



MEDICAL EXAMINING BOARD
Room 121A, 1400 East Washington Avenue, Madison
Contact: Tom Ryan (608) 266-2112
December 21, 2016

The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a record of the actions of the Board.

AGENDA

8:00 A.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

- A) Adoption of Agenda (1-4)**
- B) Minutes of November 16, 2016 – Review and Approval (5-9)**
- C) Conflicts of Interest**
- D) Administrative Updates**
 - 1) Department and Staff Updates
 - 2) Board Members – Term Expiration Dates
 - a) Mary Jo Capodice – 07/01/2018
 - b) Michael Carton – 07/01/2020
 - c) Padmaja Doniparthi – 07/01/2017
 - d) Rodney Erickson – 07/01/2019
 - e) Bradley Kudick – 07/01/2020
 - f) Lee Ann Lau – 07/01/2020
 - g) Carolyn Ogland Vukich – 07/01/2017
 - h) David Roelke – 07/01/2017
 - i) Kenneth Simons – 07/01/2018
 - j) Timothy Westlake – 07/01/2020
 - k) Robert Zoeller – 07/01/2019
 - l) Robert Zondag – 07/01/2018
 - 3) Introductions, Announcements and Recognition
 - 4) Wis. Stat. § 15.085 (3)(b) – Affiliated Credentialing Boards’ Biannual Meeting with the Medical Examining Board to Consider Matters of Joint Interest
 - 5) Informational Items
- E) Appointments, Reappointments, Confirmations, and Committee, Panel and Liaison Appointments**
- F) 8:00 A.M. Public Hearing: Emergency Rule EmR1631 and Clearinghouse Rule 16-070 – Med 13 Relating to Continuing Medical Education for Prescribing Opioids(10-55)**
 - 1) Review and Respond to Public Comments and Legislative Reference Bureau Edits
 - 2) Federation of State Medical Boards Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain
- G) Legislation and Rule Matters – Discussion and Consideration (10-55)**
 - 1) Scope and Limitations of a Physician Assistant’s Practice under Med 8.07 (**53-55**)
 - 2) Update on Med 24 Relating to Telemedicine

- 3) Update on Med 1 and 14 Relating to General Update and Cleanup of Rules
- 4) Update on Other Legislation and Pending or Possible Rulemaking Projects

H) Discussion and Consideration of Council Appointment Methods (56-60)

- 1) Review of the Proposed Medical Examining Board Application for Council Member Appointment

I) Interstate Medical Licensure Compact Commission – Report from Wisconsin’s Commissioners

J) American Association of Osteopathic Examiners Call for Nominations (61)

- 1) Candidacy of Dr. Mary Jo Capodice

K) Federation of State Medical Boards (FSMB) Matters (62-63)

- 1) Consideration of Nominations for Elective Office and Committee Appointments
- 2) April 20-22, 2017 Annual Meeting, Public Member Scholarship Award – Board Consideration

L) Speaking Engagement(s), Travel, or Public Relation Request(s), and Report(s)

M) Newsletter Matters

N) Screening Panel Report

O) Informational Items (64)

- 1) Final AHRQ Technical Brief on Medication-Assisted Treatment Models of Care for Opioid Use Disorder in Primary Care Settings (64)
- 2) 2016 Report from Interim Meeting of the American Medical Association (65-67)

P) Items Added After Preparation of Agenda

- 1) Introductions, Announcements and Recognition
- 2) Administrative Updates
- 3) Elections, Appointments, Reappointments, Confirmations, and Committee, Panel and Liaison Appointments
- 4) Education and Examination Matters
- 5) Credentialing Matters
- 6) Practice Matters
- 7) Future Agenda Items
- 8) Legislation/Administrative Rule Matters
- 9) Liaison Report(s)
- 10) Newsletter Matters
- 11) Annual Report Matters
- 12) Informational Item(s)
- 13) Disciplinary Matters
- 14) Presentations of Petition(s) for Summary Suspension
- 15) Presentation of Proposed Stipulation(s), Final Decision(s) and Order(s)
- 16) Presentation of Proposed Decisions
- 17) Presentation of Interim Order(s)
- 18) Petitions for Re-Hearing
- 19) Petitions for Assessments
- 20) Petitions to Vacate Order(s)
- 21) Petitions for Designation of Hearing Examiner
- 22) Requests for Disciplinary Proceeding Presentations
- 23) Motions
- 24) Petitions
- 25) Appearances from Requests Received or Renewed
- 26) Speaking Engagement(s), Travel, or Public Relation Request(s), and Reports

Q) Future Agenda Items

R) Public Comments

CONVENE TO CLOSED SESSION to deliberate on cases following hearing (§ 19.85 (1) (a), Stats.); to consider licensure or certification of individuals (§ 19.85 (1) (b), Stats.); to consider closing disciplinary investigations with administrative warnings (§ 19.85 (1) (b), Stats. and § 448.02 (8), Stats.); to consider individual histories or disciplinary data (§ 19.85 (1) (f), Stats.); and to confer with legal counsel (§ 19.85 (1) (g), Stats.).

