

2001 DRAFTING REQUEST

Bill

Received: **08/07/2001**

Received By: **kunkemd**

Wanted: **As time permits**

Identical to LRB:

For: **Legislative Council - JLC**

By/Representing: **Russ Whitesel**

This file may be shown to any legislator: **NO**

Drafter: **kunkemd**

May Contact:

Addl. Drafters:

Subject: **Health - miscellaneous
Occupational Reg. - misc**

Extra Copies: **DAK**

Submit via email: **NO**

Pre Topic:

No specific pre topic given

Topic:

Prescriptions for children with attention deficit hyperactivity disorder

Instructions:

See Attached

Drafting History:

<u>Vers.</u>	<u>Drafted</u>	<u>Reviewed</u>	<u>Typed</u>	<u>Proofed</u>	<u>Submitted</u>	<u>Jacketcd</u>	<u>Required</u>
/P1	kunkemd 08/09/2001	csicilia 08/13/2001	rschluet 08/14/2001	_____	lrb_docadmin 08/14/2001		State
	kunkemd 08/16/2001	csicilia 08/29/2001		_____			
/1			rschluet 08/29/2001	_____	lrb_docadmin 08/29/2001	lrb_docadminState 12/03/2001	

FE Sent For: **08/29/2001, ~~08/29/2001, 08/29/2001~~**

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<END>

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	kunkemd 08/16/2001	csicilia 08/29/2001		_____			
/1			rschluet 08/29/2001	_____	lrb_docadmin 08/29/2001		State

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u/i" 8/29/01
RU MPK

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*PA: please request
a fiscal
estimate
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-MOT*

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/P1	kunkemd 08/09/2001	csicilia 08/13/2001	rschluet 08/14/2001		lrb_docadmin 08/14/2001		State

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[Handwritten signatures and initials]
8-29-01 <END>

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/?	kunkemd		lc conversion 8/13/01				

FE Sent For:

1 qs 8/13/01  <END>
8.13.01

1 **AN ACT** *to amend* 448.02 (3) (a); and *to create* 448.35 of the statutes; **relating to:**
2 information provided by a physician when certain substances are prescribed for
3 children.

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

JOINT LEGISLATIVE COUNCIL PREFATORY NOTE: This draft was prepared for the joint legislative council's special committee on use of prescription drugs for children.

PROVISION OF CERTAIN INFORMATION BY PHYSICIANS PRESCRIBING A SCHEDULE II CONTROLLED SUBSTANCE FOR A CHILD

The draft requires any physician who diagnoses a child with attention deficit/hyperactivity disorder (ADHD) or other behavioral or emotional disorder and prescribes a Schedule II controlled substance for treatment of the disorder for 30 days or longer to provide certain information about the controlled substance to the parent or guardian of the child. If the child is 14 years of age or older, the physician must also provide the information to the child. If the physician treats a child for ADHD or other behavioral or emotional disorder with a Schedule II controlled substance on a long-term basis, the physician must provide this information to the parent or guardian and to the child, as required, at least once every 3 years.

Under the circumstances described above, a physician must provide all of the following information:

1. A detailed explanation of the method of diagnosis used, including the results of any tests or evaluations.
2. Any materials pertaining to the prescribed substance which have been prepared by the department of health and family services (DHFS). The requirement for DHFS to prepare materials is described below.
3. Information on alternative modes of treatment, as provided in s. 448.30, stats., which provides as follows:

“448.30 Information on alternate modes of treatment. Any physician who treats a patient shall inform the patient about the

availability of all alternate, viable medical modes of treatment and about the benefits and risks of these treatments. The physician's duty to inform the patient under this section does not require disclosure of:

- (1) Information beyond what a reasonably well-qualified physician in a similar medical classification would know.
- (2) Detailed technical information that in all probability a patient would not understand.
- (3) Risks apparent or known to the patient.
- (4) Extremely remote possibilities that might falsely or detrimentally alarm the patient.
- (5) Information in emergencies where failure to provide treatment would be more harmful to the patient than treatment.
- (6) Information in cases where the patient is incapable of consenting.”.

The physician must obtain certification in writing from the parent or guardian of the child that the physician has provided all of the information set forth above. If the child for whom the controlled substance is prescribed is 14 years of age or older, the physician must provide the information set forth above to the child as well as the child's parent or guardian. The physician must obtain certification in writing from the parent or guardian and, when applicable, the child, that the physician has provided the information as required. The physician must keep the certification on file for ___ years.

***PENALTY FOR FAILURE TO PROVIDE INFORMATION;
EXEMPTION FROM LIABILITY***

Under the draft, a physician who fails to provide the information required is subject to disciplinary action by the medical examining board for unprofessional conduct. The draft provides that a physician is not subject to disciplinary action for failure to provide the materials or obtain the certification required if the physician made a reasonably diligent effort to obtain the materials from DHFS and DHFS did not make materials available at the time the physician was required to provide them.

PREPARATION OF INFORMATIONAL MATERIALS BY DHFS

The draft requires DHFS, in consultation with the controlled substances board, to determine which Schedule II controlled substances are routinely prescribed by physicians in this state to treat ADHD and other behavioral or emotional disorders in children. For each of these substances, DHFS must, in consultation with the controlled substances

board, prepare informational materials and make those materials available to physicians in electronic form and, upon request, in written form. The department must annually review the materials for accuracy and exercise reasonable diligence in providing materials that are accurate and current.

Statement That the Substance is a Schedule II Controlled Substance

The informational materials pertaining to each substance must contain a statement that the substance is a Schedule II controlled substance under s. 961.16. The materials must also explain that Schedule II controlled substances have a high potential for abuse and that abuse of a Schedule II controlled substance may lead to severe psychological or physical dependence.

Information Regarding Risks, Side Effects and Long-Term Effects

The informational materials pertaining to each substance must include a description of any known or suspected significant risks, side effects or long-term effects of use of the substance to treat ADHD or other behavioral or emotional disorders in children.

The materials must also contain a brief summary of the results of any studies published in major scientific or medical journals relating to the risks, side effects or long-term effects, including effects on sleep patterns, growth rates and academic achievement, of the substance when used to treat ADHD or other behavioral or emotional disorders in children. If the department determines that the long-term effects of use of the substance to treat ADHD or other behavioral disorders in children are unknown, the materials must contain a statement of that fact.

Effect on Eligibility to Serve in Armed Forces

DHFS must determine if the use of a particular Schedule II controlled substance to treat ADHD or other behavioral or emotional disorder may affect a person's eligibility to serve in the U.S. Armed Forces. If the department so finds, it must include that information in the materials pertaining to substance.

Effect on Eligibility to Obtain Health Insurance Coverage

The department must determine if the use of a particular Schedule II controlled substance to treat ADHD or other behavioral or emotional disorder may affect a person's ability to obtain health insurance coverage. If the department so finds, it must include that information in the materials pertaining to the substance.

Treatment Other Than Prescription Drugs and Practice of Christian Science

The materials must include a statement that parents may seek treatment other than prescription drugs and must include the complete text of s. 448.03 (6), stats., which reads as follows:

“448.03 (6) PRACTICE OF CHRISTIAN SCIENCE. No law of this state regulating the practice of medicine and surgery may be construed to interfere with the practice of Christian Science. A person who elects Christian Science treatment in lieu of medical or surgical treatment for the cure of disease may not be compelled to submit to medical or surgical treatment.”.

DHFS must prepare these materials approximately 5 months after the effective date of the bill, and physicians are responsible to provide the information required and the materials prepared by DHFS approximately 9 months after the effective date of the bill.

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

2 448.02 (3) (a) The board shall investigate allegations of unprofessional conduct and
3 negligence in treatment by persons holding a license, certificate or limited permit granted by
4 the board. An allegation that a physician has violated s. 253.10 (3), 448.30, 448.35 or 450.13
5 (2) or has failed to mail or present a medical certification required under s. 69.18 (2) within
6 21 days after the pronouncement of death of the person who is the subject of the required
7 certificate or that a physician has failed at least 6 times within a 6-month period to mail or
8 present a medical certificate required under s. 69.18 (2) within 6 days after the pronouncement
9 of death of the person who is the subject of the required certificate is an allegation of
10 unprofessional conduct. Information contained in reports filed with the board under s. 49.45
11 (2) (a) 12r., 50.36 (3) (b), 609.17 or 632.715, or under 42 CFR 1001.2005, shall be investigated
12 by the board. Information contained in a report filed with the board under s. 655.045 (1), as
13 created by 1985 Wisconsin Act 29, which is not a finding of negligence or in a report filed with
14 the board under s. 50.36 (3) (c) may, within the discretion of the board, be used as the basis
15 of an investigation of a person named in the report. The board may require a person holding
16 a license, certificate or limited permit to undergo and may consider the results of one or more

1 physical, mental or professional competency examinations if the board believes that the
2 results of any such examinations may be useful to the board in conducting its investigation.

