

5

6

7

8

9

10

11

## State of Misconsin 2011 - 2012 LEGISLATURE



## ASSEMBLY SUBSTITUTE AMENDMENT 1, TO 2011 SENATE BILL 306

March 13, 2012 - Offered by Representatives Pocan, Berceau, Sinicki, Pope-Roberts, Hebl, Turner and C. Taylor.

1	$AN\ ACT$ to amend $441.07\ (1)\ (f),448.02\ (3)\ (a)$ and $457.26\ (2)\ (gm);$ and to create
2	146.39 of the statutes; relating to: voluntary and informed consent for erectile
3	dysfunction medications and providing a penalty.

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

**Section 1.** 146.39 of the statutes is created to read:

## 146.39 Voluntary and informed consent; prescription of erectile dysfunction medications. (1) Definitions. In this section:

(a) "Qualified person assisting the physician" means a social worker certified under ch. 457, a registered nurse, or a physician assistant to whom a physician who is to prescribe a medication to treat erectile dysfunction has delegated the responsibility, as the physician's agent, for providing the information required under sub. (2) (c) 2.

 $\mathbf{2}$ 

- (b) "Qualified physician" means a physician who by training or experience is qualified to provide the information required under sub. (2) (c) 1.
- (2) VOLUNTARY AND INFORMED CONSENT. (a) *Generally*. Medications to treat erectile dysfunction may not be prescribed or given unless the man who is to receive the medications has given voluntary and informed written consent under the requirements of this section.
- (b) Voluntary consent. Consent under this section to erectile dysfunction medications is voluntary only if the consent is given freely and without coercion by any person. The physician who is to prescribe or give the erectile dysfunction medications shall determine whether the individual's consent is, in fact, voluntary. Notwithstanding par. (c) 3., the physician shall make the determination by speaking to the individual in person, out of the presence of anyone other than a person working for or with the physician. If the physician has reason to suspect that the individual is in danger of being physically harmed by anyone who is coercing the individual to consent to erectile dysfunction medications against his will, the physician shall inform the individual of services for victims or individuals at risk of domestic abuse and provide him with private access to a telephone.
- (c) *Informed consent*. An individual's consent to receive erectile dysfunction medications is informed only if all of the following first take place:
- 1. At least 24 hours before the erectile dysfunction medication is to be given, the physician who prescribes or gives the erectile dysfunction medication or any other qualified physician has, in person, orally informed the individual of all of the following:
- a. Whether or not, according to the reasonable medical judgment of the physician, the individual is a candidate for erectile dysfunction medication.

25

paragraph are met.

1	b. The probable condition of the man's body and sexual organs at the time that
2	the information is provided. The physician or other qualified physician shall also
3	provide this information to the individual in writing at this time.
4	c. The particular medical risks, if any, associated with the man's sexual
5	condition.
6	d. The probable anatomical and physiological characteristics of the man's
7	sexual organs.
8	e. The details of the medical method that would be used to treat the erectile
9	dysfunction.
10	f. The medical risks associated with the particular erectile dysfunction
11	medication that would be used.
12	g. The recommended general medical instructions for the individual to follow
13	after taking erectile dysfunction medications to enhance his safe recovery and the
14	name and telephone number of a physician to call if complications arise after taking
15	an erectile dysfunction medication.
16	h. That the individual has a right to refuse to consent to erectile dysfunction
17	medications, that his consent is not voluntary if anyone is coercing him to consent
18	to taking erectile dysfunction medications against his will, and that it is unlawful for
19	the physician to prescribe or give erectile dysfunction medications without his
20	voluntary consent.
21	i. That the individual may withdraw his consent to take erectile dysfunction
22	medications at any time.
23	j. That the individual is not required to pay any amount for erectile dysfunction

