

Representative Paul Ray proposes the following substitute bill:

INFORMATION ON PHARMACEUTICAL PRODUCTS

2013 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Paul Ray

Senate Sponsor: Brian E. Shiozawa

LONG TITLE

General Description:

This bill amends the Division of Occupational and Professional Licensing Act related to commercial and academic detailing for prescription drugs.

Highlighted Provisions:

This bill:

- ▶ defines terms;
- ▶ creates standards for providing educational information to health care providers about prescription drugs;
- ▶ expands the application of federal regulations that apply to a pharmaceutical manufacturer's drug representatives to other health care providers who make educational statements about a prescription drug;
- ▶ creates certain exceptions to the application of the federal regulations; and
- ▶ creates a private right of action if the federal regulations are violated.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:



26 ENACTS:

27 **58-1-501.7**, Utah Code Annotated 1953



29 *Be it enacted by the Legislature of the state of Utah:*

30 Section 1. Section **58-1-501.7** is enacted to read:

31 **58-1-501.7. Standards of conduct for prescription drug education -- Academic**
32 **and commercial detailing.**

33 (1) For purposes of this section:

34 (a) "Academic detailing":

35 (i) means a health care provider who is licensed under this title to prescribe or dispense
36 a prescription drug and employed by someone other than a pharmaceutical manufacturer:

37 (A) for the purpose of countering information provided in commercial detailing; and

38 (B) to disseminate educational information about prescription drugs to other health
39 care providers in an effort to better align clinical practice with scientific research; and

40 (ii) does not include a health care provider who:

41 (A) is disseminating educational information about a prescription drug as part of
42 teaching or supervising students or graduate medical education students at an institution of
43 higher education or through a medical residency program;

44 (B) is disseminating educational information about a prescription drug to a patient or a
45 patient's representative; or

46 (C) is acting within the scope of practice for the health care provider regarding the
47 prescribing or dispensing of a prescription drug.

48 (b) "Commercial detailing" means an educational practice employed by a
49 pharmaceutical manufacturer in which clinical information and evidence about a prescription
50 drug is shared with health care professionals.

51 (c) "Manufacture" is as defined in Section 58-37-2.

52 (d) "Pharmaceutical manufacturer" is a person who manufactures a prescription drug.

53 (2) (a) Except as provided in Subsection (3), the provisions of this section apply to an
54 academic detailer beginning July 1, 2013.

55 (b) An academic detailer and a commercial detailer who educate another health care
56 provider about prescription drugs through written or oral educational material is subject to

57 federal regulations regarding:

58 (i) false and misleading advertising in 21 C.F.R., Part 201 (2007);

59 (ii) prescription drug advertising in 21 C.F.R., Part 202 (2007); and

60 (iii) the federal Office of the Inspector General's Compliance Program Guidance for

61 Pharmaceutical Manufacturers issued in April 2003, as amended.

62 (c) A person who is injured by a violation of this section has a private right of action
63 against a person engaged in academic detailing, if:

64 (i) the actions of the person engaged in academic detailing, that are a violation of this
65 section, are:

66 (A) the result of gross negligence by the person; or

67 (B) willful and wanton behavior by the person; and

68 (ii) the damages to the person are ~~H~~→ **reasonable, foreseeable, and** ←~~H~~ proximately
68a caused by the violations of this section.

69 (3) (a) For purposes of this Subsection, "accident and health insurer:

70 (i) is as defined in Section 31A-1-301; and

71 (ii) includes a self funded health benefit plan and an administrator for a self funded
72 health benefit plan.

73 (b) This section does not apply to a person who engages in academic detailing if that
74 person is engaged in academic detailing on behalf of:

75 (i) an accident and health insurer, including when an accident and health insurer
76 contracts with or offers:

77 (A) the state Medicaid program, including the primary care network within the state's
78 Medicaid program;

79 (B) the Children's Health Insurance Program created in Section 26-40-103;

80 (C) the state's high risk insurance program created in Section 31A-29-104;

81 (D) a Medicare plan; and

82 (E) a Medicare supplement plan;

83 (ii) a hospital as defined in Section 26-21-2;

84 (iii) any class of pharmacy as defined in Section 58-17b-102, including any affiliated
85 pharmacies;

86 (iv) an integrated health system as defined in Section 13-5b-102; or

87 (v) a medical clinic.

88 (c) This section does not apply to communicating or disseminating information about a
89 prescription drug for the purpose of conducting research using prescription drugs at a health
90 care facility as defined in Section 26-21-2, or a medical clinic.