LRBs0337

2001 DRAFTING REQUEST

Assembly Substitute Amendment (ASA-AB672)

Received: **02/21/2002**

Received By: **grantpr**

Wanted: **As time permits**

Identical to LRB:

For: **Glenn Grothman (608) 264-8486**

By/Representing: **Mary Matthias, LC**

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

Drafter: **grantpr**

May Contact:

Addl. Drafters:

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

Extra Copies:

Submit via email: **YES**

Requester's email: **Rep.Grothman@legis.state.wi.us**

Carbon copy (CC:) to:

Pre Topic:

No specific pre topic given

Topic:

Require physicians to provide certain patients with prescription information

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Instructions:

See Attached

Drafting History:

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/?	grantpr 02/21/2002	csicilia 02/22/2002					
/1			pgreensl 02/22/2002		lrb_docadmin 02/22/2002	lrb_docadmin 02/22/2002	
/2	grantpr	csicilia	jfrantze		lrb_docadmin	lrb_docadmin	

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
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FE Sent For:

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12 2/25/02 gjs 2/26 2/26

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Drafting History:

Vers.	Drafted	Reviewed	Typed	Proofed	Submitted	Jacketed	Required
/?	grantpr	/1 ijs 2/28 02	2/22 pg	~~2/22~~ 2/22 pg/kjf			

FE Sent For:

<END>

2/26 2/26

Kunkel, Mark

From: Matthias, Mary
Sent: Wednesday, February 20, 2002 2:44 PM
To: Kunkel, Mark
Subject: AB 672

do for Leg. Council

GROTHMAN

Hi Mark-

The sub should require DHFS to prepare informational sheets (8.5 by 11 inches) that consist of a reproduction of all of the information contained in the labeling of the substance under 21 USC 352(f). What he wants is "everything on the little folded up piece of paper that is stuck inside the box or bag the piils come in" reprinted in larger size print and he wants the physician to hand it directly to the patient (or parent or other adult). The package insert that was handed out to the committee, which is what he wants the sub to require the MD to hand out, was written by Novartis and is titled "Prescribing Information". I will fax you a copy. I want to make sure the USC cite is accurate to identify this piece of paper he is talking about.

thanks!!!

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

- replace all reqiments that apply to MD giving info to patient
- sheet for schedule II only
- nothing for I

89002402

4/17

NOVARTIS

T1999-70
89002402

Ritalin® hydrochloride
methylphenidate hydrochloride tablets USP C II

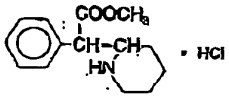
Ritalin-SR®
methylphenidate hydrochloride USP sustained-release tablets C II

Rx only

Prescribing Information

DESCRIPTION

Ritalin hydrochloride, methylphenidate hydrochloride USP, is a mild central nervous system (CNS) stimulant, available as tablets of 5, 10, and 20 mg for oral administration; Ritalin-SR is available as sustained-release tablets of 20 mg for oral administration. Methylphenidate hydrochloride is methyl α-phenyl-2-piperidineacetate hydrochloride, and its structural formula is



Methylphenidate hydrochloride USP is a white, odorless, fine crystalline powder. Its solutions are acid to litmus. It is freely soluble in water and in methanol, soluble in alcohol, and slightly soluble in chloroform and in acetone. Its molecular weight is 269.77.

Inactive Ingredients. Ritalin tablets: D&C Yellow No. 10 (5-mg and 20-mg tablets), FD&C Green No. 3 (10-mg tablets), lactose, magnesium stearate, polyethylene glycol, starch (5-mg and 10-mg tablets), sucrose, talc, and tragacanth (20-mg tablets).

Ritalin-SR tablets: Cellulose compounds, cetostearyl alcohol, lactose, magnesium stearate, mineral oil, povidone, titanium dioxide, and zein.

CLINICAL PHARMACOLOGY

Ritalin is a mild central nervous system stimulant.

