

STATE OF WISCONSIN
DENTISTRY EXAMINING BOARD

IN THE MATTER OF RULEMAKING	:	PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE	:	DENTISTRY EXAMINING
	:	BOARD
DENTISTRY EXAMINING	:	ADOPTING RULES
BOARD	:	(CLEARINGHOUSE RULE 15-057)

PROPOSED ORDER

An order of the Dentistry Examining Board to create DE Chapter 14 relating to informed consent.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted:

Section 447.40, Stats.

Statutory authority:

Sections 15.08 (5) (b), 227.11 (2) (a), 447.40, and 447.02 (2) (i), Stats.

Explanation of agency authority:

Section 15.08 (5) (b), Stats. Each examining board shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains, and define and enforce professional conduct and unethical practices not inconsistent with the law relating to the particular trade or profession.

Section 227.11 (2) (a), Stats., provides that “[e]ach agency may promulgate rules interpreting the provisions of any statute enforced or administered by the agency, if the agency considers it necessary to effectuate the purpose of the statute, but a rule is not valid if the rule exceeds the bounds of correct interpretation.”

Section 447.40, Stats. Any dentist who treats a patient shall inform the patient about the availability of reasonable alternate modes of treatment and about the benefits and risks of these treatments. The reasonable dentist standard is the standard for informing a patient under this section. The reasonable dentist standard requires disclosure only of information that a reasonable dentist would know and disclose under the circumstances. The dentist's duty to inform the patient under this section does not require disclosure of any of the following:

- (1) Detailed technical information that in all probability a patient would not understand.
- (2) Risks apparent or known to the patient.
- (3) Extremely remote possibilities that might falsely or detrimentally alarm the patient.
- (4) Information in emergencies where failure to provide treatment would be more harmful to the patient than treatment.
- (5) Information in cases where the patient is incapable of consenting.
- (6) Information about alternate modes of treatment for any condition the dentist has not included in his or her diagnosis at the time the dentist informs the patient.

Section 447.02 (2) (i), Stats. The examining board shall promulgate rules specifying the provisions for implementing s. 447.40.

Related statute or rule:

Sections 446.08, 448.697, and 449.25, Stats.

Plain language analysis:

The duty of certain health care professionals, other than physicians, to obtain informed consent from their patients before conducting treatment had not been codified as a statutory duty prior to the passage of 2013 Wisconsin Act 345. Act 345 sets forth the dentists' duty to obtain informed consent from their patients and institutes the reasonable dentist standard as the standard for informing patients regarding their treatment options. The reasonable dentist standard requires disclosure only of the information that a reasonable dentist would know and disclose under the circumstances.

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

Although several federal agencies require investigators to obtain informed consent of human subjects participating in investigative trials, there are no specific federal regulations regarding dentists obtaining informed consent from their patients or the reasonable dentist standard.

Comparison with rules in adjacent states:

Illinois: Illinois Administrative Code is silent with regards to dentists' duty to obtain informed consent (68 Il. Admin. Code pt. 1220).

Iowa: Iowa Administrative Code regarding record keeping states that dental records must include, at a minimum, documentation of informed consent that includes a discussion of procedures, treatment options, potential complications, and known risks, and patient's consent to proceed with treatment (Iowa Admin. Code r. 650-27.11).

Michigan: Michigan Administrative Code is silent with regards to dentists' duty to obtain informed consent (Mich. Admin. Code r. 338.11101 - 338.11821).

Minnesota: Minnesota Administrative Code requires that dental records must include a notation that the dentist, advanced dental therapist, or dental therapist discussed with the patient the treatment options and the prognosis, benefits, and risks of each; and the patient has consented to the treatment chosen (Minn. R. 3100.9600 subp. 9).

Summary of factual data and analytical methodologies:

No factual data or analytical methodologies were used in drafting the proposed rule due to the proposed rule being prompted by the passage of 2013 WI Act 345. Adjacent states' requirements were reviewed.

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

The rule was posted for public comment on the economic impact of the proposed rule, including how this proposed rule may affect businesses, local government units, and individuals, for a period of 14 days. No comments were received.

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis document is attached.

Effect on small business:

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 Eric.Esser@wisconsin.gov, or by calling (608) 267-2435.

Agency contact person:

Katie Vieira (Paff), Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 1400 East Washington Avenue, Room 151, P.O. Box 8935, Madison, Wisconsin 53708; telephone 608-261-4472; email at Kathleen.Vieira@wisconsin.gov.

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

Comments may be submitted to Katie Vieira (Paff), 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 Kathleen.Vieira@wisconsin.gov. Comments must be received on or before the public hearing to be held on September 2, 2015 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Chapter DE 14 is created to read:

CHAPTER DE 14

INFORMED CONSENT

DE 14.01 Authority and purpose. (1) **AUTHORITY.** The rules in this chapter are adopted pursuant to the authority delegated in ss. 15.08 (5) (b), 227.11 (2) (a), and 447.02 (2) (i), Stats.

(2) **PURPOSE.** The purpose of the rules is to define the obligation of a dentist to communicate alternate modes of treatment to a patient.

DE 14.02 Informed consent. Any dentist who treats a patient shall inform the patient about the availability of reasonable alternate modes of treatment and about the benefits and risks of these treatments prior to treating the patient. The reasonable dentist standard is the standard for informing a patient under this section. The reasonable dentist standard requires disclosure only of information that a reasonable dentist would know and disclose under the circumstances.

DE 14.03 Recordkeeping. A dentist's patient record shall include documentation that alternate modes of treatment have been communicated to the patient and informed consent has been obtained from the patient.

DE 14.04 Exceptions to communication of alternate modes of treatment. A dentist is not required to disclose the types of information listed in ss. 447.40 (1) to (6), Stats.

Note: Section 447.40, Stats., reads: "Any dentist who treats a patient shall inform the patient about the availability of reasonable alternate modes of treatment and about the benefits and risks of these treatments. The reasonable dentist standard is the standard for informing a patient under this section. The reasonable dentist standard requires disclosure only of information that a reasonable dentist would know and disclose under the circumstances. The dentist's duty to inform the patient under this section does not require disclosure of any of the following: (1) Detailed technical information that in all probability a patient would not understand. (2) Risks apparent or known to the patient. (3) Extremely remote possibilities that might falsely or detrimentally alarm the patient. (4) Information in emergencies where failure to provide treatment would be more harmful to the patient than treatment. (5) Information in cases where the patient is incapable of consenting. (6) Information about alternate modes of treatment for any condition the dentist has not included in his or her diagnosis at the time the dentist informs the patient."

SECTION 2. **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)

This Proposed Order of the Dentistry Examining Board is approved for submission to the Governor and Legislature.

Dated _____

Agency _____

Board Member
Dentistry Examining Board