S) 9:00 A.M. APPEARANCE – DLSC Attorney Joost Kap and Attorney John. Zwieg on Behalf of Petitioner – Review of Administrative Warning WARN00000582/DLSC Case No. 14 MED 577 (70-89)

T) Deliberation on Division of Legal Services and Compliance (DLSC) Matters

1) Complaints

a) 14 MED 300 – D.J.H., M.D. **(90-96)**

2) Administrative Warnings

a) 15 MED 444 – A.A.M. **(97-99)**

b) 16 MED 075 – B.D.E. **(100-102)**

c) 16 MED 279 – R.E.Y. **(103-104)**

3) Proposed Stipulations, Final Decisions and Orders

a) 15 MED 081 – Amy E. Bernards, P.A. **(105-113)**

b) 15 MED 081 – Jennifer K. Nale, P.A. **(114-122)**

c) 16 MED 023 – Ann A. Tran, M.D. **(123-128)**

4) Case Closings

a) 15 MED 256 **(129-133)**

b) 16 MED 077 **(134-136)**

c) 16 MED 318 **(137-147)**

5) Monitoring

U) Requests for Waiver of 24 Months of ACGME/AOA Approved Post Graduate Training

1) Joseph Baker, D.O. **(148-241)**

2) Ashish Khandelwal, M.D. **(242-271)**

3) Bulent Mamikoglu, M.D. **(272-310)**

4) Helen Manning, M.D. **(311-404)**

V) Open Cases

W) Consulting With Legal Counsel

X) Deliberation of Items Added After Preparation of the Agenda

1) Education and Examination Matters

2) Credentialing Matters

3) Disciplinary Matters

4) Monitoring Matters

5) Professional Assistance Procedure (PAP) Matters

6) Petition(s) for Summary Suspensions

7) Proposed Stipulations, Final Decisions and Orders

8) Administrative Warnings

9) Proposed Decisions

10) Matters Relating to Costs

11) Complaints

12) Case Closings

13) Case Status Report

14) Petition(s) for Extension of Time

15) Proposed Interim Orders

16) Petitions for Assessments and Evaluations

17) Petitions to Vacate Orders

18) Remedial Education Cases

- 19) Motions
- 20) Petitions for Re-Hearing
- 21) Appearances from Requests Received or Renewed

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

- Y) Open Session Items Noticed Above not Completed in the Initial Open Session
- Z) Vote on Items Considered or Deliberated Upon in Closed Session, if Voting is Appropriate
- AA) Delegation of Ratification of Examination Results and Ratification of Licenses and Certificates

ADJOURNMENT

ORAL EXAMINATION OF THREE (3) CANDIDATES FOR LICENSURE

ROOM 124D/E

10:15 A.M., OR IMMEDIATELY FOLLOWING THE FULL BOARD MEETING

CLOSED SESSION – Reviewing Applications and Conducting Oral Examinations of three (3) Candidates for Licensure –Dr. Roelke & Dr. Simons

NEXT MEETING DATE JANUARY 18, 2017

**MEDICAL EXAMINING BOARD
MEETING MINUTES
November 16, 2016**

PRESENT: Mary Jo Capodice, D.O.; Rodney Erickson, M.D.; Bradley Kudick; Lee Ann Lau, M.D.; Carolyn Ogland Vukich, M.D.; David Roelke, M.D.; Kenneth Simons, M.D.; Timothy Westlake, M.D.; Robert Zoeller, M.D.; Robert Zondag

EXCUSED: Michael Carton, Padmaja Doniparthi, M.D.; Russell Yale, M.D.

STAFF: Tom Ryan, Executive Director; Nifty Lynn Dio, Bureau Assistant; and other Department staff

CALL TO ORDER

Kenneth Simons, Chair, called the meeting to order at 8:03 a.m. A quorum of ten (10) members was confirmed.

ADOPTION OF AGENDA

Amendments to the Agenda:

- *Correct Oral Examination Candidates to One (1)*
- *Added: Waiver Request of Timothy Lawler to Item U*
- *Added: CME Memo to Item F.2*

MOTION: Carolyn Ogland Vukich moved, seconded by Timothy Westlake, to adopt the agenda as amended. Motion carried unanimously.

MINUTES OF OCTOBER 19, 2016 – REVIEW AND APPROVAL

MOTION: Mary Jo Capodice moved, seconded by Rodney Erickson, to approve the minutes of October 19, 2016 as published. Motion carried unanimously.

**8:00 A.M. PUBLIC HEARING: CLEARINGHOUSE RULE 15-087 – MED 24 RELATING TO
TELEMEDICINE**

MOTION: Lee Ann Lau moved, seconded by Mary Jo Capodice, to authorize the Chair to approve the Legislative Report and Draft for Clearinghouse Rule 15-087 creating Med 24 relating to telemedicine for submission to the Governor's Office and Legislature. Motion carried unanimously.

LEGISLATIVE/ADMINISTRATIVE RULE MATTERS

Wisconsin Medical Examining Board Opioid Prescribing Guideline

MOTION: Carolyn Ogland Vukich moved, seconded by Bradley Kudick, to amend the Opioid Prescribing Guideline as directed by the Board at the meeting today. Motion carried unanimously.

Update on Med 13 Relating to Continuing Medical Education for Prescribing Opioids

MOTION: Carolyn Ogland Vukich moved, seconded by Bradley Kudick, to appoint Timothy Westlake as the Opioid Prescribing Guideline CME Liaison, and Rodney

Erickson as alternate to approve and/or deny courses and programs and to request additional information if necessary. Motion carried unanimously.

FEDERATION OF STATE MEDICAL BOARDS (FSMB) MATTERS

MOTION: Timothy Westlake moved, seconded by Lee Ann Lau, to support Kenneth Simons' candidacy for election to the FSMB Board of Directors. Motion carried unanimously.