medications until at least 24 hours have elapsed after the requirements of this

- k. That the man must return to the facility for a follow-up visit 12 to 18 days after the use of an erectile dysfunction medication to confirm the efficacy of the medication and evaluate the man's medical condition.
- 2. At least 24 hours before prescribing or giving the erectile dysfunction medication, the physician who is to prescribe or give the medication, a qualified person assisting the physician, or another qualified physician has, in person, done all of the following:
- a. Orally informed the man that he has the right to receive and review the printed materials described in par. (d). The physician or qualified person assisting the physician shall physically give the materials to the individual and shall, in person, orally inform him that the materials are free of charge and have been provided by the state and shall provide him with the current updated copies of the printed materials free of charge.
- b. Orally informed the man that the printed materials described in par. (d) contain information on services available for victims or individuals at risk of domestic abuse.
- c. Orally inform the man that the printed materials described in par. (d) contain information on the availability of public and private agencies and services to provide the individual with information on erectile dysfunction.
- d. Shown the man a video, developed by the department, depicting erectile dysfunction, the risks of taking erectile dysfunction medications, and alternative treatments for erectile dysfunction.
- 3. The information that is required under subds. 1. and 2. is provided to the individual in an individual setting that protects his privacy, maintains the confidentiality of his decision, and ensures that the information he receives focuses

SECTION 1

- on his individual circumstances. This subdivision may not be construed to prevent the individual from having a family member, or any other person of his choice, present during his private counseling.
- 4. Whoever provides the information that is required under subd. 1. or 2., or both, provides adequate opportunity for the man to ask questions and provides the information that is requested or indicates to the man where he can obtain the information.
- 5. The individual certifies in writing on a form that the department shall provide, prior to prescription or giving of erectile dysfunction medications, that the information that is required under subds. 1. and 2. has been provided to him in the manner specified in subd. 3., that he has been offered the information described in par. (d), and that all of his questions, as specified under subd. 4., have been answered in a satisfactory manner. The physician who is to prescribe or give the erectile dysfunction medications or the qualified person assisting the physician shall write on the certification form the name of the physician who is to prescribe or give the erectile dysfunction medications. The individual shall indicate on the certification form who provided the information to him or her and when it was provided.
- 6. Prior to the prescription or giving of erectile dysfunction medications, the physician who is to prescribe or give the medications or the qualified person assisting the physician receives the written certification that is required under subd. 5. The physician or qualified person assisting the physician shall place the certification in the individual's medical record and shall provide the individual with a copy of the certification.
- 7. If the individual considering erectile dysfunction medications is a minor, the requirements to provide information to the minor under subds. 1. to 6. apply also to

- require provision of the information to the individual whose consent is required. If the individual considering erectile dysfunction medications is an individual adjudicated incompetent in this state, the requirements to provide information to the individual under subds. 1. to 6. apply to also require provision of the information to the person appointed as the individual's guardian.
- (d) *Printed information*. By the date that is 60 days after May 1, 2012, the department shall cause to be published in English, Spanish, and other languages spoken by a significant number of state residents, as determined by the department, materials that are in an easily comprehensible format and are printed in type of not less than 12-point size. The department shall distribute a reasonably adequate number of the materials to county departments under s. 46.215, 46.22, or 46.23 and, upon request, shall annually review the materials for accuracy and shall exercise reasonable diligence in providing materials that are accurate and current. The materials shall be all of the following:
- 1. Geographically indexed materials that are designed to inform an individual about public and private agencies and services that are available to provide information on erectile dysfunction and provide imaging services. The materials shall include a comprehensive list of the agencies available, a description of the services that they offer and a description of the manner in which they may be contacted, including telephone numbers and addresses, or, at the option of the department, the materials shall include a toll-free, 24-hour telephone number that may be called to obtain an oral listing of available agencies and services in the locality of the caller and a description of the services that the agencies offer and the manner in which they may be contacted. The materials shall provide information on the availability of governmentally funded programs that serve individuals with erectile

SECTION 1

1

 $\mathbf{2}$ 

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

dysfunction. Services identified for the individual shall include Medical Assistance.

The materials shall state that it is unlawful to prescribe or give erectile dysfunction medications for which consent has been coerced and that any physician who prescribes or gives erectile dysfunction medication without obtaining the

individual's voluntary and informed consent is liable to him for damages in a civil

action and is subject to a civil penalty. The materials shall state that imaging

services may be obtainable by individuals with erectile dysfunction and individuals

who wish to use them and shall describe the services. The materials shall include

information on services in the state that are available for victims or individuals at

risk of domestic abuse.

