

**CERTIFICATE**

**STATE OF WISCONSIN**

**DEPARTMENT OF SAFETY AND PROFESSIONAL SERVICES**

*I, Tom Ryan, Executive Director, Division of Policy Development in the Wisconsin Department of Safety and Professional Services and custodian of the official records of the Podiatry Affiliated Credentialing Board, do hereby certify that the annexed rules relating to the duty to obtain informed consent were duly approved and adopted by the Podiatry Affiliated Credentialing Board.*

*I further certify that said copy has been compared by me with the original on file in this office and that the same is a true copy thereof, and of the whole of such original.*

*IN TESTIMONY WHEREOF, I have hereunto set my hand at 1400 East Washington Avenue, Madison, Wisconsin this 29<sup>th</sup> day of June, 2016.*



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*Tom Ryan, Executive Director  
Division of Policy Development  
Department of Safety & Professional Services*

**CR 15-076**

STATE OF WISCONSIN  
PODIATRY AFFILIATED CREDENTIALING BOARD

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|                             |   |                             |
|-----------------------------|---|-----------------------------|
| IN THE MATTER OF RULEMAKING | : | ORDER OF THE                |
| PROCEEDINGS BEFORE THE      | : | PODIATRY AFFILIATED         |
|                             | : | CREDENTIALING BOARD         |
| PODIATRY AFFILIATED         | : | ADOPTING RULES              |
| CREDENTIALING BOARD         | : | (CLEARINGHOUSE RULE 15-076) |

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ORDER

An order of the Podiatry Affiliated Credentialing Board to amend Pod 4.03 (2) (b) and create Pod 4.04 and Chapter 8 relating to the duty to obtain informed consent.

Analysis prepared by the Department of Safety and Professional Services.

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ANALYSIS

**Statutes interpreted:**

Section 448.697, Stats.

**Statutory authority:**

Sections 15.085 (5) (b), 227.11 (2) (a), 448.675 (4), and 448.695 (1) (b), Stats.

**Explanation of agency authority:**

Section 15.085 (5) (b), Stats., provides that affiliated credentialing boards, such as the Podiatry Affiliated Credentialing Board, “[s]hall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains. . .” The proposed rule will provide guidance within the profession as to how podiatrists are to inform patients about treatment options.

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 448.675 (4), Stats., states that “[t]he affiliated credentialing board may restore a license which has been voluntarily surrendered or revoked under this subchapter on such terms and conditions as it considers appropriate.”

Section 448.695 (1) (b), Stats., provides that the Podiatry Affiliated Credentialing Board shall promulgate “rules implementing s. 448.697”. Section 448.697, Stats., requires podiatrists to inform patients of their treatment options.

**Related statute or rule:**

Sections 448.08 and 447.40, 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 podiatrists’ duty to obtain informed consent from their patients and institutes the reasonable podiatrist standard as the standard for informing patients regarding their treatment options. The reasonable podiatrist standard requires disclosure only of the information that a reasonable podiatrist would know and disclose under the circumstances. The rule will incorporate the new standard into the current rules governing podiatric practice and make any additional changes necessary to create consistency with the newly enacted legislation. The rule will also provide clarity to the process of renewing a license after 5 years by updating provisions regarding licensure reinstatement.

**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 podiatrists obtaining informed consent from their patients or the reasonable podiatrist standard.

**Comparison with rules in adjacent states:**

**Illinois:** Illinois administrative rules are silent with regards to podiatrists’ duty to inform patients of their treatment options (68 il admin 1360). A person seeking to restore a podiatric physician license after it has been expired or placed on inactive status for more than 5 years must interview before the board and submit evidence of either (1) certification of active practice in another jurisdiction and proof of 100 hours continuing education during the 2 years prior to restoration. Such evidence shall include a statement from the appropriate board or licensing authority in the other jurisdiction that the applicant was authorized to practice during the term of active practice; or (2) proof of successful completion of the PM Lexis examination within one year before applying for restoration (68 il admin 1360.60).