CLOSED SESSION

MOTION: Carolyn Ogland Vukich moved, seconded by Timothy Westlake, to convene to Closed Session to deliberate on cases following hearing (§ 19.85 (1) (a), Stats.); to consider licensure or certification of individuals (§ 19.85 (1) (b), Stats.); to consider closing disciplinary investigations with administrative warnings (§ 19.85 (1) (b), Stats. and § 448.02 (8), Stats.); to consider individual histories or disciplinary data (§ 19.85 (1) (f), Stats.); and to confer with legal counsel (§ 19.85 (1) (g), Stats.). The Chair read the language of the motion aloud for the record. The vote of each member was ascertained by voice vote. Roll Call Vote: Mary Jo Capodice – yes; Rodney Erickson – yes; Bradley Kudick – yes; Lee Ann Lau – yes; Carolyn Ogland Vukich – yes; David Roelke – yes; Kenneth Simons – yes; Timothy Westlake – yes; Robert Zoeller – yes; and Robert Zondag – yes. Motion carried unanimously.

The Board convened into Closed Session at 9:49 a.m.

RECONVENE TO OPEN SESSION

MOTION: David Roelke moved, seconded by Carolyn Ogland Vukich, to reconvene in Open Session at 10:46 a.m. Motion carried unanimously.

VOTE ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

MOTION: Carolyn Ogland Vukich moved, seconded by Bradley Kudick, to affirm all motions made and votes taken in Closed Session. Motion carried unanimously.

DELIBERATION ON DIVISION OF LEGAL SERVICES AND COMPLIANCE (DLSC) MATTERS

Administrative Warnings

15 MED 461 – L.K.K.

MOTION: Timothy Westlake moved, seconded by Robert Zoeller, to issue an Administrative Warning in the matter of DLSC Case No. 15 MED 461. Motion carried unanimously.

16 MED 156 – R.G.J.

MOTION: David Roelke moved, seconded by Lee Ann Lau, to issue an Administrative Warning in the matter of DLSC Case No. 16 MED 156. Motion carried unanimously.

16 MED 210 – I.I.S.

MOTION: David Roelke moved, seconded by Timothy Westlake, to issue an Administrative Warning in the matter of DLSC Case No. 16 MED 210. Motion carried.

Proposed Stipulations, Final Decisions and Orders

Stipulation and Interim Order in the Matter of DLSC Case No. 15 MED 187 – Gregory McClain

MOTION: Timothy Westlake moved, seconded by David Roelke, to adopt the Findings of Fact, Conclusions of Law and Interim Order in the matter of disciplinary proceedings against Gregory McClain, DLSC Case No. 15 MED 187. Motion carried unanimously.

15 MED 002 – Ronda Davis, M.D.

MOTION: Carolyn Ogland Vukich moved, seconded by Lee Ann Lau, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Ronda Davis, DLSC Case No. 15 MED 002. Motion carried unanimously.

15 MED 098 – Meenakshi Bhillakar

MOTION: Timothy Westlake moved, seconded by Robert Zoeller, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Meenakshi Bhillakar, DLSC Case No. 15 MED 098. Motion carried unanimously.

15 MED 128 – Gerald Paul Clarke

MOTION: David Roelke moved, seconded by Bradley Kudick, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Gerald Paul Clarke, DLSC Case No. 15 MED 128. Motion carried unanimously.

Case Closings

15 MED 371

MOTION: David Roelke moved, seconded by Timothy Westlake, to close DLSC Case No. 15 MED 371 against J.F.D. for No Violation. Motion carried unanimously.

15 MED 404

MOTION: Timothy Westlake moved, seconded by Rodney Erickson, to close DLSC Case No. 15 MED 404 against R.B.B. & J.S.B. for No Violation. Motion carried unanimously.

15 MED 427

MOTION: Timothy Westlake moved, seconded by Lee Ann Lau, to close DLSC Case No. 15 MED 427 against K.A.S. for No Violation. Motion carried unanimously.

16 MED 031

MOTION: Lee Ann Lau moved, seconded by Bradley Kudick, to close DLSC Case No. 16 MED 031 against T.M.K. for Prosecutorial Discretion (P5-Flag). Motion carried unanimously.

16 MED 080

MOTION: Timothy Westlake moved, seconded by Rodney Erickson, to close DLSC Case No. 16 MED 080 against M.R.J. for No Violation. Motion carried unanimously.

16 MED 107

MOTION: David Roelke moved, seconded by Lee Ann Lau, to close DLSC Case No. 16 MED 080 against R.J.J. for No Violation. Motion carried unanimously.

16 MED 147

MOTION: Lee Ann Lau moved, seconded by Robert Zoeller, to close DLSC Case No. 16 MED 147 against K.D.T. for No Violation. Motion carried unanimously.

16 MED 228

MOTION: Lee Ann Lau moved, seconded by Bradley Kudick, to close DLSC Case No. 16 MED 228 against J.D. for No Violation. Motion carried unanimously.

16 MED 256

MOTION: Timothy Westlake moved, seconded by Carolyn Ogland Vukich, to close DLSC Case No. 16 MED 256 against A.S.O. for No Violation. Motion carried unanimously.

REQUESTS FOR WAIVER OF 24 MONTH OF ACGME/AOA APPROVED POST GRADUATE TRAINING

Timothy Lawler, D.O.

MOTION: Bradley Kudick moved, seconded by David Roelke, to grant a waiver of the 24 month of ACGME/AOA approved post-graduate training to Timothy Lawler, per Wis. Stat. §448.05(2)(c). Motion carried unanimously.

MOTION: Bradley Kudick moved, seconded by David Roelke, to grant the license to practice medicine and surgery to Timothy Lawler, once all requirements are met. Motion carried unanimously.

Helen Manning, M.D.

MOTION: Robert Zoeller moved, seconded by Timothy Westlake, to table the request for waiver of the 24 month of ACGME/AOA approved post-graduate training of Helen Manning, per Wis. Stat. §448.05(2)(c), and request DSPS staff to obtain additional information. Motion carried unanimously.