NOTE: Amends the statute which authorizes the medical examining board to investigate allegations of unprofessional conduct and impose penalties against a physician who is found guilty of unprofessional conduct. Specifically, provides that an allegation that a physician violated s. 448.35, stats., which is created in SECTION 2 of the draft, is an allegation of unprofessional conduct.

3 **SECTION 2.** 448.35 of the statutes is created to read:

4 **448.35 Information regarding certain schedule II controlled substances. (1)** In this
5 section:

6 (a) "Child" means a person under 18 years of age.

7 (b) "Department" means the department of health and family services.

8 (2) Except in an emergency, any physician who diagnoses a child with attention
9 deficit/hyperactivity disorder or other behavioral or emotional disorder and prescribes a
10 substance included under s. 961.16 for treatment of the disorder for a period of 30 days or
11 longer shall:

12 (a) Provide to the parent or guardian of the child, and, if the child is 14 years of age or
13 older, the child, a detailed explanation of the method of diagnosis used, including the results
14 of any tests or evaluations.

15 (b) Provide to the parent or guardian of the child, and if the child is 14 years of age or
16 older, the child, any materials pertaining to the prescribed substance which have been prepared
17 by the department under sub. (3).

18 (c) Provide to the parent or guardian of the child, and, if the child is 14 years of age or
19 older, the child, information on alternative modes of treatment, as provided in s. 448.30.

1 (d) Obtain from the parent or guardian of the child, and, if the child is 14 years of age
2 or older, from the child, certification in writing that the physician has provided the information
3 required under pars. (a), (b) and (c). The certification shall be kept on file by the physician
4 for [] years.

COMMENT: For how long should a physician be required to keep the
certification on file?

5 (3) The department shall determine which substances identified in s. 961.16 are
6 commonly prescribed by physicians in this state to treat attention deficit/hyperactivity
7 disorder and other behavioral and emotional disorders in children. No later than the first day
8 of the sixth month beginning after the effective date of this subsection [revisor inserts date]
9 the department shall prepare and make available to physicians materials containing the
10 following information pertaining to each of those substances:

11 (a) A statement that the substance is a Schedule II controlled substance under s. 961.16
12 and an explanation that Schedule II controlled substances have a high potential for abuse and
13 abuse of a Schedule II controlled substance may lead to severe psychological or physical
14 dependence.

15 (b) A description of any known or suspected significant risks, side effects or long-term
16 effects of use of the substance to treat attention deficit/hyperactivity disorder or other
17 behavioral or emotional disorders in children.

18 (c) A brief summary of the results of any studies published in major scientific or medical
19 journals relating to the risks, side effects or long-term effects of the substance, including
20 effects on sleep patterns, growth rates, and academic achievement, when used to treat attention
21 deficit/hyperactivity disorder or other behavioral or emotional disorders in children. If the
22 department determines that the long-term effects of use of the substance to treat attention

1 deficit/hyperactivity disorder or other behavioral or emotional disorders in children are
2 unknown, the printed materials shall contain a statement of that fact.

3 (4) The department shall consult with the controlled substances board when making the
4 determination and preparing the materials under sub. (3).

5 (5) The department shall determine whether the use of a substance described in sub. (3)
6 to treat attention deficit/hyperactivity disorder or other behavioral or emotional disorder may
7 affect a person's eligibility to serve in the U.S. Armed Forces. If the department so finds, it
8 shall include that information in the materials pertaining to that substance prepared under sub.
9 (3).

10 (6) The department shall determine whether the use of a substance described in sub. (3)
11 to treat attention deficit/hyperactivity disorder or other behavioral or emotional disorder may
12 affect a person's ability to obtain health insurance coverage. If the department so finds, it shall
13 include that information in the materials pertaining to that substance prepared under sub. (3).

14 (7) The materials prepared under sub. (3) shall include a statement that parents may seek
15 treatment other than prescription drugs and shall include the complete text of s. 448.03 (6).

16 (8) A physician who treats a child for attention deficit/hyperactivity disorder or other
17 behavioral or emotional disorder on a long-term basis with a substance included under s.
18 961.16 shall provide the information and obtain the certification required under sub. (2) at
19 least once every 3 years.

20 (9) The department shall annually review the materials under sub. (3) for accuracy and
21 shall exercise reasonable diligence in providing materials that are accurate and current.

22 (10) The materials prepared under sub. (3) shall be made available to physicians in
23 electronic form, and, upon request, in printed form.

1 (11) No physician is liable under s. 448.02 (3) (a) for failure to provide the materials
2 described in sub. (3) for failure to obtain the certification required under sub. (2) if the
3 physician made a reasonably diligent effort to obtain the materials under sub. (3) from the
4 department and the department did not make the materials available at the time that the
5 physician was required to provide them to the parent or guardian.

NOTE: Creates the requirements for physicians to provide certain information when prescribing a Schedule II controlled substance for a child and for the DHFS to prepare certain informational materials, as described above in the prefatory note.

6 **SECTION 3. Initial applicability.**

7 (1) The treatment of section 448.35 (2) and (8) of the statutes first applies to
8 prescriptions that are issued on the first day of the 10th month beginning after the effective
9 date of this subsection.

NOTE: Provides that the new requirements pertaining to physicians do not take effect until the first day of the 10th month after the effective date of the bill.

10

(END)

1 **AN ACT** to amend 448.02 (3) (a); and to create 115.357 and 448.35 of the statutes;
 2 relating to: information provided by a physician when certain substances are
 3 prescribed for children.

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

JOINT LEGISLATIVE COUNCIL PREFATORY NOTE: This draft was prepared for the joint legislative council's special committee on use of prescription drugs for children.

REQUIREMENT FOR A PHYSICIAN ISSUING A PRESCRIPTION ORDER FOR A CHILD FOR TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER TO PROVIDE CERTAIN INFORMATION

Treatment of Attention Deficit Hyperactivity Disorder With a Prescription Drug

The draft requires any physician who diagnoses a child (any person less than 18 years old) with attention deficit hyperactivity disorder (ADHD) and issues a prescription order for treatment of the disorder to provide certain information to the parent or guardian of the child or to an adult who is with the child at the time the prescription order is issued, if any. If the child is 14 years of age or older, the physician must also provide the information to the child.

If a physician treats a child for ADHD with a prescription drug on a long-term basis, the physician must provide the information when issuing the initial prescription order and at least once every 2 years thereafter. A physician is not required to provide the information in an emergency or if the physician reasonably believes that another physician has issued a prescription order for the child for the same prescription drug within the past year.

Under the circumstances described above, a physician must provide all of the following information:

1. An explanation of the method of diagnosis used, including the results of any tests or evaluations.

2. Information on alternative modes of treatment, as provided in s. 448.30, stats., which provides as follows:

“448.30 Information on alternate modes of treatment. Any physician who treats a patient shall inform the patient about the availability of all alternate, viable medical modes of treatment and about the benefits and risks of these treatments. The physician’s duty to inform the patient under this section does not require disclosure of:

- (1) Information beyond what a reasonably well-qualified physician in a similar medical classification would know.
- (2) Detailed technical information that in all probability a patient would not understand.
- (3) Risks apparent or known to the patient.
- (4) Extremely remote possibilities that might falsely or detrimentally alarm the patient.
- (5) Information in emergencies where failure to provide treatment would be more harmful to the patient than treatment.
- (6) Information in cases where the patient is incapable of consenting.”.

3. A printed copy of the informational materials pertaining to the assessment and treatment of ADHD prepared by the department of health and family services (DHFS). The requirement for DHFS to prepare those materials is described below.

Treatment of ADHD With a Schedule II Controlled Substance

In addition to providing the materials described above, a physician who diagnoses a child with ADHD and prescribes a Schedule II controlled substance for treatment of the disorder must provide a printed copy of any materials pertaining to the substance which have been prepared by DHFS.

A physician who is required to provide any of the information (as described above) must obtain certification in writing from the parent or guardian of the child or the adult to whom the information is provided, if any, that the physician has provided all of the required information.