The mode of action in man is not completely understood, but Ritalin presumably activates the brain stem arousal system and cortex to produce its stimulant effect.

There is neither specific evidence which clearly establishes the mechanism whereby Ritalin produces its mental and behavioral effects in children, nor conclusive evidence regarding how these effects relate to the condition of the central nervous system.

Ritalin in the SR tablets is more slowly but as extensively absorbed as in the regular tablets. Relative bioavailability of the SR tablet compared to the Ritalin tablet, measured by the urinary excretion of Ritalin major metabolite (α phenyl-2-piperidine acetic acid) was 105% (49%-168%) in children and 101% (85%-152%) in adults. The time to peak rate in children was 4.7 hours (1.3-8.2 hours) for the SR tablets and 1.9 hours (0.3-4.4 hours) for the tablets. An average of 67% of SR tablet dose was excreted in children as compared to 86% in adults.

In a clinical study involving adult subjects who received SR tablets, plasma concentrations of Ritalin's major metabolite appeared to be greater in females than in males. No gender differences were observed for Ritalin plasma concentration in the same subjects.

INDICATIONS

Attention Deficit Disorders, Narcolepsy

Attention Deficit Disorders (previously known as Minimal Brain Dysfunction in Children). Other terms being used to describe the behavioral syndrome below include: Hyperkinetic Child Syndrome, Minimal Brain Damage, Minimal Cerebral Dysfunction, Minor Cerebral Dysfunction.

Ritalin is indicated as an integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate-to-severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity. The diagnosis of this syndrome should not be made with finality when these symptoms are only of comparatively recent origin. Nonlocalizing (soft) neurological signs, learning disability, and abnormal EEG may or may not be present, and a diagnosis of central nervous system dysfunction may or may not be warranted.

Special Diagnostic Considerations

Specific etiology of this syndrome is unknown, and there is no single diagnostic test. Adequate diagnosis requires the use not only of medical but of special psychological, educational, and social resources.

Characteristics commonly reported include: chronic history of short attention span, distractibility, emotional lability, impulsivity, and moderate-to-severe hyperactivity; minor neurological signs and abnormal EEG. Learning may or may not be impaired. The diagnosis must be based upon a complete history and evaluation of the child and not solely on the presence of one or more of these characteristics.

Drug treatment is not indicated for all children with this syndrome. Stimulants are not intended for use in the child who exhibits symptoms secondary to environmental factors and/or primary psychiatric disorders, including psychosis. Appropriate educational placement is essential and psychosocial intervention is generally necessary. When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the physician's assessment of the chronicity and severity of the child's symptoms.

CONTRAINDICATIONS

Marked anxiety, tension, and agitation are contraindications to Ritalin, since the drug may aggravate these symptoms. Ritalin is contraindicated also in patients known to be hypersensitive to the drug, in patients with glaucoma, and in patients with motor tics or with a family history or diagnosis of Tourette's syndrome.

WARNINGS

Ritalin should not be used in children under six years, since safety and efficacy in this age group have not been established.

Sufficient data on safety and efficacy of long-term use of Ritalin in children are not yet available. Although a causal relationship has not been established, suppression of growth (i.e., weight gain, and/or height) has been reported with the long-term use of stimulants in children. Therefore, patients requiring long-term therapy should be carefully monitored.

Ritalin should not be used for severe depression of either exogenous or endogenous origin. Clinical experience suggests that in psychotic children, administration of Ritalin may exacerbate symptoms of behavior disturbance and thought disorder.

Ritalin should not be used for the prevention or treatment of normal fatigue states.

There is some clinical evidence that Ritalin may lower the convulsive threshold in patients with prior history of seizures, with prior EEG abnormalities in absence of seizures, and, very rarely, in absence of history of seizures and no prior EEG evidence of seizures. Safe concomitant use of anticonvulsants and Ritalin has not been established. In the presence of seizures, the drug should be discontinued.

