State of Wisconsin
2011 - 2012 LEGISLATURE

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2011 ASSEMBLY BILL 745

March 15, 2012 - Introduced by Representative KRUSICK. Referred to Committee on Health.

AN ACT ***to amend*** 448.02 (3) (a); and ***to create*** 448.31, 448.32 and 448.40 (2) (h) of the statutes; **relating to:** obtaining informed consent for the prescription and use of drugs and devices and granting rule-making authority.

Analysis by the Legislative Reference Bureau

Under current law, a physician who treats a patient must inform the patient about the availability of all alternate, viable medical modes of treatment and about the benefits and risks of these treatments. A physician who violates this requirement is subject to discipline by the Medical Examining Board (board) for unprofessional conduct and may be fined up to $25,000 and imprisoned for up to 9 months. If the board finds that the physician has engaged in unprofessional conduct, the board may warn or reprimand the physician, or limit, suspend, or revoke any license, certificate, or limited permit granted to the physician.

Under this bill, a physician may not prescribe or use a drug or device in a manner that constitutes an off-label use without obtaining the patient's informed consent unless the board has determined that the off-label use is safe and effective. The bill defines an off-label use as a use that has not been approved by the U.S. Federal Drug Administration (FDA) to be included on the product's label. The bill specifies that a patient's consent is informed only if the physician informs the patient that the drug or device is being prescribed or used in a manner that is an off-label use and of the uses for which the drug or device has been approved by the FDA.

The bill also provides that, beginning on January 1, 2014, a physician may not prescribe or use any drug or device in which the physician has a financial interest

unless the physician obtains the patient's informed consent. Under the bill, a physician has a financial interest in a drug or device if the physician has received gifts or payments of more than $10 from the manufacturer and information about those gifts or payments is available to the public on an Internet Web site. Under federal law, information on gifts or payments of more than $10 from manufacturers to physicians must be available to the public on an Internet Web site no later than September 30, 2013. The bill specifies that a patient's consent is informed only if the physician provides the patient with any information related to gifts or payments the physician received from the manufacturer of a drug or device that is publicly available on the Internet Web site established by the federal government.

Under the bill, a physician who fails to obtain a patient's informed consent related to the off–label use of a drug or device or for the prescription or use of a drug or device in which the physician has a financial interest is subject to the same penalties as a physician who fails to inform a patient about the availability of all alternate, viable medical modes of treatment.

Because this bill creates a new crime or revises a penalty for an existing crime, the Joint Review Committee on Criminal Penalties may be requested to prepare a report concerning the proposed penalty and the costs or savings that are likely to result if the bill is enacted.

The people of the state of Wisconsin, represented in senate and assembly, do enact as follows:

SECTION 1. 448.02 (3) (a) of the statutes is amended to read:

448.02 **(3)** (a) The board shall investigate allegations of unprofessional conduct and negligence in treatment by persons holding a license, certificate or limited permit granted by the board. An allegation that a physician has violated s. 253.10 (3), 448.30, 448.31, 448.32, or 450.13 (2); or has failed to mail or present a medical certification required under s. 69.18 (2) within 21 days after the pronouncement of death of the person who is the subject of the required certificate; or ~~that a physician~~ has failed at least 6 times within a 6–month period to mail or present a medical certificate required under s. 69.18 (2) within 6 days after the pronouncement of death of the person who is the subject of the required certificate, is an allegation of unprofessional conduct. Information contained in reports filed with the board under s. 49.45 (2) (a) 12r., 50.36 (3) (b), 609.17, or 632.715, or under 42 CFR 1001.2005, shall

be investigated by the board. Information contained in a report filed with the board under s. 655.045 (1), as created by 1985 Wisconsin Act 29, which is not a finding of negligence or in a report filed with the board under s. 50.36 (3) (c) may, within the discretion of the board, be used as the basis of an investigation of a person named in the report. The board may require a person holding a license, certificate, or limited permit to undergo, and may consider the results of, one or more physical, mental, or professional competency examinations if the board believes that the results of any such examinations may be useful to the board in conducting its investigation.

SECTION 2. 448.31 of the statutes is created to read:

448.31 Informed consent; off–label uses of drugs and devices. (1) In this section:

(a) "Device" has the meaning given in 21 USC 321 (h).

(b) "Drug" has the meaning given in 21 USC 321 (g).

(c) "Off–label use" means a use that is not an intended use for which a drug or device is legally marketed under the federal Food, Drug, and Cosmetic Act, 21 USC 301 to 399d.

(2) (a) Except as provided in par. (b), a physician may not prescribe a drug or device or use a drug or device in the course of treating a patient in a manner that constitutes an off–label use unless the physician first obtains the patient's informed consent. A patient's consent is informed for purposes of this subsection only if all of the following occur:

1. The physician informs the patient that the manner in which the drug or device is being prescribed or used is an off–label use.

2. The physician informs the patient of uses for which the drug or device may be legally marketed under the federal Food, Drug, and Cosmetic Act, 21 USC 301–399a.

(b) Paragraph (a) does not apply to an off–label use that the board determines, by rule, is safe and effective.

SECTION 3. 448.32 of the statutes is created to read:

448.32 Informed consent; financial disclosures. (1) In this section, "financial interest" means that the manufacturer of a drug or device provided a payment or other transfer of value to a physician, as described under 42 USC 1320a–7h (a) (1) (A), and information about the payment or transfer of value is available to the public on an Internet Web site under 42 USC 1320a–7h (c) (1) (C).

(2) Beginning on January 1, 2014, no physician may prescribe a drug or device to a patient or use a drug or device in the course of treating a patient if the physician has a financial interest in the drug or device unless the physician first obtains the patient's informed consent. For purposes of this subsection, a patient's consent is informed only if the physician provides the patient with information that is available to the public on an Internet Web site under 42 USC 1320a–7h (c) (1) (C) that is related to any payment or other transfer of value that the manufacturer of the drug or device provided to the physician.

SECTION 4. 448.40 (2) (h) of the statutes is created to read:

448.40 **(2)** (h) Establishing off–label uses, as defined in s. 448.31 (1) (c), that are medically safe and effective.

(END)