Bulent Mamikoglu, M.D.

MOTION: Bradley Kudick moved, seconded by Mary Jo Capodice, to table the request for waiver of the 24 month of ACGME/AOA approved post-graduate training of Bulent Mamikoglu, per Wis. Stat. §448.05(2)(c), and request DSPS staff obtain additional information. Motion carried unanimously.

DELEGATION OF RATIFICATION OF EXAMINATION RESULTS AND RATIFICATION OF LICENSES AND CERTIFICATES

MOTION: Robert Zoeller moved, seconded by Lee Ann Lau, to delegate ratification of examination results to DSPS staff and to ratify all licenses and certificates as issued. Motion carried unanimously.

ADJOURNMENT

MOTION: Lee Ann Lau moved, seconded by Mary Jo Capodice, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 10:47 a.m.

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Dale Kleven Administrative Rules Coordinator		2) Date When Request Submitted: 12/9/16 Items will be considered late if submitted after 12:00 p.m. on the deadline date: ▪ 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Medical Examining Board			
4) Meeting Date: 12/21/16	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? 8:00 A.M. Public Hearing: Emergency Rule EmR1631 and Clearinghouse Rule 16-070 – Med 13 Relating to Continuing Medical Education for Prescribing Opioids 1. Review and Respond to Public Comments and Clearinghouse Report Federation of State Medical Boards Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain Legislative/Administrative Rule Matters: 1. Scope and Limitations of a Physician Assistant’s Practice Under Med 8.07 2. Update on Med 24 Relating to Telemedicine 3. Update on Med 1 and 14 Relating to General Update and Cleanup of Rules 4. Update on Other Legislation and Pending or Possible Rulemaking Projects	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes (Fill out Board Appearance Request) <input checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed: Federation of State Medical Boards Model Policy on the Use of Opioid Analgesics in the Treatment of Chronic Pain The Board is asked to consider if the FSMB model policy should continue to be listed as a resource on the Board’s website			
11) <i>Dale Kleven</i> Signature of person making this request		Authorization <i>December 9, 2016</i> Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda)		Date	
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, Provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

STATE OF WISCONSIN
MEDICAL EXAMINING BOARD

IN THE MATTER OF RULEMAKING : ORDER OF THE
PROCEEDINGS BEFORE THE : MEDICAL EXAMINING BOARD
MEDICAL EXAMINING BOARD : ADOPTING EMERGENCY RULES

The statement of scope for this rule, SS 016-16, was approved by the Governor on February 12, 2016, published in Register 722A4 on February 22, 2016, and approved by the Medical Examining Board on March 16, 2016.

This emergency rule was approved by the Governor on November 3, 2016

ORDER

An order of the Medical Examining Board to amend Med 13.02 (1) and to create Med 13.02 (1g) and (1r) and 13.03 (3), relating to continuing medical education for prescribing opioids.

Analysis prepared by the Department of Safety and Professional Services.

FINDING OF EMERGENCY

The Medical Examining Board finds that an emergency exists and that this rule is necessary for the immediate preservation of the public peace, health, safety, or welfare. A statement of facts constituting the emergency is:

This rule will establish continuing education requirements for physicians relating to the opioid prescribing guidelines issued by the Board. These requirements will be another component to the current statewide initiatives addressing prescription drug abuse, and are in the best interest of public health and safety.

As normal rule-making procedures will not allow these requirements to be established until mid-2017, an expeditious promulgation of this rule is needed to ensure public health and safety.

ANALYSIS

Statutes interpreted:

Section 448.13, Stats.

Statutory authority:

Sections 15.08 (5) (b), 227.11 (2) (a), and 448.40 (1), Stats.

Explanation of agency authority:

Section 15.08 (5) (b), Stats., provides examining boards, “shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains. . .”

Section 227.11 (2) (a), Stats., sets forth the parameters of an agency’s rule-making authority, stating an agency, “may promulgate rules interpreting provisions of any statute enforced or administered by the agency. . .but a rule is not valid if the rule exceeds the bounds of correct interpretation.”

Section 448.40 (1), Stats., provides that the Medical Examining Board “may promulgate rules to carry out the purposes of this subchapter, including rules requiring the completion of continuing education, professional development, and maintenance of certification or performance improvement or continuing medical education programs for renewal of a license to practice medicine and surgery.”

Related statute or rule:

None.

Plain language analysis:

The rules establish requirements for the completion of continuing education relating to the opioid prescribing guidelines issued by the Board as a portion of the biennial training requirements for physicians, and for Board approval of educational courses and programs.

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

None.

Comparison with rules in adjacent states:

Illinois:

Rules of the Illinois Department of Financial and Professional Regulation establish continuing medical education requirements for physicians licensed in Illinois (68 Ill. Adm. Code 1285.110). The rules do not require continuing education for prescribing opioids.

Iowa:

Rules of the Iowa Board of Medicine establish continuing education requirements for physicians licensed in Iowa (653 IAC 11). The rules do not require continuing education for prescribing opioids.

Michigan:

Rules of the Michigan Department of Licensing and Regulatory Affairs establish continuing medical education requirements for physicians licensed in Michigan (Mich Admin Code, R 338.2371 to R 338.2382). The rules do not require continuing education for prescribing opioids.

Minnesota:

Rules of the Minnesota Board of Medical Practice establish continuing education requirements for physicians licensed in Minnesota (Minnesota Rules, chapter 5605). The rules do not require continuing education for prescribing opioids.