Use cautiously in patients with hypertension. Blood pressure should be monitored at appropriate intervals in all patients taking Ritalin, especially those with hypertension.

Symptoms of visual disturbances have been encountered in rare cases. Difficulties with accommodation and blurring of vision have been reported.

Drug Interactions
Ritalin may decrease the hypotensive effect of guanethidine. Use cautiously with pressor agents and MAO inhibitors.

Human pharmacologic studies have shown that Ritalin may inhibit the metabolism of coumarin anticoagulants, anticonvulsants (phenobarbital, diphenylhydantoin, primidone), phenylbutazone, and tricyclic drugs (imipramine, clomipramine, desipramine). Downward dosage adjustments of these drugs may be required when given concomitantly with Ritalin.

Usage in Pregnancy
Adequate animal reproduction studies to establish safe use of Ritalin during pregnancy have not been conducted. However, in a recently conducted study, methylphenidate has been shown to have teratogenic effects in rabbits when given in doses of 200 mg/kg/day, which is approximately 167 times and 78 times the maximum recommended human dose on a mg/kg and a mg/m² basis, respectively. In rats, teratogenic effects were not seen when the drug was given in doses of 75 mg/kg/day, which is approximately 62.5 and 13.5 times the maximum recommended human dose on a mg/kg and a mg/m² basis, respectively. Therefore, until more information is available, Ritalin should not be prescribed for women of childbearing age unless, in the opinion of the physician, the potential benefits outweigh the possible risks.

Drug Dependence
Ritalin should be given cautiously to emotionally unstable patients, such as those with a history of drug dependence or alcoholism, because such patients may increase dosage on their own initiative.

Chronically abusive use can lead to marked tolerance and psychic dependence with varying degrees of abnormal behavior. Frank psychotic episodes can occur, especially with parenteral abuse. Careful supervision is required during drug withdrawal, since severe depression as well as the effects of chronic overactivity can be unmasked. Long-term follow-up may be required because of the patient's basic personality disturbances.

PRECAUTIONS
Patients with an element of agitation may react adversely; discontinue therapy if necessary.

Periodic CBC, differential, and platelet counts are advised during prolonged therapy.

Drug treatment is not indicated in all cases of this behavioral syndrome and should be considered only in light of the complete history and evaluation of the child. The decision to prescribe Ritalin should depend on the physician's assessment of the chronicity and severity of the child's symptoms and their appropriateness for his/her age. Prescription should not depend solely on the presence of one or more of the behavioral characteristics.

When these symptoms are associated with acute stress reactions, treatment with Ritalin is usually not indicated.

Long-term effects of Ritalin in children have not been well established.

Carcinogenesis/Mutagenesis
In a lifetime carcinogenicity study carried out in B6C3F1 mice, methylphenidate caused an increase in hepatocellular adenomas and, in males only, an increase in hepatoblastomas, at a daily dose of approximately 60 mg/kg/day. This dose is approximately 30 times and 2.5 times the maximum recommended human dose on a mg/kg and mg/m² basis, respectively. Hepatoblastoma is a relatively rare rodent malignant tumor type. There was no increase in total malignant hepatic tumors. The mouse strain used is sensitive to the development of hepatic tumors, and the significance of these results to humans is unknown.

Methylphenidate did not cause any increases in tumors in a lifetime carcinogenicity study carried out in F344 rats; the highest dose used was approximately 45 mg/kg/day, which is approximately 22 times and 4 times the maximum recommended human dose on a mg/kg and mg/m² basis, respectively.

Methylphenidate was not mutagenic in the in vitro Ames reverse mutation assay or in the in vitro mouse lymphoma cell forward mutation assay. Sister chromatid exchanges and chromosome aberrations were increased, indicative of a weak clastogenic response, in an in vitro assay in cultured Chinese Hamster Ovary (CHO) cells. The genotoxic potential of methylphenidate has not been evaluated in an in vivo assay.