Penalty for Failure to Provide Information; Exemption

Under current law, a physician who, after investigation and a hearing, is found guilty of unprofessional conduct is subject to disciplinary action by the medical examining board. The draft provides that an allegation that a physician has failed to provide the required information or obtain the required certification is an allegation of unprofessional conduct.

However, the draft provides that it is not unprofessional conduct for a physician to fail to provide the informational materials prepared by DHFS, if the physician made a reasonably diligent effort to obtain the materials from DHFS and DHFS did not make materials available at the time the physician was required to provide them.

PREPARATION OF INFORMATIONAL MATERIALS BY DHFS

Materials Pertaining to the Assessment and Treatment of ADHD

The draft requires DHFS to prepare informational materials on the assessment and treatment of ADHD. These are the materials which must be provided by a physician who prescribes any prescription drug for the treatment of ADHD in a child. The materials must contain the following:

1. A summary of the practice parameters for the assessment and treatment of children and adolescents with ADHD published by the American Academy of Child and Adolescent Psychiatry.
2. A statement that a parent or guardian may seek treatment other than prescription drugs for a child with ADHD.

Materials Pertaining to Schedule II Controlled Substances

In addition to the materials above, the draft requires DHFS to prepare informational materials on certain Schedule II controlled substances. These are the additional materials that must be provided by a physician who prescribes any Schedule II controlled substance for treatment of ADHD in a child. DHFS must, in consultation with the State Medical Society, determine which Schedule II controlled substances are routinely prescribed by physicians in this state to treat ADHD in children. For each of these substances, DHFS must prepare materials containing the following information:

1. A statement that the substance is a Schedule II controlled substance under s. 961.16.
2. A summary of information included in the labeling of the substance required by federal law pertaining to the safety and effectiveness of the substance when used to treat ADHD in children, including any information relating to the potential for abuse or development of dependence upon the drug.
3. A statement that use of a the Schedule II controlled substance to treat ADHD may affect a person's eligibility to serve in the U.S. Armed Forces, if the department so finds.

4. A statement that the use of a Schedule II controlled substance to treat ADHD may affect the cost of a person's health insurance.

DHFS must prepare all of the informational materials within approximately 5 months after the effective date of the bill. Physicians are first required to provide the required information beginning approximately 9 months after the effective date of the bill.

DISSEMINATION OF MATERIALS BY THE DEPARTMENT OF PUBLIC INSTRUCTION

The draft requires the department of public instruction (DPI) to disseminate the informational materials prepared by DHFS to appropriate public school staff.

1 **SECTION 1.** 115.357 of the statutes is created to read:

2 **115.357 Information on attention deficit hyperactivity disorder.** The department
3 shall disseminate to appropriate public school staff the information regarding the diagnosis
4 and treatment of attention deficit hyperactivity disorder and prescription drugs used to treat
5 the disorder prepared by the department of health and family services under s. 448.35 (2).

NOTE: Requires the DPI to distribute the informational materials prepared by DHFS to appropriate public school staff.

6 **SECTION 2.** 448.02 (3) (a) of the statutes is amended to read:

7 **448.02 (3) (a)** The board shall investigate allegations of unprofessional conduct and
8 negligence in treatment by persons holding a license, certificate or limited permit granted by
9 the board. An allegation that a physician has violated s. 253.10 (3), 448.30, 448.35 (3) or
10 450.13 (2) or has failed to mail or present a medical certification required under s. 69.18 (2)
11 within 21 days after the pronouncement of death of the person who is the subject of the
12 required certificate or that a physician has failed at least 6 times within a 6-month period to
13 mail or present a medical certificate required under s. 69.18 (2) within 6 days after the
14 pronouncement of death of the person who is the subject of the required certificate is an
15 allegation of unprofessional conduct. Information contained in reports filed with the board

1 under s. 49.45 (2) (a) 12r., 50.36 (3) (b), 609.17 or 632.715, or under 42 CFR 1001.2005, shall
2 be investigated by the board. Information contained in a report filed with the board under s.
3 655.045 (1), as created by 1985 Wisconsin Act 29, which is not a finding of negligence or in
4 a report filed with the board under s. 50.36 (3) (c) may, within the discretion of the board, be
5 used as the basis of an investigation of a person named in the report. The board may require
6 a person holding a license, certificate or limited permit to undergo and may consider the results
7 of one or more physical, mental or professional competency examinations if the board
8 believes that the results of any such examinations may be useful to the board in conducting
9 its investigation.

NOTE: Amends the statute which authorizes the medical examining board to investigate allegations of unprofessional conduct and impose penalties against a physician who is found guilty of unprofessional conduct. Specifically, provides that an allegation that a physician violated s. 448.35 (3), stats., requiring physicians to provide certain informational materials, as created in SECTION 3 of the draft, is an allegation of unprofessional conduct. SECTION 3 of the draft also creates an exemption which provides that a physician is not guilty of unprofessional conduct for failure to provide the informational materials prepared by DHFS if the physician made a reasonably diligent effort to obtain the materials from DHFS and DIIFS did not make the materials available.

10 **SECTION 3.** 448.35 of the statutes is created to read:

11 **448.35 Attention deficit hyperactivity disorder. (1) DEFINITIONS.** In this section:

- 12 (a) "Child" means a person under 18 years of age.
- 13 (b) "Department" means the department of health and family services.
- 14 (c) "Prescription drug" has the meaning given in s. 450.01 (20).
- 15 (d) "Prescription order" has the meaning given in s. 450.01 (21).
- 16 (e) "Schedule II controlled substance" means any substance included under s. 961.16.

1 (2) INFORMATIONAL MATERIALS. (a) The department shall prepare informational
2 materials which contain the following:

3 1. A summary of the practice parameters for the assessment and treatment of children
4 and adolescents with attention deficit hyperactivity disorder published by the American
5 Academy of Child and Adolescent Psychiatry.

6 2. A statement that a parent or guardian may seek treatment other than prescription
7 drugs for a child with attention deficit hyperactivity disorder.

8 (b) The department shall, in consultation with the State Medical Society, determine
9 which Schedule II controlled substances are commonly prescribed by physicians in this state
10 to treat attention deficit hyperactivity disorder and shall prepare informational materials
11 pertaining to each of those substances containing the following information:

12 1. A statement that the substance is a Schedule II controlled substance.

13 2. A summary of the information included in the labeling of the substance under 21 USC
14 502 (n) which relates to the safety and effectiveness of the substance when used to treat
15 attention deficit hyperactivity disorder in children and the potential for abuse or development
16 of dependence upon the substance.

17 3. A statement that use of the substance to treat attention deficit hyperactivity disorder
18 may affect a person's eligibility to serve in the U.S. Armed Forces, if the department so finds.

19 4. A statement that a person's use of the substance to treat attention deficit hyperactivity
20 disorder may affect the cost of health insurance for that person.

21 (c) The materials prepared under pars. (a) and (b) shall be made available to physicians
22 and to the public on the department's internet site. Upon the request of a physician, the
23 materials under pars. (a) and (b) shall be provided to the physician in printed form.

1 (d) The materials under pars. (a) and (b) shall be made available to physicians and to
2 the public no later than the first day of the 6th month beginning after the effective date of this
3 subsection [revisor inserts date].

4 (e) The department shall periodically review the materials under pars. (a) and (b) and
5 shall exercise reasonable diligence in providing materials that are accurate and current.

6 (3) REQUIREMENTS FOR PHYSICIANS. (a) Except in an emergency and as provided under
7 par. (e), a physician who diagnoses a child with attention deficit hyperactivity disorder and
8 issues a prescription order for treatment of the disorder shall provide the following
9 information to the persons specified in par. (c):

10 1. An explanation of the method of diagnosis used, including the results of any tests or
11 evaluations.

12 2. Information on alternative modes of treatment, as provided in s. 448.30.

13 3. A printed copy of the materials prepared under sub. (2) (a).

14 (b) In addition to the information required under par. (a), except in an emergency and
15 as provided under par. (e), a physician who diagnoses a child with attention deficit
16 hyperactivity disorder and issues a prescription order for a Schedule II controlled substance
17 for treatment of the disorder shall provide a printed copy of any materials pertaining to the
18 prescribed substance which have been prepared by the department under sub. (2) (b) to the
19 persons specified in par. (c).

20 (c) A physician required to provide information under this section shall provide the
21 information to the parent or guardian of the child if the parent or guardian of the child is present
22 when the prescription order is issued. If the child is 14 years of age or older, the physician shall
23 also provide the information to the child. If the child's parent or guardian is not present at the

1 time the prescription order is issued, the physician shall provide the information to an adult
2 who is with the child at the time the prescription is issued, if any.

