 NINETY-NINE-H OF THIS TITLE, NOT MORE THAN TEN THOUSAND DOLLARS PER
39 VIOLATION.

40 S 6. Section 6509 of the education law is amended by adding a new
41 subdivision 16 to read as follows:

42 (16) A VIOLATION OF SUBDIVISION ONE OF SECTION TWENTY-NINE HUNDRED
43 NINETY-NINE-H OF THE PUBLIC HEALTH LAW.

44 S 7. Section 6530 of the education law is amended by adding a new
45 subdivision 51 to read as follows:

46 51. A VIOLATION OF SUBDIVISION ONE OF SECTION TWENTY-NINE HUNDRED
47 NINETY-NINE-H OF THE PUBLIC HEALTH LAW.

48 S 8. This act shall take effect January 1, 2011; provided, however,
49 that

50 (a) the commissioner of health is authorized to promulgate such rules
51 and regulations as are necessary to implement the provisions of this act
52 prior to such effective date; and

53 (b) the amendment to article 2-A of the public health law made by
54 section two of this act shall not affect the repeal of such article and
55 shall be deemed repealed therewith.