Summary of factual data and analytical methodologies:

The rules were developed by obtaining input and feedback from the Medical Examining Board.

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

These rules do not require additional hours of continuing medical education. The purpose of the rules is to require a portion of the continuing medical education hours currently required relate to the opioid prescribing guidelines issued by the Medical Examining Board. The cost of attending the 2 hours of continuing medical education for 2 renewal periods as required by the rules is anticipated to be comparable to that of other courses and programs currently available to physicians.

Fiscal estimate:

These rules will not have a fiscal impact.

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 8366, Madison, Wisconsin 53708; telephone 608-261-4472; email at Dale2.Kleven@wisconsin.gov.

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

Comments may be submitted to Dale Kleven, 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, or by email to DSPSAdminRules@wisconsin.gov. Comments must be submitted by the date and time at which the public hearing on these rules is conducted. Information as to the place, date, and time of the public hearing will be published on the Department of Safety and Professional Services’ website and in the Wisconsin Administrative Register.

TEXT OF RULE

SECTION 1. Med 13.02 (1) is amended to read:

Med 13.02 Continuing medical education required; waiver. (1) Each physician required to complete the biennial training requirements provided under s. 448.13, Stats., shall, in each second year at the time of making application for a certificate of registration as required under s. 448.07, Stats., sign a statement on the application for registration certifying that the physician has completed at least 30 hours of acceptable continuing medical educational programs within the ~~2 calendar years immediately preceding the calendar year for which application for registration is made~~ biennial registration period.

SECTION 2. Med 13.02 (1g) and (1r) are created to read:

Med 13.02 (1g) (a) Except as provided in par. (b), for a renewal date occurring in 2017 or 2018, a minimum of 2 of the 30 hours of continuing medical education required under sub. (1) shall be an educational course or program related to the guidelines issued by the board under s. 440.035 (2m), Stats., that is approved under s. Med 13.03 (3) at the time of the physician's attendance.

(b) This subsection does not apply to a physician who, at the time of making application for a certificate of registration, does not hold a U.S. Drug Enforcement Administration number to prescribe controlled substances.

(1r) (a) Except as provided in par. (b), for a renewal date occurring in 2019 or 2020, a minimum of 2 of the 30 hours of continuing medical education required under sub. (1) shall be an educational course or program related to the guidelines issued by the board under s. 440.035 (2m), Stats., that is approved under s. Med 13.03 (3) at the time of the physician's attendance.

(b) This subsection does not apply to a physician who, at the time of making application for a certificate of registration, does not hold a U.S. Drug Enforcement Administration number to prescribe controlled substances.

SECTION 3. Med 13.03 (3) is created to read:

Med 13.03 (3) (a) Only educational courses and programs approved by the board may be used to satisfy the requirement under s. Med 13.02 (1g) (a) and (1r) (a). To apply for approval of a continuing education course or program, a provider shall submit to the board an application on forms provided by the department. The application shall include all of the following concerning the course or program:

1. The title.
2. A general description and a detailed outline of the content.
3. The dates and locations.
4. The name and qualifications of the instructor.

5. The sponsor.

Note: An application for continuing education course or program approval may be obtained from the board at the Department of Safety and Professional Services, Office of Education and Examinations, P.O. Box 8366, Madison, Wisconsin, 53708, or from the department's website at <http://dsps.wi.gov>.

(b) A continuing education course or program must meet all of the following criteria to be approved:

1. The course or program is accepted by the board under sub. (1) (b).

2. The subject matter of the course pertains to the guidelines issued by the board under s. 440.035 (2m), Stats.

3. The provider agrees to monitor the attendance and furnish a certificate of attendance to each participant. The certificate of attendance shall certify successful completion of the course or program.

4. The provider is approved by the board.

5. The course or program content and instructional methodologies are approved by the board.

(c) A separate application shall be submitted for each continuing education course or program approval request.

(d) A course or program sponsor may repeat a previously approved course or program without application, if the subject matter and instructor has not changed.

SECTION 4. EFFECTIVE DATE. The rules adopted in this order shall take effect upon publication in the official state newspaper, pursuant to s. 227.22 (2) (c), Stats.

(END OF TEXT OF RULE)

Dated _____

Agency _____

Vice Chairperson
Medical Examining Board

STATE OF WISCONSIN
MEDICAL EXAMINING BOARD

IN THE MATTER OF RULEMAKING : PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE : MEDICAL EXAMINING BOARD
MEDICAL EXAMINING BOARD : ADOPTING RULES
: (CLEARINGHOUSE RULE)

PROPOSED ORDER

An order of the Medical Examining Board to amend Med 13.02 (1) and to create Med 13.02 (1g) and (1r) and 13.03 (3), relating to continuing medical education for prescribing opioids.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted:

Section 448.13, Stats.

Statutory authority:

Sections 15.08 (5) (b), 227.11 (2) (a), and 448.40 (1), Stats.

Explanation of agency authority:

Section 15.08 (5) (b), Stats., provides examining boards, “shall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains. . .”

Section 227.11 (2) (a), Stats., sets forth the parameters of an agency’s rule-making authority, stating an agency, “may promulgate rules interpreting provisions of any statute enforced or administered by the agency. . .but a rule is not valid if the rule exceeds the bounds of correct interpretation.”

Section 448.40 (1), Stats., provides that the Medical Examining Board “may promulgate rules to carry out the purposes of this subchapter, including rules requiring the completion of continuing education, professional development, and maintenance of certification or performance improvement or continuing medical education programs for renewal of a license to practice medicine and surgery.”

Related statute or rule:

None.