3 (d) A physician shall obtain from the parent or guardian of the child, or the adult to
4 whom the information is provided, if any, certification in writing that the physician has
5 provided the information required under this section.

6 (e) A physician who treats a child for attention deficit hyperactivity disorder on a
7 long-term basis with the same prescription drug shall provide the information and obtain the
8 certification required under this section when issuing the initial prescription order for that
9 prescription drug and at least once every 2 years thereafter. A physician is not required to
10 provide the information under sub. (2) if the physician reasonably believes that another
11 physician has issued a prescription order for the child for the same prescription drug within
12 the past year.

13 (4) EXEMPTION. It is not unprofessional conduct under s. 448.02 (3) (a) for a physician
14 to fail to provide the materials required under this section if the physician made a reasonably
15 diligent effort to obtain the materials from the department and the department did not make
16 the materials available at the time that the physician was required to provide them.

NOTE: Creates the requirements for physicians to provide certain
information when issuing a prescription order to treat ADHD in a child,
and for DHFS to prepare those informational materials, as described
above in the prefatory note.

Also creates an exemption to an allegation of unprofessional conduct as
described in the note following SECTION 2.

17 **SECTION 4. Initial applicability.**

18 (1) The treatment of section 448.35 (3) of the statutes first applies to prescriptions that
19 are issued on the first day of the 10th month beginning after the effective date of this
20 subsection.

NOTE: Provides that the requirements pertaining to physicians do not take effect until the first day of the 10th month after the effective date of the bill.

1

(END)

Kunkel, Mark

From: Matthias, Mary
Sent: Wednesday, August 08, 2001 2:44 PM
To: Kunkel, Mark
Cc: Whitesel, Russ
Subject: RE: ADHD question

I think the correct provision is 21 USC 352(f). You are correct, (n) deals with advertising. 502 must be the section in the public law. I guess got confused using the FDA website. I just couldn't stay focused.....

MISBRANDED DRUGS AND DEVICES

SEC. 502. [352] A drug or device shall be deemed to be misbranded -

* * * *

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users, except that where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

-----Original Message-----

From: Whitesel, Russ
Sent: Wednesday, August 08, 2001 8:36 AM
To: Matthias, Mary
Subject: FW: ADHD question

Mary--Let's talk about this before I call Mark back. rw

-----Original Message-----

From: Kunkel, Mark
Sent: Tuesday, August 07, 2001 4:05 PM
To: Whitesel, Russ
Subject: ADHD question

Russ:

I'm almost done looking at the Leg. Council draft (WLC:0101/3) regarding ADHD, but I have one question. In proposed s. 448.35 (2) (b) 2., there is a reference to 21 USC 502 (n). I'm not sure whether that is the correct cite. Section 502 of the pertinent federal act is codified at 21 USC 352. However, I'm not sure whether the cite to paragraph (n) in 21 USC 352 is correct. That paragraph refers to advertising, but it appears that you want to refer to a labeling requirement instead. Can you take a look at this?

-- Mark

Grant, Peter

To: Whitesel, Russ; Matthias, Mary
Cc: Kunkel, Mark
Subject: Draft on use of prescription drugs for
 Russ and Mary -

Mark asked me if I would look at WLC:0101/1 for him and let you know my comments. For what they're worth, here they are:

1. Page 5, lines 18-19: isn't this already required under s. 448.30? What if the child is under 14? Doesn't s. 448.30 still apply?
2. Page 6, lines 15-16, line 19, and line 22: is it your intent that "long-term effects" include beneficial effects? If so, never mind.
3. Page 7, lines 5-9 and lines 10-13: can the department make these two determinations *without* consulting the controlled substances board? If so, never mind.
4. Page 7, line 14: this only mentions the parents. Can a child who is at least 14 also seek different treatment?
5. Since the statement on page 6, lines 11-14 is true for all substances under s. 961.16, and since the statement on page 7, lines 14-15 is true regardless of the prescription being written, why not simply require the physician to provide the parent (and child, if 14) with that information instead of directing DHFS to include the information in the materials? In other words, I'd suggest moving those provisions into sub. (2).
6. Page 7, line 17: "long-term basis" isn't defined. Maybe it doesn't need to be; I assume it means "for at least three years." On the other hand, maybe it would be better to say "for at least three years" instead of "on a long-term basis."
7. Page 7, lines 20-21: line 20 uses only "accuracy," but line 21 uses "accurate and current." Is a difference intended?
8. Page 8, lines 1-5: does "no physician is *liable*" mean that, notwithstanding s. 448.02(3)(a), it's *not unprofessional conduct* for a physician to fail to provide the materials or fail to get certification under the circumstances specified? If so, I think I'd phrase it that way instead of using "liable."
9. Page 8, line 4: this says "at the time that the physician was required....," but there is no requirement as to time s. 448.35(2).
10. Regarding the initial applicability: is it your intent that, although DHFS would be required to make the materials available to physicians beginning in six months, the requirement for a physician to provide the materials to parents and kids would not apply for an additional four months?
11. Page 8, line 8: do you think "issued" means "first issued"? In other words, does the sentence also apply to prescription orders that are renewed?
12. Under the draft, a physician who does not obtain the certification required under s. 448.35(2)(d) has engaged in unprofessional conduct, but how can a physician force a patient to provide the certification?
13. Can the drugs included in s. 961.16 be provided by a physician to a patient *without* a prescription? For example, could a physician provide samples instead of writing a scrip? If so, does the draft need to address that situation?
14. This is minor, but would it be OK to refer to ADHD without the slash between "deficit" and "hyperactivity"? Our editors hate slashes, and I notice in the materials on your web site that NIH does not use the slash

05/09/2001

Peter Grant, Managing Attorney
Wisconsin Legislative Reference Bureau
(608) 267-3362
peter.grant@legis.state.wi.us

Assembly Bill

Kunkel, Mark

From: Grant, Peter
Sent: Thursday, June 28, 2001 8:44 PM
To: Kunkel, Mark
Subject: FW: leg council draft

Mark, I think this is yours.

-----Original Message-----

From: Nelson, Robert P.
Sent: Thursday, June 28, 2001 4:47 PM
To: Grant, Peter
Subject: FW: leg council draft

Russ Whitsell thought this belonged to your team, not me. If you have questions, call Russ.

-----Original Message-----

From: Matthias, Mary
Sent: Thursday, June 28, 2001 2:54 PM
To: Nelson, Robert P.
Subject: leg council draft

The Council approved WLC 0101/3 (the ADHD draft) for introduction yesterday. Let Russ Whitesel or me know if you have any questions while drafting that for us. It changed quite a bit since the version we sent over to you earlier but I tried to incorporate your comments as best i could.

thanks for your help!

Mary Matthias
Senior Staff Attorney
Wisconsin Legislative Council Staff
ph.: (608)266-0932; fax: (608)266-3830
mary.matthias@legis.state.wi.us

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-3587/P1dn
MDK:::pg

are issued on the first day of the 10th month beginning after the effective date of the bill.

¶ 8. In the prefatory note, under the heading "Preparation of Informational Materials by DHFS" and the subheading "Materials Pertaining to Schedule II Controlled Substances," I changed "department" to "DHFS" to maintain consistency of usage with the other material under that subheading.

Russ Whitesel:

This bill is identical to the Legislative Council draft that was provided, except for the following:

1. The bill refers to the State Medical Society of *Wisconsin*, which is consistent with other such references in the statutes.
2. The bill uses lower case when referring to the U.S. armed forces.
3. The reference to federal law is corrected.
4. The relating clause is revised.

If you have any questions or redraft instructions, please contact me.

Mark D. Kunkel
Legislative Attorney
Phone: (608) 266-0131
E-mail: mark.kunkel@legis.state.wi.us

¶ 5. I have changed "prescription" to "prescription order" on page 7, line 19, and on page 8, line 12, to maintain consistency of usage with the rest of the bill.

¶ 6. On page 8, line 2, I added the word "described" to the cross-reference, "under sub. (2)," to clarify that the cross-reference ~~to~~ modifies the noun "information" rather than the verb "required."

¶ 7. I added the treatment of section 448.02(3)(a) to the initial applicability provision to clarify that that section first applies to prescription orders that

like
S. 448.35
(3)



D-NOTE

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

By Tues.
8/14

WANTED
TUE
8/14

LPS:
proof word - for
word against
the attached
paper copy of
WLC: 0101/3

Gen Cat

g/c

- 1 AN ACT ...; relating to: requiring physicians to provide certain information when
- 2 when issuing prescription orders to treat children with attention deficit
- 3 hyperactivity disorder.