ADVERSE REACTIONS
Nervousness and insomnia are the most common adverse reactions but are usually controlled by reducing dosage and omitting the drug in the afternoon or evening. Other reactions include hypersensitivity (including skin rash, urticaria, fever, arthralgia, exfoliative dermatitis, erythema multiforme with histopathological findings of necrotizing vasculitis, and thrombocytopenic purpura); anorexia; nausea; dizziness; palpitations; headache; dyskinesia; drowsiness; blood pressure and pulse changes, both up and down; tachycardia; angina; cardiac arrhythmia; abdominal pain; weight loss during prolonged therapy. There have been rare reports of Tourette's syndrome. Toxic psychosis has been reported. Although a definite causal relationship has not been established, the following have been reported in patients taking this drug: instances of abnormal liver function, ranging from transaminase elevation to hepatic coma; isolated cases of cerebral arteritis and/or occlusion; leukopenia and/or anemia; transient depressed mood; a few instances of scalp hair loss. Very rare reports of neuroleptic malignant syndrome (NMS) have been received, and, in most of these, patients were concurrently receiving therapies associated with NMS. In a single report, a ten year old boy who had been taking methylphenidate for approximately 18 months experienced an NMS-like event within 45 minutes of ingesting his first dose of venlafaxine. It is uncertain whether this case represented a drug-drug interaction, a response to either drug alone, or some other cause.

In children, loss of appetite, abdominal pain, weight loss during prolonged therapy, insomnia, and tachycardia may occur more frequently; however, any of the other adverse reactions listed above may also occur.

DOSAGE AND ADMINISTRATION
Dosage should be individualized according to the needs and responses of the patient.

Adults
Tablets: Administer in divided doses 2 or 3 times daily, preferably 30 to 45 minutes before meals. Average dosage is 20 to 30 mg daily. Some patients may require 40 to 60 mg daily. In others, 10 to 15 mg daily will be adequate. Patients who are unable to sleep if medication is taken late in the day should take the last dose before 6 p.m.

SR Tablets: Ritalin-SR tablets have a duration of action of approximately 8 hours. Therefore, Ritalin-SR tablets may be used in place of Ritalin tablets when the 8-hour dosage of Ritalin-SR corresponds to the titrated 8-hour dosage of Ritalin. Ritalin-SR tablets must be swallowed whole and never crushed or chewed.

Children (6 years and over)
Ritalin should be initiated in small doses, with gradual weekly increments. Daily dosage above 60 mg is not recommended.

If improvement is not observed after appropriate dosage adjustment over a

Ritalin® hydrochloride
methylphenidate hydrochloride tablets USP

Ritalin-SR® methylphenidate hydrochloride USP
sustained-release tablets

one-month period, the drug should be discontinued.

Tablets: Start with 5 mg twice daily (before breakfast and lunch) with gradual increments of 5 to 10 mg weekly.

SR Tablets: Ritalin-SR tablets have a duration of action of approximately 8 hours. Therefore, Ritalin-SR tablets may be used in place of Ritalin tablets when the 8-hour dosage of Ritalin-SR corresponds to the titrated 8-hour dosage of Ritalin. Ritalin-SR tablets must be swallowed whole and never crushed or chewed.

If paradoxical aggravation of symptoms or other adverse effects occur, reduce dosage, or, if necessary, discontinue the drug.

Ritalin should be periodically discontinued to assess the child's condition. Improvement may be sustained when the drug is either temporarily or permanently discontinued.

Drug treatment should not and need not be indefinite and usually may be discontinued after puberty.

OVERDOSAGE

Signs and symptoms of acute overdosage, resulting principally from overstimulation of the central nervous system and from excessive sympathomimetic effects, may include the following: vomiting, agitation, tremors, hyperreflexia, muscle twitching, convulsions (may be followed by coma), euphoria, confusion, hallucinations, delirium, sweating, flushing, headache, hyperpyrexia, tachycardia, palpitations, cardiac arrhythmias, hypertension, mydriasis, and dryness of mucous membranes.