**Iowa:** Iowa administrative rules are silent with regards to podiatrists’ duty to inform patients of their treatment options (645 IAC 220, 222, 223, and 224). A person seeking to reactivate a podiatry license that has been on inactive status for more than five years, must provide the following: (1) verification of the license(s) from every jurisdiction in which the

applicant is or has been licensed and is or has been practicing during the time period the Iowa license was inactive, sent directly from the jurisdiction(s) to the board office, and (2) verification of completion of 80 hours of continuing education within two years of application for reactivation (645 IAC 220.15 (3) (b)). A licensee whose license has been revoked, suspended, or voluntarily surrendered must reinstate their license in accordance with the terms and conditions of the order of revocation or suspension, unless the order of revocation provides that the license is permanently revoked. If the order of revocation or suspension did not establish terms and conditions upon which reinstatement might occur, or if the license was voluntarily surrendered, an initial application for reinstatement may not be made until one year has elapsed from the date of the order or the date of the voluntary surrender. An application for reinstatement shall allege facts which, if established, will be sufficient to enable the board to determine that the basis for the revocation or suspension of the respondent's license no longer exists and that it will be in the public interest for the license to be reinstated. If the board determines that the license can be reinstated, then the license reactivation process is followed (645 IAC 220.16, 645 IAC 11.31)

**Michigan:** Michigan administrative rules are silent with regards to podiatrists' duty to inform patients of their treatment options (mich admin code r 338.8101 - 338.8136). "Reinstatement" is defined as the granting of a license or registration, with or without limitations or conditions, to a person whose license or registration has been revoked. "Relicensure" or "reregistration" is defined as the granting of a registration or license to a person whose license or registration has lapsed for failure to renew within 60 days after the expiration date (Michigan Statutes 339.402). An applicant for relicensure whose license has lapsed for 3 years or more and who holds a current license as a podiatrist in another state may be relicensed by completing 150 hours of continuing podiatric medical education credit within the 3 year period immediately preceding the date of application and taking and achieving a converted score of not less than 75 on the podiatric jurisprudence examination (mich admin code r 338.8111 (1)). An applicant for relicensure whose license has lapsed for 3 years or more and who does not hold a current license as a podiatrist in another state may be relicensed by taking and achieving a score of pass on part III of the examination developed and scored by the NBPME and taking and achieving a score of not less than 75 on the podiatric jurisprudence examination (mich admin code r 338.8111 (2)).

**Minnesota:** Minnesota administrative rules are silent with regards to podiatrists' duty to inform patients of their treatment options (mn r 6900.0010 – 6900.0500). To reinstate a podiatrist license, the applicant must submit: (1) verification of licensure status from each state in which the podiatrist has held an active license during the five years preceding application; (2) for each year the license has been inactive, evidence of participation in one-half the number of hours of acceptable continuing education required for biennial renewal up to five years, (3) if the license has been inactive for more than five years, the continuing education must be obtained during the five years immediately before application; and (4) other evidence as the board may reasonably require. No license that has been suspended or revoked by the board will be reinstated unless the former licensee provides evidence of full rehabilitation from the cause for which the license was suspended or revoked and complies with the other reasonable conditions imposed by the board for the purpose of establishing the extent of rehabilitation. In addition, if the disciplinary action was based in part on

failure to meet continuing education requirements, the license will not be reinstated until the former licensee has successfully completed the requirements (mn r 6900.0210).

**Summary of factual data and analytical methodologies:**

No factual data or analytical methodologies, aside from reviewing adjacent states' requirements, were used in drafting the rule due to the majority of the rule being prompted by the passage of 2013 WI Act 345.

**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 rule, including how this 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 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 Jeffrey.Weigand@wisconsin.gov, or by calling (608) 267-2435.

**Agency contact person:**

Dale Kleven, 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 Dale2.Kleven@wisconsin.gov.

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TEXT OF RULE

SECTION 1. Pod 4.03 (2) (b) is amended to read:

**Pod 4.03 (2) (b)** If the licensee applies for renewal of the license more than 5 years after its expiration, the board shall make an inquiry to determine whether the applicant is competent to practice under the license in this state, and shall impose any reasonable conditions on ~~reinstatement~~ the renewal of the license, including oral examination, as the board deems appropriate. All applicants under this paragraph shall be required to pass the open book examination on statutes and rules, which is the same examination given to initial applicants. This section does not apply to licensees who have unmet disciplinary requirements or whose licenses have been surrendered or revoked.

SECTION 2. Pod 4.04 is created to read:

**Pod 4.04 License reinstatement.** A licensee who has unmet disciplinary requirements and failed to renew a license within 5 years of the renewal date or whose license has been surrendered or revoked may apply to have a license reinstated if the applicant provides all of the following:

(1) Evidence of completion of requirements in s. 4.03 (2) (b) if the licensee has not held an active Wisconsin license within the last 5 years.

(2) Evidence of completion of disciplinary requirements, if applicable.

(3) Evidence of rehabilitation or a change in circumstances, warranting reinstatement of the license.

SECTION 3. Chapter Pod 8 is created to read:

#### CHAPTER POD 8

#### INFORMED CONSENT

**Pod 8.01 Authority and purpose.** (1) **AUTHORITY.** The rules in this chapter adopted pursuant to the authority delegated in ss. 15.085 (5) (b), 227.11 (2) (a), and 448.695 (1) (b), Stats.