Analysis by the Legislative Reference Bureau

This bill is explained in NOTES provided by the joint legislative council in the bill.

For further information see the *state* fiscal estimate, which will be printed as an appendix to this bill.

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

PREFATORY NOTE: This bill was prepared for the joint legislative council's special committee on use of prescription drugs for children.

REQUIREMENT FOR A PHYSICIAN ISSUING A PRESCRIPTION ORDER FOR A CHILD FOR TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER TO PROVIDE CERTAIN INFORMATION

Treatment of Attention Deficit Hyperactivity Disorder With a Prescription Drug

close up

The bill requires any physician who diagnoses a child (any person less than 18 years old) with attention deficit hyperactivity disorder (ADHD) and issues a prescription order for treatment of the disorder to provide certain information to the parent or

guardian of the child or to an adult who is with the child at the time the prescription order is issued, if any. If the child is 14 years of age or older, the physician must also provide the information to the child.

close up ↷

If a physician treats a child for ADHD with a prescription drug on a long-term basis, the physician must provide the information when issuing the initial prescription order and at least once every 2 years thereafter. A physician is not required to provide the information in an emergency or if the physician reasonably believes that another physician has issued a prescription order for the child for the same prescription drug within the past year.

close up ↷

Under the circumstances described above, a physician must provide all of the following information:

close up ↷

1. An explanation of the method of diagnosis used, including the results of any tests or evaluations.

close up ↷

2. Information on alternative modes of treatment, as provided in s. 448.30, stats., which provides as follows:

close up ↷

“448.30 Information on alternate modes of treatment. Any physician who treats a patient shall inform the patient about the availability of all alternate, viable medical modes of treatment and about the benefits and risks of these treatments. The physician’s duty to inform the patient under this section does not require disclosure of:

close up →

(1) Information beyond what a reasonably well-qualified physician in a similar medical classification would know.

close up →

(2) Detailed technical information that in all probability a patient would not understand.

close up →

(3) Risks apparent or known to the patient.

close up →

(4) Extremely remote possibilities that might falsely or detrimentally alarm the patient.

close up →

(5) Information in emergencies where failure to provide treatment would be more harmful to the patient than treatment.

close up →

(6) Information in cases where the patient is incapable of consenting.”.

close up →

3. A printed copy of the informational materials pertaining to the assessment and treatment of ADHD prepared by the department of health and family services (DHFS). The requirement for DHFS to prepare those materials is described below.

Treatment of ADHD With a Schedule II Controlled Substance

close up →

In addition to providing the materials described above, a physician who diagnoses a child with ADHD and prescribes a Schedule II controlled substance for treatment of the disorder must provide a printed copy of any materials pertaining to the substance which have been prepared by DHFS.

close up →

A physician who is required to provide any of the information (as described above) must obtain certification in writing from the parent or guardian of the child or the adult to whom the information is provided, if any, that the physician has provided all of the required information.

Penalty for Failure to Provide Information; Exemption

close up →

Under current law, a physician who, after investigation and a hearing, is found guilty of unprofessional conduct is subject to disciplinary action by the medical examining board. The bill provides that an allegation that a physician has failed to provide the

required information or obtain the required certification is an allegation of unprofessional conduct. However, the bill provides that it is not unprofessional conduct for a physician to fail to provide the informational materials prepared by DHFS, if the physician made a reasonably diligent effort to obtain the materials from DHFS and DHFS did not make materials available at the time the physician was required to provide them.

PREPARATION OF INFORMATIONAL MATERIALS BY DHFS

Materials Pertaining to the Assessment and Treatment of ADHD

close up →

The bill requires DHFS to prepare informational materials on the assessment and treatment of ADHD. These are the materials which must be provided by a physician who prescribes any prescription drug for the treatment of ADHD in a child. The materials must contain the following:

close up →

1. A summary of the practice parameters for the assessment and treatment of children and adolescents with ADHD published by the American Academy of Child and Adolescent Psychiatry.

close up →

2. A statement that a parent or guardian may seek treatment other than prescription drugs for a child with ADHD.

Materials Pertaining to Schedule II Controlled Substances

close up →

In addition to the materials above, the bill requires DHFS to prepare informational materials on certain Schedule II controlled substances. These are the additional materials that must be provided by a physician who prescribes any Schedule II controlled substance for treatment of ADHD in a child. DHFS must, in consultation with the State Medical Society of Wisconsin, determine which Schedule II controlled substances are routinely prescribed by physicians in this state to treat ADHD in children. For each of these substances, DHFS must prepare materials containing the following information:

close up →

1. A statement that the substance is a Schedule II controlled substance under s. 961.16.

close up →

2. A summary of information included in the labeling of the substance required by federal law pertaining to the safety and effectiveness of the substance when used to treat ADHD in children, including any information relating to the potential for abuse or development of dependence upon the drug.

close up →

3. A statement that use of a the Schedule II controlled substance to treat ADHD may affect a person's eligibility to serve in the U.S. armed forces, if the (department) so finds.
 DHFS

close up →

4. A statement that the use of a Schedule II controlled substance to treat ADHD may affect the cost of a person's health insurance.

close up →

DHFS must prepare all of the informational materials within approximately 5 months after the effective date of the bill. Physicians are first required to provide the required information beginning approximately 9 months after the effective date of the bill.

close up →

Dissemination of Materials by the Department of Public Instruction

The bill requires the department of public instruction (DPI) to disseminate the informational materials prepared by DHFS to appropriate public school staff.

1

SECTION 1. 115.357 of the statutes is created to read:

2

115.357 Information on attention deficit hyperactivity disorder. The

3

department shall disseminate to appropriate public school staff the information

1 regarding the diagnosis and treatment of attention deficit hyperactivity disorder and
2 prescription drugs used to treat the disorder prepared by the department of health
3 and family services under s. 448.35 (2).

NOTE: Requires the DPI to distribute the informational materials prepared by
DHFS to appropriate public school staff.

4 **SECTION 2.** 448.02 (3) (a) of the statutes is amended to read:

5 448.02 (3) (a) The board shall investigate allegations of unprofessional conduct
6 and negligence in treatment by persons holding a license, certificate or limited
7 permit granted by the board. An allegation that a physician has violated s. 253.10
8 (3), 448.30, 448.35 (3), or 450.13 (2) or has failed to mail or present a medical
9 certification required under s. 69.18 (2) within 21 days after the pronouncement of
10 death of the person who is the subject of the required certificate or that a physician
11 has failed at least 6 times within a 6-month period to mail or present a medical
12 certificate required under s. 69.18 (2) within 6 days after the pronouncement of death
13 of the person who is the subject of the required certificate is an allegation of
14 unprofessional conduct. Information contained in reports filed with the board under
15 s. 49.45 (2) (a) 12r., 50.36 (3) (b), 609.17 or 632.715, or under 42 CFR 1001.2005, shall
16 be investigated by the board. Information contained in a report filed with the board
17 under s. 655.045 (1), as created by 1985 Wisconsin Act 29, which is not a finding of
18 negligence or in a report filed with the board under s. 50.36 (3) (c) may, within the
19 discretion of the board, be used as the basis of an investigation of a person named in
20 the report. The board may require a person holding a license, certificate or limited
21 permit to undergo and may consider the results of one or more physical, mental or
22 professional competency examinations if the board believes that the results of any
23 such examinations may be useful to the board in conducting its investigation.

NOTE: Amends the statute which authorizes the medical examining board to investigate allegations of unprofessional conduct and impose penalties against a physician who is found guilty of unprofessional conduct. Specifically, provides that an allegation that a physician violated s. 448.35 (3), stats., requiring physicians to provide certain informational materials, as created in SECTION 3 of the bill, is an allegation of unprofessional conduct. SECTION 3 of the bill also creates an exemption which provides that a physician is not guilty of unprofessional conduct for failure to provide the informational materials prepared by DHFS if the physician made a reasonably diligent effort to obtain the materials from DHFS and DHFS did not make the materials available.

X
1 SECTION 3. 448.35 of the statutes is created to read:

2 448.35 Attention deficit hyperactivity disorder. (1) DEFINITIONS. In this
3 section:

4 (a) "Child" means a person under 18 years of age.

5 (b) "Department" means the department of health and family services.

6 (c) "Prescription drug" has the meaning given in s. 450.01 (20).

7 (d) "Prescription order" has the meaning given in s. 450.01 (21).