Consult with a Certified Poison Control Center regarding treatment for up-to-date guidance and advice.

Treatment consists of appropriate supportive measures. The patient must be protected against self-injury and against external stimuli that would aggravate overstimulation already present. Gastric contents may be evacuated by gastric lavage. In the presence of severe intoxication, use a carefully titrated dosage of a *short-acting* barbiturate before performing gastric lavage. Other measures to detoxify the gut include administration of activated charcoal and a cathartic.

Intensive care must be provided to maintain adequate circulation and respiratory exchange; external cooling procedures may be required for hyperpyrexia.

Efficacy of peritoneal dialysis or extracorporeal hemodialysis for Ritalin overdosage has not been established.

HOW SUPPLIED

Tablets 5 mg — round, yellow (imprinted CIBA 7)
Bottles of 100 ..... NDC 0083-0007-30

Tablets 10 mg — round, pale green, scored (imprinted CIBA 9)
Bottles of 100 ..... NDC 0083-0003-30

Tablets 20 mg — round, pale yellow, scored (imprinted CIBA 34)
Bottles of 100 ..... NDC 0083-0034-30

Do not store above 30°C (86°F). Protect from light.
Dispense in tight, light-resistant container (USP).

SR Tablets 20 mg — round, white, coated (imprinted CIBA 16)
Bottles of 100 ..... NDC 0083-0016-30
Note: SR Tablets are color-additive free.

Do not store above 30°C (86°F). Protect from moisture.
Dispense in tight, light-resistant container (USP).

REV: NOVEMBER 1999 Printed in U.S.A. T1999-70
8900202

NOVARTIS

Novartis Pharmaceuticals Corporation.
East Hanover, New Jersey 07936

2001 – 2002 LEGISLATURE

LRB–3587/1
MDK:cjs:rs

2001 ASSEMBLY BILL 672

December 7, 2001 – Introduced by JOINT LEGISLATIVE COUNCIL. Referred to Committee on Health.

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

Analysis by the Legislative Reference Bureau

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.

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

115.357 Information on attention deficit hyperactivity disorder. The department shall disseminate to appropriate public school staff the information regarding the diagnosis and treatment of attention deficit hyperactivity disorder and prescription drugs used to treat 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.

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

448.02 **(3)** (a) The board shall investigate allegations of unprofessional conduct and negligence in treatment by persons holding a license, certificate or limited permit granted by the board. An allegation that a physician has violated s. 253.10 (3), 448.30, 448.35 (3), 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.

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.

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

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

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

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

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

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

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

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

~~1. A summary of the practice parameters for the assessment and treatment of children and adolescents with attention deficit hyperactivity disorder 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 attention deficit hyperactivity disorder.~~

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

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

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

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

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

(b) The materials prepared under par. (a) shall be made available to physicians and to the public on the department's internet site. Upon the request of a physician, the materials under par. (a) shall be provided to the physician printed on paper that is 8.5 inches wide and 11 inches long.

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

(d) The department shall periodically review the materials under par. (a) and shall exercise reasonable diligence in providing materials that are accurate and current.

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

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.

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

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

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

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

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

(e) A physician who treats a child for attention deficit hyperactivity disorder on a long–term basis with the same prescription drug shall provide the information and obtain the certification required under this section when issuing the initial prescription order for that prescription drug and at least once every 2 years thereafter. A physician is not required to provide the information described under sub. (2) 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.

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

the department did not make 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.

SECTION 4. Initial applicability.

(1) The treatment of sections 448.02 (3) (a) and 448.35 (3) of the statutes first applies to prescription orders that are issued on the first day of the 10th month 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.

(END)

Grant, Peter

From: Matthias, Mary
Sent: Monday, February 25, 2002 4:15 PM
To: Grant, Peter
Cc: Whitesel, Russ; Emerson, James; Sweet, Richard
Subject: RE: LRBs0337

Peter: Glenn would like one small change to the sub: He would like it to specifically state that the informational materials the physician must provide to the patient/parent must be printed on paper that is 8.5 x 11 inches in size. Could you make that one change? Underheim is planning to exec the bill on Thursday, so Glenn needs the sub by 8:30 Wed. morning.

thanks!