- 2. Materials, including videos, photographs, pictures, or drawings, that are designed to show erectile dysfunction and treatments for erectile dysfunction. The pictures, drawings, and videos must be realistic and appropriate for the stage of erectile dysfunction depicted. The materials shall be objective, nonjudgmental and designed to convey only accurate scientific information about erectile dysfunction at the various stages. The materials shall also contain objective, accurate information describing the methods of erectile dysfunction treatments commonly employed, and the medical and psychological risks commonly associated with each such procedure.
- 3. A certification form for use under par. (c) 5. that lists, in a check-off format, all of the information required to be provided under that subdivision.
- (e) Requirement to obtain materials. A physician who intends to prescribe erectile dysfunction medication or another qualified physician, who reasonably believes that he or she might have a patient for whom the information under par. (d) is required to be given, shall request a reasonably adequate number of the materials

 $\mathbf{2}$ 

- that are described under par. (d) from the department under par. (d) or from a county department under s. 46.215, 46.22, or 46.23.
- (f) *Presumptions*. Satisfaction of the conditions required under par. (c) creates a rebuttable presumption that the individual's consent and, if the individual is a minor, the consent of the individual who also gives consent, to an erectile dysfunction medication is informed. The presumption of informed consent may be overcome by a preponderance of evidence that establishes that the consent was obtained through fraud, negligence, deception, misrepresentation or omission of a material fact. There is no presumption that consent to erectile dysfunction medication is voluntary.
- (3) PENALTY. Any person who violates sub. (2) shall be required to forfeit not less than \$1,000 nor more than \$10,000. No penalty may be assessed against the man who is prescribed or who receives erectile dysfunction medication.
- (4) CIVIL REMEDIES. (a) A person who violates sub. (2) is liable to the man for whom the erectile dysfunction medication was prescribed or to whom the erectile dysfunction medication was given for damages arising out of the prescription or giving of erectile dysfunction medication, including damages for personal injury and emotional and psychological distress.
- (b) A person who has been awarded damages under par. (a) shall, in addition to any damages awarded under par. (a), be entitled to not less than \$1,000 nor more than \$10,000 in punitive damages for a violation that satisfies a standard under s. 895.043 (3).
- (c) A conviction under sub. (3) is not a condition precedent to bringing an action, obtaining a judgment, or collecting the judgment under this subsection.

(d) Notwithstanding s. 814.04 (1), a person who recovers damages under pa
(a) or (b) may also recover reasonable attorney fees incurred in connection with the
action.

- (e) A contract is not a defense to an action under this subsection.
- (f) Nothing in this subsection limits the common law rights of a person that are not in conflict with sub. (2).
- (5) AFFIRMATIVE DEFENSE. No person is liable under sub. (3) or (4) or under s. 441.07 (1) (f), 448.02 (3) (a), or 457.26 (2) (gm) for failure under sub. (2) (c) 2. to provide the printed materials described in sub. (2) (d) to an individual or for failure under sub. (2) (c) 2. to describe the contents of the printed materials if the person has made a reasonably diligent effort to obtain the printed materials under sub. (2) (e) and the department and the county department under s. 46.215, 46.22, or 46.23 have not made the printed materials available at the time that the person is required to give them to the individual.
- **(6)** Prescription of medications. (a) No person may give a medication to treat erectile dysfunction to a man unless all of the following are satisfied:
- 1. The physician who prescribed the medication to treat erectile dysfunction performs a physical exam on the man before the information is provided under sub. (2).
- 2. The physician who prescribed the medication to treat erectile dysfunction is physically present in the room when the drug is given to the man.
- (b) Any person who violates this subsection is guilty of a Class I felony. No penalty may be assessed against a man for whom a medication to treat erectile dysfunction is prescribed.

**SECTION 2.** 441.07 (1) (f) of the statutes is amended to read:

 $\mathbf{2}$ 

3

4

5

6

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

441.07 **(1)** (f) A violation of the requirements of s. <u>146.39 (2) (c) 2., 3., 4., 5., 6.</u>, or 7. or 253.10 (3) (c) 2., 3., 4., 5., 6. or 7.

**SECTION 3.** 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. 146.39 (2), 253.10 (3), 448.30 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 4.** 457.26 (2) (gm) of the statutes is amended to read:

LRBs0418/1 TJD:cjs&wlj:ch **SECTION 4** 

1 457.26 (2) (gm) Violated the requirements of s. <u>146.39 (2) (c) 2., 3., 4., 5., 6., or</u>

 $2 \qquad \quad \underline{7. \text{ or } 253.10 \ (3) \ (c) \ 2., \ 3., \ 4., \ 5., \ 6. \text{ or } 7.}$ 

3 (END)