8 (e) "Schedule II controlled substance" means any substance included under s.
9 961.16.

10 (2) INFORMATIONAL MATERIALS. (a) The department shall prepare informational
11 materials which contain the following:

12 1. A summary of the practice parameters for the assessment and treatment of
13 children and adolescents with attention deficit hyperactivity disorder published by
14 the American Academy of Child and Adolescent Psychiatry.

15 2. A statement that a parent or guardian may seek treatment other than
16 prescription drugs for a child with attention deficit hyperactivity disorder.

17 (b) The department shall, in consultation with the State Medical Society of
18 Wisconsin, determine which Schedule II controlled substances are commonly
19 prescribed by physicians in this state to treat attention deficit hyperactivity disorder

1 and shall prepare informational materials pertaining to each of those substances
2 containing the following information:

3 1. A statement that the substance is a Schedule II controlled substance. ✓

4 2. A summary of the information included in the labeling of the substance
5 under 21 USC 352 (f) which relates to the safety and effectiveness of the substance
6 when used to treat attention deficit hyperactivity disorder in children and the
7 potential for abuse or development of dependence upon the substance. ✓

8 3. A statement that use of the substance to treat attention deficit hyperactivity
9 disorder may affect a person's eligibility to serve in the U.S. armed forces, if the
10 department so finds. ✓

11 4. A statement that a person's use of the substance to treat attention deficit
12 hyperactivity disorder may affect the cost of health insurance for that person. ✓

13 (c) The materials prepared under pars. (a) and (b) shall be made available to
14 physicians and to the public on the department's internet site. Upon the request of
15 a physician, the materials under pars. (a) and (b) shall be provided to the physician
16 in printed form.

17 (d) The materials under pars. (a) and (b) shall be made available to physicians
18 and to the public no later than the first day of the 6th month beginning after the
19 effective date of this subsection [revisor inserts date].

20 (e) The department shall periodically review the materials under pars. (a) and
21 (b) and shall exercise reasonable diligence in providing materials that are accurate
22 and current.

23 (3) REQUIREMENTS FOR PHYSICIANS. (a) Except in an emergency and as provided
24 under par. (e), a physician who diagnoses a child with attention deficit hyperactivity

1 disorder and issues a prescription order for treatment of the disorder shall provide
2 the following information to the persons specified in par. (c):

3 1. An explanation of the method of diagnosis used, including the results of any
4 tests or evaluations.

5 2. Information on alternative modes of treatment, as provided in s. 448.30.

6 3. A printed copy of the materials prepared under sub. (2) (a).

7 (b) In addition to the information required under par. (a), except in an
8 emergency and as provided under par. (e), a physician who diagnoses a child with
9 attention deficit hyperactivity disorder and issues a prescription order for a Schedule
10 II controlled substance for treatment of the disorder shall provide a printed copy of
11 any materials pertaining to the prescribed substance which have been prepared by
12 the department under sub. (2) (b) to the persons specified in par. (c).

13 (c) A physician required to provide information under this section shall provide
14 the information to the parent or guardian of the child if the parent or guardian of the
15 child is present when the prescription order is issued. If the child is 14 years of age
16 or older, the physician shall also provide the information to the child. If the child's
17 parent or guardian is not present at the time the prescription order is issued, the
18 physician shall provide the information to an adult who is with the child at the time
19 the prescription order is issued, if any.

20 (d) A physician shall obtain from the parent or guardian of the child, or the
21 adult to whom the information is provided, if any, certification in writing that the
22 physician has provided the information required under this section.

23 (e) A physician who treats a child for attention deficit hyperactivity disorder
24 on a long-term basis with the same prescription drug shall provide the information
25 and obtain the certification required under this section when issuing the initial

described

1 prescription order for that prescription drug and at least once every 2 years
2 thereafter. A physician is not required to provide the information under sub. (2) if
3 the physician reasonably believes that another physician has issued a prescription
4 order for the child for the same prescription drug within the past year. ✓

5 (4) EXEMPTION. It is not unprofessional conduct under s. 448.02 (3) (a) for a
6 physician to fail to provide the materials required under this section if the physician
7 made a reasonably diligent effort to obtain the materials from the department and
8 the department did not make the materials available at the time that the physician
9 was required to provide them. ✓

NOTE: Creates the requirements for physicians to provide certain information when issuing a prescription order to treat ADHD in a child, and for DHFS to prepare those informational materials, as described above in the prefatory note.

Also creates an exemption to an allegation of unprofessional conduct as described in the note following SECTION 2. ✓

10 **SECTION 4. Initial applicability.** *448.02(3)(a) and*

11 (1) The treatment of section ^s 448.35 (3) of the statutes first applies to
12 ^{orders} prescription orders that are issued on the first day of the 10th month beginning after the
13 effective date of this subsection. ✓

NOTE: Provides that the requirements pertaining to physicians do not take effect until the first day of the 10th month after the effective date of the bill.

14 (END)

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-3587/P1dn
MDK:ejs:rs

August 14, 2001

Russ Whitesel:

This bill is identical to the Legislative Council draft that was provided, except for the following:

1. The bill refers to the State Medical Society of *Wisconsin*, which is consistent with other such references in the statutes.
2. The bill uses lower case when referring to the U.S. armed forces.
3. The reference to federal law is corrected.
4. The relating clause is revised.
5. I have changed "prescription" to "prescription order" on page 7, line 19, and on page 8, line 12, to maintain consistency of usage with the rest of the bill.
6. On page 8, line 2, I added the word "described" to the cross-reference, "under sub. (2)," to clarify that the cross-reference modifies the noun "information" rather than the verb "required."
7. I added the treatment of section 448.02 (3) (a) to the initial applicability provision to clarify that that section, like s. 448.35 (3), first applies to prescription orders that are issued on the first day of the 10th month beginning after the effective date of the bill.
8. In the prefatory note, under the heading "Preparation of Informational Materials by DHFS" and the subheading "Materials Pertaining to Schedule II Controlled Substances," I changed "department" to "DHFS" to maintain consistency of usage with the other material under that subheading.

If you have any questions or redraft instructions, please contact me.

Mark D. Kunkel
Legislative Attorney
Phone: (608) 266-0131
E-mail: mark.kunkel@legis.state.wi.us

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-3587/1dn

MDK:/:....

ejs

Russ Whitesel:

This version is identical to the preliminary draft.

Mark D. Kunkel
Legislative Attorney
Phone: (608) 266-0131
E-mail: mark.kunkel@legis.state.wi.us

T
stys

2

SOON

D-NOTE

PRELIMINARY DRAFT - NOT READY FOR INTRODUCTION

No CHANGES

Regen cat

1 AN ACT to amend 448.02 (3) (a); and to create 115.357 and 448.35 of the statutes;
 2 relating to: requiring physicians to provide certain information when issuing
 3 prescription orders to treat children with attention deficit hyperactivity
 4 disorder.

Analysis by the Legislative Reference Bureau

This bill is explained in NOTES provided by the joint legislative council in the bill.

For further information see the *state* fiscal estimate, which will be printed as an appendix to this bill.

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

PREFATORY NOTE: This bill was prepared for the joint legislative council's special committee on use of prescription drugs for children.

REQUIREMENT FOR A PHYSICIAN ISSUING A PRESCRIPTION ORDER FOR A CHILD FOR TREATMENT OF ATTENTION DEFICIT HYPERACTIVITY DISORDER TO PROVIDE CERTAIN INFORMATION

Treatment of Attention Deficit Hyperactivity Disorder With a Prescription Drug

The bill requires any physician who diagnoses a child (any person less than 18 years old) with attention deficit hyperactivity disorder (ADHD) and issues a prescription

order for treatment of the disorder to provide certain information to the parent or guardian of the child or to an adult who is with the child at the time the prescription order is issued, if any. If the child is 14 years of age or older, the physician must also provide the information to the child.

If a physician treats a child for ADHD with a prescription drug on a long-term basis, the physician must provide the information when issuing the initial prescription order and at least once every 2 years thereafter. A physician is not required to provide the information in an emergency or if the physician reasonably believes that another physician has issued a prescription order for the child for the same prescription drug within the past year.

Under the circumstances described above, a physician must provide all of the following information:

1. An explanation of the method of diagnosis used, including the results of any tests or evaluations.

2. Information on alternative modes of treatment, as provided in s. 448.30, stats., which provides as follows:

“448.30 Information on alternate modes of treatment. Any physician who treats a patient shall inform the patient about the availability of all alternate, viable medical modes of treatment and about the benefits and risks of these treatments. The physician’s duty to inform the patient under this section does not require disclosure of:

(1) Information beyond what a reasonably well-qualified physician in a similar medical classification would know.