Plain language analysis:

The proposed rules establish requirements for the completion of continuing education relating to the opioid prescribing guidelines issued by the Board as a portion of the

biennial training requirements for physicians, and for Board approval of educational courses and programs.

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

None.

Comparison with rules in adjacent states:

Illinois:

Rules of the Illinois Department of Financial and Professional Regulation establish continuing medical education requirements for physicians licensed in Illinois (68 Ill. Adm. Code 1285.110). The rules do not require continuing education for prescribing opioids.

Iowa:

Rules of the Iowa Board of Medicine establish continuing education requirements for physicians licensed in Iowa (653 IAC 11). The rules do not require continuing education for prescribing opioids.

Michigan:

Rules of the Michigan Department of Licensing and Regulatory Affairs establish continuing medical education requirements for physicians licensed in Michigan (Mich Admin Code, R 338.2371 to R 338.2382). The rules do not require continuing education for prescribing opioids.

Minnesota:

Rules of the Minnesota Board of Medical Practice establish continuing education requirements for physicians licensed in Minnesota (Minnesota Rules, chapter 5605). The rules do not require continuing education for prescribing opioids.

Summary of factual data and analytical methodologies:

The proposed rules were developed by obtaining input and feedback from the Medical Examining Board.

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

The proposed rules will be posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

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 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 8366, Madison, Wisconsin 53708; telephone 608-261-4472; email at Dale2.Kleven@wisconsin.gov.

TEXT OF RULE

SECTION 1. Med 13.02 (1) is amended to read:

Med 13.02 Continuing medical education required; waiver. (1) Each physician required to complete the biennial training requirements provided under s. 448.13, Stats., shall, in each second year at the time of making application for a certificate of registration as required under s. 448.07, Stats., sign a statement on the application for registration certifying that the physician has completed at least 30 hours of acceptable continuing medical educational programs within the ~~2 calendar years immediately preceding the calendar year for which application for registration is made~~ biennial registration period.

SECTION 2. Med 13.02 (1g) and (1r) are created to read:

Med 13.02 (1g) (a) Except as provided in par. (b), for a renewal date occurring in 2017 or 2018, a minimum of 2 of the 30 hours of continuing medical education required under sub. (1) shall be an educational course or program related to the guidelines issued by the board under s. 440.035 (2m), Stats., that is approved under s. Med 13.03 (3) at the time of the physician's attendance.

(b) This subsection does not apply to a physician who, at the time of making application for a certificate of registration, does not hold a U.S. Drug Enforcement Administration number to prescribe controlled substances.

(1r) (a) Except as provided in par. (b), for a renewal date occurring in 2019 or 2020, a minimum of 2 of the 30 hours of continuing medical education required under sub. (1) shall be an educational course or program related to the guidelines issued by the board under s. 440.035 (2m), Stats., that is approved under s. Med 13.03 (3) at the time of the physician's attendance.

(b) This subsection does not apply to a physician who, at the time of making application for a certificate of registration, does not hold a U.S. Drug Enforcement Administration number to prescribe controlled substances.

SECTION 3. Med 13.03 (3) is created to read:

Med 13.03 (3) (a) Only educational courses and programs approved by the board may be used to satisfy the requirement under s. Med 13.02 (1g) (a) and (1r) (a). To apply for approval of a continuing education course or program, a provider shall submit to the board an application on forms provided by the department. The application shall include all of the following concerning the course or program:

1. The title.

2. A general description and a detailed outline of the content.
3. The dates and locations.
4. The name and qualifications of the instructor.
5. The sponsor.

Note: An application for continuing education course or program approval may be obtained from the board at the Department of Safety and Professional Services, Office of Education and Examinations, P.O. Box 8366, Madison, Wisconsin, 53708, or from the department's website at <http://dsps.wi.gov>.

(b) A continuing education course or program must meet all of the following criteria to be approved:

1. The course or program is accepted by the board under sub. (1) (b).
2. The subject matter of the course pertains to the guidelines issued by the board under s. 440.035 (2m), Stats.
3. The provider agrees to monitor the attendance and furnish a certificate of attendance to each participant. The certificate of attendance shall certify successful completion of the course or program.
4. The provider is approved by the board.
5. The course or program content and instructional methodologies are approved by the board.

(c) A separate application shall be submitted for each continuing education course or program approval request.

(d) A course or program sponsor may repeat a previously approved course or program without application, if the subject matter and instructor has not changed.

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.

(END OF TEXT OF RULE)

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
 Original Updated Corrected

2. Administrative Rule Chapter, Title and Number
Med 13

3. Subject
Continuing medical education for prescribing opioids

4. Fund Sources Affected <input type="checkbox"/> GPR <input type="checkbox"/> FED <input type="checkbox"/> PRO <input checked="" type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S	5. Chapter 20, Stats. Appropriations Affected 20.165(1)(hg)
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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

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)

8. Would Implementation and Compliance Costs Be Greater Than \$20 million?
 Yes No

9. Policy Problem Addressed by the Rule
The proposed rules will establish continuing education requirements for physicians relating to the opioid prescribing guidelines issued by the Board. These requirements will be another component to the current statewide initiatives addressing prescription drug abuse, and are in the best interest of public health and safety.

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.
The proposed rule was posted on the Department of Safety and Professional Services' website for 14 days in order to solicit comments from businesses, representative associations, local governmental units, and individuals that may be affected by the rule. No comments were received.

11. Identify the local governmental units that participated in the development of this EIA.
No local governmental units participated in the development of this EIA.

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 not have a significant impact on specific businesses, business sectors, public utility rate payers, local governmental units or the state's economy as a whole.

13. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit to implementing the rule is adding a component to the current statewide initiatives addressing prescription drug abuse. Not implementing the rule would be inconsistent with these initiatives.

14. Long Range Implications of Implementing the Rule
The long range implication of implementing the rule is increased physician awareness of prescription drug abuse.

15. Compare With Approaches Being Used by Federal Government
None

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

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

Illinois:

Rules of the Illinois Department of Financial and Professional Regulation establish continuing medical education requirements for physicians licensed in Illinois (68 Ill. Adm. Code 1285.110). The rules do not require continuing education for prescribing opioids.

Iowa:

Rules of the Iowa Board of Medicine establish continuing education requirements for physicians licensed in Iowa (653 IAC 11). The rules do not require continuing education for prescribing opioids.

Michigan:

Rules of the Michigan Department of Licensing and Regulatory Affairs establish continuing medical education requirements for physicians licensed in Michigan (Mich Admin Code, R 338.2371 to R 338.2382). The rules do not require continuing education for prescribing opioids.

Minnesota:

Rules of the Minnesota Board of Medical Practice establish continuing education requirements for physicians licensed in Minnesota (Minnesota Rules, chapter 5605). The rules do not require continuing education for prescribing opioids.

17. Contact Name

Dale Kleven

18. Contact Phone Number

(608) 261-4472

This document can be made available in alternate formats to individuals with disabilities upon request.

Kleven, Dale - DSPS

From: Software-Notification@legis.wisconsin.gov
Sent: Tuesday, November 15, 2016 8:18 PM
To: DSPS Admin Rules
Subject: Public comment on Emergency Rule 1631

Name: Frank Mraz

Address: [REDACTED]

Email: [REDACTED]

Organization:

Comments: Respectfully, The burden upon practicing physicans to attend live courses interferes with patient care. It would be quite reasonable for the Board to offer an online course that would comply with the purposes of this rule. Practically speaking, in order to attend a two hour live course that would require any amount of travel especially in our rural areas, would mean forgoing at least half of a clinical day, if not more. Moreover, the emergency nature of this rule requiring compliance without even having courses already in place seems to put the cart before the horse. Perhaps, the purposes of the rule can be better served if those physicans who have abused their prescribing powers were vigorously disciplined and or prosecuted.



WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

Scott Grosz
Clearinghouse Director

Margit Kelley
Clearinghouse Assistant Director

Terry C. Anderson
Legislative Council Director

Jessica Karls-Ruplinger
Legislative Council Deputy Director

CLEARINGHOUSE RULE 16-070

Comments

[NOTE: All citations to “Manual” in the comments below are to the Administrative Rules Procedures Manual, prepared by the Legislative Reference Bureau and the Legislative Council Staff, dated December 2014.]

2. Form, Style and Placement in Administrative Code

In the rule summary, a section and entry should be inserted for the deadline and place to submit comments on the proposed rule. [s. 1.02 (2) (a) 13., Manual.]

3. Conflict With or Duplication of Existing Rules

Section Med 13.03 (3) (a) (Note) includes a reference to where the requisite course approval application form may be obtained. However, the current rule already includes a different reference to where the requisite form may be obtained with a different location. Should the new reference to the form replace the old reference to the form?

MODEL POLICY ON THE USE OF OPIOID ANALGESICS IN THE TREATMENT OF CHRONIC PAIN

Adopted as policy by the House of Delegates of the Federation of State Medical Boards in July 2013

INTRODUCTION

The Federation of State Medical Boards (FSMB) is committed to assisting state Medical Boards in protecting the public and improving the quality and integrity of health care in the United States. In 1997, the FSMB undertook an initiative to develop model guidelines and to encourage state medical boards and other health care regulatory agencies to adopt policies encouraging safe and effective treatment of patients with pain, including, if indicated, the use of opioid analgesics. [1]. The FSMB updated its guidelines in 2003 [2] so that its Model Policy would reflect the best available evidence on management of pain and give adequate attention to both the undertreatment and overtreatment of pain and the inappropriate use of opioid analgesics.

Through these initiatives, the FSMB has sought to provide a resource for use by state medical boards in educating their licensees about cautious and responsible prescribing of controlled substances while alleviating fears of regulatory scrutiny. The FSMB recognizes that inappropriate prescribing can contribute to adverse outcomes such as reduced function, opioid addiction, overdose, and death [3-5]. By promulgating its Model Policies, the FSMB has sought to provide a framework for the legitimate medical use of opioid analgesics for the treatment of pain while emphasizing the need to safeguard against their misuse and diversion.

Since their publication, the 1998 and 2004 Model Policies have been widely distributed to state medical boards, medical professional organizations, other health care regulatory boards, patient advocacy groups, pharmaceutical companies, state and federal regulatory agencies, and practicing physicians and other health care providers. The policies have been endorsed by the American Academy of Pain Medicine, the Drug Enforcement Administration, the American Pain Society, and the National Association of State Controlled Substances Authorities. Many states have adopted all or part of the Model Policies.¹

The updated Model Policy presented here reflects the considerable body of research and experience accrued since the 2004 revision was adopted [2]. While recognizing that adequate evidence is currently lacking as to the effectiveness and safety of long-term opioid therapy, this Model Policy is designed to promote the public health by encouraging state medical boards to adopt consistent policy regarding the treatment of pain, particularly chronic pain, and to promote patient access to appropriate pain management and, if indicated, substance abuse and addiction treatment. The Model Policy emphasizes the professional and ethical responsibility of physicians to appropriately assess and manage patients' pain, assess the relative level of risk for misuse and addiction, monitor for aberrant behaviors and intervene as appropriate. It also includes references and the definitions of key terms used in pain management.

