

INFORMATION ON PHARMACEUTICAL PRODUCTS

2013 GENERAL SESSION

STATE OF UTAH

Chief Sponsor: Paul Ray

Senate Sponsor: _____

LONG TITLE

General Description:

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

Highlighted Provisions:

This bill:

- ▶ defines terms;
- ▶ creates standards for providing educational information to health care providers about prescription drugs and devices;
- ▶ 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 or device;
- ▶ creates certain exceptions to the application of the federal regulations; and
- ▶ makes it unprofessional conduct to violate the federal regulations.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

ENACTS:

58-1-501.7, Utah Code Annotated 1953



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

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

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

(1) For purposes of this section:

(a) "Academic detailing":

(i) means a health care provider who is:

(A) licensed under this title to prescribe or dispense a prescription drug or device; and

(B) employed by someone other than a pharmaceutical manufacturer to disseminate educational information about prescription drugs or devices to other health care providers across a broad range of interventions in an effort to better align clinical practice with scientific research; and

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

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

(B) is disseminating educational information about a prescription drug or device to a patient or a patient's representative.

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

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

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

(2) (a) The provisions of this section apply to an academic detailer beginning July 1, 2013.

(b) An academic detailer and a commercial detailer who educate another health care provider about prescription drugs or devices through written or oral educational material is subject to federal regulations regarding:

(i) labeling and 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) It is unprofessional conduct for a health care provider licensed under this title to
63 violate the provisions of this section.

Legislative Review Note
as of 2-6-13 8:59 AM

Office of Legislative Research and General Counsel