(2) Detailed technical information that in all probability a patient would not understand.

(3) Risks apparent or known to the patient.

(4) Extremely remote possibilities that might falsely or detrimentally alarm the patient.

(5) Information in emergencies where failure to provide treatment would be more harmful to the patient than treatment.

(6) Information in cases where the patient is incapable of consenting.”

3. A printed copy of the informational materials pertaining to the assessment and treatment of ADHD prepared by the department of health and family services (DHFS). The requirement for DHFS to prepare those materials is described below.

Treatment of ADHD With a Schedule II Controlled Substance

In addition to providing the materials described above, a physician who diagnoses a child with ADHD and prescribes a Schedule II controlled substance for treatment of the disorder must provide a printed copy of any materials pertaining to the substance which have been prepared by DHFS.

A physician who is required to provide any of the information (as described above) must obtain certification in writing from the parent or guardian of the child or the adult to whom the information is provided, if any, that the physician has provided all of the required information.

Penalty for Failure to Provide Information; Exemption

Under current law, a physician who, after investigation and a hearing, is found guilty of unprofessional conduct is subject to disciplinary action by the medical examining board. The bill provides that an allegation that a physician has failed to provide the required information or obtain the required certification is an allegation of unprofessional conduct. However, the bill provides that it is not unprofessional conduct for a physician to fail to provide the informational materials prepared by DHFS, if the physician made a reasonably diligent effort to obtain the materials from DHFS and DHFS did not make materials available at the time the physician was required to provide them.

PREPARATION OF INFORMATIONAL MATERIALS BY DHFS

Materials Pertaining to the Assessment and Treatment of ADHD

The bill requires DHFS to prepare informational materials on the assessment and treatment of ADHD. These are the materials which must be provided by a physician who prescribes any prescription drug for the treatment of ADHD in a child. The materials must contain the following:

1. A summary of the practice parameters for the assessment and treatment of children and adolescents with ADHD published by the American Academy of Child and Adolescent Psychiatry.
2. A statement that a parent or guardian may seek treatment other than prescription drugs for a child with ADHD.

Materials Pertaining to Schedule II Controlled Substances

In addition to the materials above, the bill requires DHFS to prepare informational materials on certain Schedule II controlled substances. These are the additional materials that must be provided by a physician who prescribes any Schedule II controlled substance for treatment of ADHD in a child. DHFS must, in consultation with the State Medical Society of Wisconsin, determine which Schedule II controlled substances are routinely prescribed by physicians in this state to treat ADHD in children. For each of these substances, DHFS must prepare materials containing the following information:

1. A statement that the substance is a Schedule II controlled substance under s. 961.16.
2. A summary of information included in the labeling of the substance required by federal law pertaining to the safety and effectiveness of the substance when used to treat ADHD in children, including any information relating to the potential for abuse or development of dependence upon the drug.
3. A statement that use of a the Schedule II controlled substance to treat ADHD may affect a person's eligibility to serve in the U.S. armed forces, if the DHFS so finds.
4. A statement that the use of a Schedule II controlled substance to treat ADHD may affect the cost of a person's health insurance.

DHFS must prepare all of the informational materials within approximately 5 months after the effective date of the bill. Physicians are first required to provide the required information beginning approximately 9 months after the effective date of the bill.

Dissemination of Materials by the Department of Public Instruction

The bill requires the department of public instruction (DPI) to disseminate the informational materials prepared by DHFS to appropriate public school staff.

1 **SECTION 1.** 115.357 of the statutes is created to read:

2 **115.357 Information on attention deficit hyperactivity disorder.** The
3 department shall disseminate to appropriate public school staff the information
4 regarding the diagnosis and treatment of attention deficit hyperactivity disorder and
5 prescription drugs used to treat the disorder prepared by the department of health
6 and family services under s. 448.35 (2).

NOTE: Requires the DPI to distribute the informational materials prepared by DHFS to appropriate public school staff.

7 **SECTION 2.** 448.02 (3) (a) of the statutes is amended to read:

1 448.02 (3) (a) The board shall investigate allegations of unprofessional conduct
2 and negligence in treatment by persons holding a license, certificate or limited
3 permit granted by the board. An allegation that a physician has violated s. 253.10
4 (3), 448.30, 448.35 (3), or 450.13 (2) or has failed to mail or present a medical
5 certification required under s. 69.18 (2) within 21 days after the pronouncement of
6 death of the person who is the subject of the required certificate or that a physician
7 has failed at least 6 times within a 6-month period to mail or present a medical
8 certificate required under s. 69.18 (2) within 6 days after the pronouncement of death
9 of the person who is the subject of the required certificate is an allegation of
10 unprofessional conduct. Information contained in reports filed with the board under
11 s. 49.45 (2) (a) 12r., 50.36 (3) (b), 609.17 or 632.715, or under 42 CFR 1001.2005, shall
12 be investigated by the board. Information contained in a report filed with the board
13 under s. 655.045 (1), as created by 1985 Wisconsin Act 29, which is not a finding of
14 negligence or in a report filed with the board under s. 50.36 (3) (c) may, within the
15 discretion of the board, be used as the basis of an investigation of a person named in
16 the report. The board may require a person holding a license, certificate or limited
17 permit to undergo and may consider the results of one or more physical, mental or
18 professional competency examinations if the board believes that the results of any
19 such examinations may be useful to the board in conducting its investigation.

NOTE: Amends the statute which authorizes the medical examining board to investigate allegations of unprofessional conduct and impose penalties against a physician who is found guilty of unprofessional conduct. Specifically, provides that an allegation that a physician violated s. 448.35 (3), stats., requiring physicians to provide certain informational materials, as created in SECTION 3 of the bill, is an allegation of unprofessional conduct. SECTION 3 of the bill also creates an exemption which provides that a physician is not guilty of unprofessional conduct for failure to provide the informational materials prepared by DHFS if the physician made a reasonably diligent effort to obtain the materials from DHFS and DHFS did not make the materials available.

20 **SECTION 3.** 448.35 of the statutes is created to read:

1 **448.35 Attention deficit hyperactivity disorder. (1) DEFINITIONS.** In this
2 section:

3 (a) “Child” means a person under 18 years of age.

4 (b) “Department” means the department of health and family services.

5 (c) “Prescription drug” has the meaning given in s. 450.01 (20).

6 (d) “Prescription order” has the meaning given in s. 450.01 (21).

7 (e) “Schedule II controlled substance” means any substance included under s.
8 961.16.

9 **(2) INFORMATIONAL MATERIALS.** (a) The department shall prepare informational
10 materials which contain the following:

11 1. A summary of the practice parameters for the assessment and treatment of
12 children and adolescents with attention deficit hyperactivity disorder published by
13 the American Academy of Child and Adolescent Psychiatry.

14 2. A statement that a parent or guardian may seek treatment other than
15 prescription drugs for a child with attention deficit hyperactivity disorder.

16 (b) The department shall, in consultation with the State Medical Society of
17 Wisconsin, determine which Schedule II controlled substances are commonly
18 prescribed by physicians in this state to treat attention deficit hyperactivity disorder
19 and shall prepare informational materials pertaining to each of those substances
20 containing the following information:

21 1. A statement that the substance is a Schedule II controlled substance.

22 2. A summary of the information included in the labeling of the substance
23 under 21 USC 352 (f) which relates to the safety and effectiveness of the substance
24 when used to treat attention deficit hyperactivity disorder in children and the
25 potential for abuse or development of dependence upon the substance.

1 3. A statement that use of the substance to treat attention deficit hyperactivity
2 disorder may affect a person's eligibility to serve in the U.S. armed forces, if the
3 department so finds.

4 4. A statement that a person's use of the substance to treat attention deficit
5 hyperactivity disorder may affect the cost of health insurance for that person.

6 (c) The materials prepared under pars. (a) and (b) shall be made available to
7 physicians and to the public on the department's internet site. Upon the request of
8 a physician, the materials under pars. (a) and (b) shall be provided to the physician
9 in printed form.

10 (d) The materials under pars. (a) and (b) shall be made available to physicians
11 and to the public no later than the first day of the 6th month beginning after the
12 effective date of this paragraph [revisor inserts date].

13 (e) The department shall periodically review the materials under pars. (a) and
14 (b) and shall exercise reasonable diligence in providing materials that are accurate
15 and current.