MM

-----Original Message-----
From: Grant, Peter
Sent: Monday, February 25, 2002 11:15 AM
To: Matthias, Mary
Subject: LRBs0337

Here you go:

<< File: 01s0337/1 >>
Peter

State of Wisconsin
2001 – 2002 LEGISLATURE

LRBs0337/1
MDK/PG:cjs:pg

ASSEMBLY SUBSTITUTE AMENDMENT ,

TO 2001 ASSEMBLY BILL 672

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

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

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

448.02 **(3)** (a) The board shall investigate allegations of unprofessional conduct and negligence in treatment by persons holding a license, certificate or limited permit granted by the board. An allegation that a physician has violated s. 253.10 (3), 448.30, 448.35 (3), or 450.13 (2) or has failed to mail or present a medical certification required under s. 69.18 (2) within 21 days after the pronouncement of death of the person who is the subject of the required certificate or that a physician has failed at least 6 times within a 6–month period to mail or present a medical

certificate required under s. 69.18 (2) within 6 days after the pronouncement of death of the person who is the subject of the required certificate is an allegation of unprofessional conduct. Information contained in reports filed with the board under s. 49.45 (2) (a) 12r., 50.36 (3) (b), 609.17 or 632.715, or under 42 CFR 1001.2005, shall be investigated by the board. Information contained in a report filed with the board under s. 655.045 (1), as created by 1985 Wisconsin Act 29, which is not a finding of negligence or in a report filed with the board under s. 50.36 (3) (c) may, within the discretion of the board, be used as the basis of an investigation of a person named in the report. The board may require a person holding a license, certificate or limited permit to undergo and may consider the results of one or more physical, mental or professional competency examinations if the board believes that the results of any such examinations may be useful to the board in conducting its investigation.

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

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

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

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

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

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

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

(2) INFORMATIONAL MATERIALS. (a) The department shall, in consultation with the State Medical Society of Wisconsin, determine which Schedule II controlled substances are commonly prescribed by physicians in this state to treat attention

deficit hyperactivity disorder in children and shall prepare informational materials pertaining to each of those substances containing the following information:

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

2. The information included in the labeling of the substance under 21 USC 352 (f).

(b) The materials prepared under par. (a) shall be made available to physicians and to the public on the department's Internet site. Upon the request of a physician, the materials under par. (a) shall be provided to the physician printed on paper that is 8.5 inches wide and 11 inches long.

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

(d) The department shall periodically review the materials under par. (a) and shall exercise reasonable diligence in providing materials that are accurate and current.

(3) REQUIREMENTS FOR PHYSICIANS. (a) Except in an emergency and as provided under par. (d), a physician who diagnoses a child with attention deficit hyperactivity disorder and issues a prescription order for a Schedule II controlled substance for treatment of the disorder shall provide a printed copy of the materials pertaining to the prescribed substance that have been prepared by the department under sub. (2) (a) to the persons specified in par. (b).

(b) A physician required to provide information under this section shall provide the information to the parent or guardian of the child if the parent or guardian of the child is present when the prescription order is issued. If the child is 14 years of age or older, the physician shall also provide the information to the child. If the child's

and that have been printed on paper that is 8.5 inches wide and 11 inches long

parent or guardian is not present at the time the prescription order is issued, the physician shall provide the information to an adult who is with the child at the time the prescription order is issued, if any.

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

(d) A physician who treats a child for attention deficit hyperactivity disorder on a long–term basis with the same prescription drug shall provide the information and obtain the certification required under this section when issuing the initial prescription order for that prescription drug and at least once every 2 years thereafter. A physician is not required to provide the information described under sub. (2) 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.

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

SECTION 3. Initial applicability.

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

(END)