STATE OF WISCONSIN
MEDICAL EXAMINING BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE MEDICAL EXAMINING BOARD	:	NOTICE OF PUBLIC HEARING

NOTICE IS HEREBY GIVEN that pursuant to authority vested in the Medical Examining Board in §§15.08 (5) (b), 227.11 (2) (a), and 448.40 (2) (a), Stats., 2013 Wisconsin Act 111 , Wis. Stats., and interpreting § 448.30, Wis. Stats., the Medical Examining Board will hold a public hearing at the time and place indicated below to consider an order to amend Med 18.02 (3), 18.04 (3) and (5) and 18.05; to repeal and recreate Med 18.03 (title); and to create Med 18.04 (6), relating to physicians and informed consent.

Hearing Date, Time and Location

Date:	**August 20, 2014**
Time:	**8:30 AM**
Location:	**1400 East Washington Avenue** **Room 121A** **Madison, Wisconsin**

APPEARANCES AT THE HEARING:

Interested persons are invited to present information at the hearing. Persons appearing may make an oral presentation but are urged to submit facts, opinions and argument in writing as well. Facts, opinions and argument may also be submitted in writing without a personal appearance by mail addressed to the Department of Safety and Professional Services, Division of Policy Development, P.O. Box 8366, Madison, Wisconsin 53708. Written comments must be received at or before the public hearing to be included in the record of rule-making proceedings.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted:

Section 448.30, Stats

Statutory authority:

Sections 15.08 (5) (b), 227.11 (2) (a), and 448.40 (2) (a), Stats., 2013 Wisconsin Act 111

Explanation of agency authority:

Examining boards are authorized by s. 15.08 (5) (b), Stats., to promulgate rules that will provide guidance within their profession. Section 227.11 (2) (a), Stats., grants authority to boards to promulgate rules interpreting the statutes it enforces or administers as long as the proposed rule does not exceed proper interpretation of the statute. This proposed rule will interpret s. 448.30, Stats., which sets forth the guidelines physicians must follow in order to properly inform their patients regarding alternate modes of treatment. Section 448.40 (2) (a), Stats. grants express authority from the legislature to the Medical Examining Board to draft rules regarding informed consent.

Related statute or rule:

None.

Plain language analysis:

Recent legislation, 2013 Wisconsin Act 111, significantly impacted s. 448.30, Stats., and Wis. Admin Code s. Med 18. Before the Act, physicians had a duty to inform their patients, under s. 448.30, Stats., of all alternate viable medical modes of treatment and about the benefits and risks of those treatments. After the passage of Act 111, physicians are required to inform their patients of reasonable alternate medical modes of treatment. The latter standard is not as broad as the former standard and in fact lessens the burden on physicians.

Another major change is the reasonable physician standard has replaced the reasonable patient standard. The reasonable physician standard requires doctors to disclose only the information that a reasonable physician in the same or similar medical specialty would know and disclose under the circumstances. The reasonable patient standard requires a physician to disclose information necessary for a reasonable person to make an intelligent decision with respect to the choices of treatment. The reasonable physician standard is a more objective approach and is the standard to which Wisconsin physicians must now adhere.

Summary of, and comparison with, existing or proposed federal regulation

Several federal agencies, including but not limited to the Food and Drug Administration, have rules protecting human subjects participating in investigative trials. Investigators are required to obtain informed consent of each person that will participate in experimental studies, 21 CFR 50.20, including experiments involving drugs for human use found in 21 CFR 312.60. Obtaining informed consent from participants in the investigatory research is not intended to preempt any applicable federal, state, or local

laws which require additional information to be disclosed in order for informed consent to be legally effective.

Comparison with rules in adjacent states:

Illinois: Illinois does not have a comparable statute or rule.

Iowa: Iowa statutes create a presumption that informed consent was given if it is documented in writing. "A consent in writing to any medical or surgical procedure or course of procedure in patient care which meets the requirements of this section shall create a presumption that informed consent was given." IOWA CODE § 147.137.

Michigan: Michigan's statute has comparable language which is directed towards physicians who are treating breast cancer patients. Physicians are required to inform patients verbally and in writing about alternative modes of treatment of cancer. The statute sets forth the reasonable physician standards. "A physician's duty to inform a patient under this section does not require disclosure of information beyond what a reasonably well-qualified physician licensed under this article would know." MCLS §333.17013 (6).

Minnesota: Minnesota does not have comparable statute or rule.

Summary of factual data and analytical methodologies:

No factual data was required for the rule-making in this proposal, due to the changes being necessitated by the passage of 2013 Wisconsin Act 111. For that reason, no factual data or analytical methodologies were used in the preparation of these proposed rules.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Tom.Engels@wisconsin.gov, or by calling (608) 266-8608.

Fiscal estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis is attached.

Initial Regulatory Flexibility Analysis or Summary:

N/A

Agency contact person:

Shawn Leatherwood, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-4438; email at Shancethea.Leatherwood@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:

Comments may be submitted to Shawn Leatherwood, Administrative Rules Coordinator Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8366, Madison, WI 53708-8935, or by email to Shancethea.Leatherwood@wisconsin.gov. Comments must be received at or before the public hearing to be held on August 20, 2014, to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Chapter Med 18 (title) is repealed and recreated to read:

CHAPTER MED 18 (title)
INFORMED CONSENT

SECTION 2. Med 18.02 (3) is amended to read:

Med 18.02 (3) ~~" Viable"~~ "Modes of treatment" ~~as sued in s. 448.30, Stats., to modify the term "medical modes of treatment" means modes of treatment~~ means treatment, including diagnostic procedures, generally considered by the medical profession to be within the scope of current, acceptable standards of care.

SECTION 3. Med 18.03 (title) is repealed and recreated to read:

Med 18.03 (title) Informed Consent. Any physician who treats a patient shall inform the patient about the availability of reasonable alternate medical modes of treatment and about the benefits and risks of these treatments. The reasonable physician standard is the standard for informing a patient. The reasonable physician standard requires disclosure only of information that a reasonable physician in the same or a similar medical specialty would know and disclose under the circumstances.

SECTION 4. Med 18.04 (3) and (5) are amended to read:

Med 18.04 (3) A physician is not required to communicate any mode of treatment ~~which is not viable~~ which is not a reasonable alternate mode of treatment or which is experimental.

Med 18.04 (5) A physician may simplify or omit communication of ~~viable~~ reasonable alternate modes of treatment if the communication would unduly confuse or frighten a patient or if a patient refuses to receive the communication.

SECTION 5. Med 18.04 (6) is created to read:

Med 18.04 (6) Information about alternate medical modes of treatment for any condition the physician has not included in his or her diagnosis at the time the physician informs the patient.

SECTION 6. Med 18.05 is amended to read:

Med 18.05 Recordkeeping. A physician shall indicate on a patient's medical record he or she has communicated to the patient reasonable alternate ~~viable~~ modes of treatment.

SECTION 7. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

COPIES OF RULE

Copies of this proposed rule are available upon request to Shawn Leatherwood, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, P.O. Box 8366, Madison, Wisconsin 53708, by email at Shancethea.Leatherwood@wisconsin.gov or on our website at http://dsps.wi.gov/Default.aspx?Page=44e541e8-abdd-49da-8fde-046713617e9e.