16 **(3) REQUIREMENTS FOR PHYSICIANS.** (a) Except in an emergency and as provided
17 under par. (e), a physician who diagnoses a child with attention deficit hyperactivity
18 disorder and issues a prescription order for treatment of the disorder shall provide
19 the following information to the persons specified in par. (c):

20 1. An explanation of the method of diagnosis used, including the results of any
21 tests or evaluations.

22 2. Information on alternative modes of treatment, as provided in s. 448.30.

23 3. A printed copy of the materials prepared under sub. (2) (a).

24 (b) In addition to the information required under par. (a), except in an
25 emergency and as provided under par. (e), a physician who diagnoses a child with

1 attention deficit hyperactivity disorder and issues a prescription order for a Schedule
2 II controlled substance for treatment of the disorder shall provide a printed copy of
3 any materials pertaining to the prescribed substance which have been prepared by
4 the department under sub. (2) (b) to the persons specified in par. (c).

5 (c) A physician required to provide information under this section shall provide
6 the information to the parent or guardian of the child if the parent or guardian of the
7 child is present when the prescription order is issued. If the child is 14 years of age
8 or older, the physician shall also provide the information to the child. If the child's
9 parent or guardian is not present at the time the prescription order is issued, the
10 physician shall provide the information to an adult who is with the child at the time
11 the prescription order is issued, if any.

12 (d) A physician shall obtain from the parent or guardian of the child, or the
13 adult to whom the information is provided, if any, certification in writing that the
14 physician has provided the information required under this section.

15 (e) A physician who treats a child for attention deficit hyperactivity disorder
16 on a long-term basis with the same prescription drug shall provide the information
17 and obtain the certification required under this section when issuing the initial
18 prescription order for that prescription drug and at least once every 2 years
19 thereafter. A physician is not required to provide the information described under
20 sub. (2) if the physician reasonably believes that another physician has issued a
21 prescription order for the child for the same prescription drug within the past year.

22 (4) EXEMPTION. It is not unprofessional conduct under s. 448.02 (3) (a) for a
23 physician to fail to provide the materials required under this section if the physician
24 made a reasonably diligent effort to obtain the materials from the department and

1 the department did not make the materials available at the time that the physician
2 was required to provide them.

NOTE: Creates the requirements for physicians to provide certain information when issuing a prescription order to treat ADHD in a child, and for DHFS to prepare those informational materials, as described above in the prefatory note.

Also creates an exemption to an allegation of unprofessional conduct as described in the note following SECTION 2.

3 **SECTION 4. Initial applicability.**

4 (1) The treatment of sections 448.02 (3) (a) and 448.35 (3) of the statutes first
5 applies to prescription orders that are issued on the first day of the 10th month
6 beginning after the effective date of this subsection.

NOTE: Provides that the requirements pertaining to physicians do not take effect until the first day of the 10th month after the effective date of the bill.

7

(END)

DRAFTER'S NOTE
FROM THE
LEGISLATIVE REFERENCE BUREAU

LRB-3587/1dn
MDK:cjs:rs

August 29, 2001

Russ Whitesel:

This version is identical to the preliminary draft.

Mark D. Kunkel
Legislative Attorney
Phone: (608) 266-0131
E-mail: mark.kunkel@legis.state.wi.us

Barman, Mike

From: Kunkel, Mark
Sent: Monday, December 03, 2001 2:04 PM
To: Barman, Mike
Subject: Jacket request

Mike:

Can you (or someone else) jacket LRB-3587 for the Assembly and send to Russ Whitesel of Legislative Council?

Thanks.

Mark D. Kunkel
Legislative Attorney
Legislative Reference Bureau
(608) 266-0131

Memo

To: Leg. Council
Attn: Russ Whitesel (The Bill's Requestor)

Attached is a fiscal estimate prepared for your 2001 draft that has not yet been introduced.

LRB Number: LRB -3587

Version: “/1”

Entered In Computer And Copy Sent To Requestor Via E-Mail: 09/04/2001

Fiscal Estimate Prepared By: (agency abbr.) DPI

If you have questions about the attached fiscal estimate, you may contact the agency/individual who prepared the fiscal estimate. If you disagree with the enclosed fiscal estimate, please contact the LRB drafter of your proposal to discuss your options under the fiscal estimate procedure.

* * * * *

To: LRB – Legal Section PA's

Subject: Fiscal Estimate Received For A Un-Introduced Draft

- If this is **re-drafted** to a new version please attach this early fiscal estimate to the back of the draft's file between the old version and the new version.
- If this draft gets **introduced** ... and the version of the attached fiscal estimate is correct ... please write the drafts intro. number below and give this fiscal estimate to Mike (or Lynn) to process.

THIS DRAFT WAS INTRODUCED AS: 2001 ABL072

- If this draft gets **introduced** ... and the version of the attached fiscal estimate is for a previous version ... please attach this early fiscal estimate to the back of the draft's file between the old version and the new version. Have Mike (or Lynn) get the ball rolling on getting a fiscal estimate prepared for the introduced version.

Barman, Mike

From: Barman, Mike
Sent: Wednesday, September 05, 2001 9:25 AM
To: Whitesel, Russ
Cc: Kunkel, Mark
Subject: LRB-3587/1 (FE by DPI - Attached - For Your Review)



FE_Leg_Council.pdf

FE_Leg_Council

Memo

To: **Leg. Council**
Attn: Russ Whitesel (The Bill's Requestor)

Attached is a fiscal estimate prepared for your 2001 draft that has not yet been introduced.

LRB Number: LRB **-3587**

Version: **"/ 1 "**

Entered In Computer And Copy Sent To Requestor Via E-Mail: **10 / 09 / 2001**

Fiscal Estimate Prepared By: (agency abbr.) **DORL**

If you have questions about the attached fiscal estimate, you may contact the agency/individual who prepared the fiscal estimate. If you disagree with the enclosed fiscal estimate, please contact the LRB drafter of your proposal to discuss your options under the fiscal estimate procedure.

* * * * *

To: LRB – Legal Section PA's

Subject: Fiscal Estimate Received For A Un-Introduced Draft

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- If this draft gets **introduced** ... and the version of the attached fiscal estimate is correct ... please write the drafts intro. number below and give this fiscal estimate to Mike (or Lynn) to process.

THIS DRAFT WAS INTRODUCED AS: 2001 **ABU72**

- If this draft gets **introduced** ... and the version of the attached fiscal estimate is for a previous version ... please attach this early fiscal estimate to the back of the draft's file between the old version and the new version. Have Mike (or Lynn) get the ball rolling on getting a fiscal estimate prepared for the introduced version.

Barman, Mike

From: Barman, Mike
Sent: Tuesday, October 09, 2001 12:44 PM
To: Whitesel, Russ
Subject: LRB-3587/1 (FE by DORL - attached - for your review)



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cil.pdf

FE-3587_Leg_Council.pdf

Memo

To: **Leg. Council**

Attn: Russ Whitesel

(The Bill's Requestor)

Attached is a fiscal estimate prepared for your 2001 draft that has not yet been introduced.

LRB Number: LRB **- 3587**

Version: **"/ 1 "**

Entered In Computer And Copy Sent To Requestor Via E-Mail: **10 / 15 / 2001**

Fiscal Estimate Prepared By: (agency abbr.) **DHFS**

If you have questions about the attached fiscal estimate, you may contact the agency/ individual who prepared the fiscal estimate. If you disagree with the enclosed fiscal estimate, please contact the LRB drafter of your proposal to discuss your options under the fiscal estimate procedure.

* * * * *

To: LRB – Legal Section PA's

Subject: Fiscal Estimate Received For A Un-Introduced Draft

- If this is **re-drafted** to a new version please attach this early fiscal estimate to the back of the draft's file between the old version and the new version.
- If this draft gets **introduced** ... and the version of the attached fiscal estimate is correct ... please write the drafts intro. number below and give this fiscal estimate to Mike (or Lynn) to process.

THIS DRAFT WAS INTRODUCED AS: 2001 AB672

- If this draft gets **introduced** ... and the version of the attached fiscal estimate is for a previous version ... please attach this early fiscal estimate to the back of the draft's file between the old version and the new version. Have Mike (or Lynn) get the ball rolling on getting a fiscal estimate prepared for the introduced version.

Barman, Mike

From: Barman, Mike
Sent: Monday, October 15, 2001 11:18 AM
To: Whitesel, Russ
Subject: LRB-3587/1 (FE by DHFS - attached - for your review)



FE-3587_DHFS.pdf

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