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

**Pod 8.02 Informed consent.** Any podiatrist 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 podiatrist standard is the standard for informing a patient under this section. The reasonable podiatrist standard requires disclosure only of information that a reasonable podiatrist would know and disclose under the circumstances.

**Pod 8.03 Exceptions to communication of alternate modes of treatment.** The podiatrist'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 podiatrist has not included in his or her diagnosis at the time the podiatrist informs the patient.

**Pod 8.04 Recordkeeping.** A podiatrist'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 as required under s. Pod 6.01.

SECTION 4. 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.

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(END OF TEXT OF RULE)  
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Dated

6/23/16

Agency



Chairperson

Podiatry Affiliated Credentialing Board

*William W. DPH*

## ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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1. Type of Estimate and Analysis

Original    Updated    Corrected

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2. Administrative Rule Chapter, Title and Number

Pod 1, 4, 8

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3. Subject

Duty to obtain informed Consent

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4. Fund Sources Affected

GPR    FED    PRO    PRS    SEG    SEG-S

5. Chapter 20, Stats. Appropriations Affected

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6. Fiscal Effect of Implementing the Rule

No Fiscal Effect       Increase Existing Revenues       Increase Costs  
 Indeterminate       Decrease Existing Revenues       Could Absorb Within Agency's Budget  
 Decrease Cost

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7. The Rule Will Impact the Following (Check All That Apply)

State's Economy       Specific Businesses/Sectors  
 Local Government Units       Public Utility Rate Payers  
 Small Businesses (if checked, complete Attachment A)

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8. Would Implementation and Compliance Costs Be Greater Than \$20 million?

Yes       No

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9. Policy Problem Addressed by the Rule

This proposed rule is a result of recent legislation. 2013 Wisconsin Act 345 instituted a new standard regarding how podiatrists are to obtain informed consent from their patients. As a result of Act 345, podiatrists must obtain informed consent from their patients by advising them of reasonable alternate medical modes of treatment and the benefits and risks of those treatments in a manner consistent with the reasonable podiatrist standard. The reasonable podiatrist standard requires disclosure only of information that a reasonable podiatrist would know and disclose under the circumstances. The proposed rule will incorporate this new standard into the current podiatrist rules.

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10. Summary of the businesses, business sectors, associations representing business, local governmental units, and individuals that may be affected by the proposed rule that were contacted for comments.

This proposed rule was posted on the Department of Safety and Professional Services website and on the Wisconsin government website for 14 business days to solicit comments from the public. No businesses, business sectors, associations representing business, local governmental units, or individuals contacted the department about the proposed rule during that time period

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11. Identify the local governmental units that participated in the development of this EIA.

None. This rule does not affect local government units.

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12. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)

This proposed rule will have no economic or fiscal impact on specific businesses, business sectors, public utility rate payers, local governmental units or the state's economy as a whole.

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13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

## ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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Podiatrists will advise their patients in a manner that is consistent with current law. There is no alternative to implementing the proposed rule due to the changes being necessitated by passage of legislation.

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#### 14. Long Range Implications of Implementing the Rule

Podiatrists consistently advising patients of reasonable alternate medical modes of treatment options will result in chiropractors upholding their duty to inform patients in accordance with the statutes.

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#### 15. Compare With Approaches Being Used by Federal Government

None

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#### 16. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

**Illinois:** Illinois administrative rules are silent with regards to podiatrists' duty to inform patients of their treatment options (68 il admin 1360). A person seeking to restore a podiatric physician license after it has been expired or placed on inactive status for more than 5 years must interview before the board and submit evidence of either (1) certification of active practice in another jurisdiction and proof of 100 hours continuing education during the 2 years prior to restoration. Such evidence shall include a statement from the appropriate board or licensing authority in the other jurisdiction that the applicant was authorized to practice during the term of active practice; or (2) proof of successful completion of the PM Lexis examination within one year before applying for restoration (68 il admin 1360.60).

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## ADMINISTRATIVE RULES

### Fiscal Estimate & Economic Impact Analysis

during the five years immediately before application; and (4) other evidence as the board may reasonably require. No license that has been suspended or revoked by the board will be reinstated unless the former licensee provides evidence of full rehabilitation from the cause for which the license was suspended or revoked and complies with the other reasonable conditions imposed by the board for the purpose of establishing the extent of rehabilitation. In addition, if the disciplinary action was based in part on failure to meet continuing education requirements, the license will not be reinstated until the former licensee has successfully completed the requirements (mn r 6900.0210).

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| 17. Contact Name<br>Katie Vieira (Paff) | 18. Contact Phone Number<br>608-261-4472 |
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