¹ As of March 7, 2012, 57 of 70 State Medical Boards have policy, rules, regulations or statutes reflecting the Federation's 1997 or 2004 *Model Guidelines for the Use of Controlled Substances for the Treatment of Pain*.

Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain

The FSMB encourages every state medical board to work with the state attorney general to evaluate the state's policies, regulations and laws in an effort to identify any barriers to the effective and appropriate use of opioids to relieve pain, while ensuring that adequate safeguards are in place to deter and rapidly detect those who would obtain opioid analgesics for nonmedical purposes [6-7].

The FSMB acknowledges with gratitude the efforts of the state board members and directors who collaborated to prepare this updated Model Policy, as well as the contributions of the independent experts and medical organizations that advised the drafting committee and reviewed its work. The FSMB also thanks SAMHSA for its support of this important project.

ISSUES ADDRESSED IN THE NEW MODEL POLICY

There is a significant body of evidence suggesting that many Americans suffer from chronic pain and much of that pain is inadequately or ineffectively treated[8-10]. Since the 2004 revision, evidence for risk associated with opioids has surged, while evidence for benefits has remained controversial and insufficient. Over the last decade, there has been a parallel increase in opioid sales and an increase in morbidity and mortality associated with these drugs. At the same time, approximately one in four patients seen in primary care settings suffers from pain so intense as to interfere with the activities of daily living [4]. Pain arises from multiple causes and often is categorized as either *acute pain* (such as that from traumatic injury and surgery) or *chronic pain* (such as the pain associated with terminal conditions such as cancer or severe vascular disease or with non-terminal conditions such as arthritis or neuropathy) [4,8]. This model policy applies most directly to the treatment of chronic pain and the use of opioid analgesics but many of the strategies to improve appropriate prescribing and mitigate risks can be applied to the use of other controlled medications and to the treatment of acute pain.

Undertreatment of pain is recognized as a serious public health problem that compromises patients' functional status and quality of life [4,9]. A myriad of psychological, social, economic, political, legal and educational factors—including inconsistencies and restrictions in state pain policies—can either facilitate or impede the ability and willingness of physicians to manage patients with pain [6,10-11].

While acknowledging that undertreatment of pain exists, it must be understood that chronic pain often is intractable, that the current state of medical knowledge and medical therapies, including opioid analgesics, does not provide for complete elimination of chronic pain in most cases, and that the existence of persistent and disabling pain does not in and of itself constitute evidence of undertreatment [4,8,12]. Indeed, some cases of intractable pain actually result from overtreatment in terms of procedures and medications.

Complicating the picture, adverse outcomes associated with the misuse, abuse and diversion of prescription opioids have increased dramatically since the FSMB's last review [3]. Physicians and other health care professionals have contributed—often inadvertently—to these increases.

Circumstances that contribute to both the inadequate treatment of pain and the inappropriate prescribing of opioids by physicians may include: (1) physician uncertainty or lack of knowledge as to prevailing best clinical practices; (2) inadequate research into the sources of and treatments for pain; (3) sometimes conflicting clinical guidelines for appropriate treatment of pain; (4) physician concerns that prescribing needed amounts of opioid analgesics will result in added scrutiny by regulatory authorities; (5) physician misunderstanding of causes and manifestations of opioid dependence and addiction; (6) fear on the part of physicians of causing addiction or being deceived by a patient who seeks drugs for purposes of misuse; (7) physicians practicing outside the bounds

Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain

of professional conduct by prescribing opioid analgesics without a legitimate medical purpose; and (8) inadequate physician education about regulatory policies and processes [3-4,12,14-20]. Inappropriate treatment also can result from a mistaken belief on the part of patients and their physicians that complete eradication of pain is an attainable goal, and one that can be achieved without disabling adverse effects. Additionally, treatment options may be limited based on availability and/or health plan policies on covered benefits or drug formularies.

Patients share with physicians a responsibility for appropriate use of opioid analgesics [21-22]. This responsibility encompasses providing the physician with complete and accurate information and adhering to the treatment plan. While many patients take their medication safely as prescribed and do not use opioids problematically, some patients—intentionally or unintentionally—are less than forthcoming or have unrealistic expectations regarding the need for opioid therapy or the amount of medication required. Other patients may begin to use medications as prescribed, then slowly deviate from the therapeutic regimen. Still others may not comply with the treatment plan because they misunderstood the physician's instructions. Some patients share their drugs with others without intending harm (a pattern of misuse that is seen quite often among older adults [15]). Then there are patients who deliberately misuse or are addicted to opioids, and who mislead, deceive or fail to disclose information to their physicians in order to obtain opioids to sustain their addiction and avoid withdrawal [19-23].

Patients often leave medications unsecured where they can be stolen by visitors, workers and family members, which is another important source of diversion. Thus a prescription that is quite appropriate for an elderly patient may ultimately contribute to the death of a young person who visits or lives in the patient's home. Therefore, the physician's duty includes not only appropriate prescribing of opioid analgesics, but also appropriate education of patients regarding the secure storage of medications and their appropriate disposal once the course of treatment is completed [18,23].

A more problematic individual is the criminal patient, whose primary purpose is to obtain drugs for resale. Whereas many addicted patients seek a long-term relationship with a prescriber, criminal patients sometimes move rapidly from one prescriber (or dispenser) to another. Such individuals often visit multiple practitioners (a practice sometimes characterized as "doctor shopping") and travel from one geographic area to another not for the purposes of relief of legitimate pain but in search of unsuspecting targets [19-21]. Physicians' attention to patient assessment and the routine use of state prescription drug monitoring programs (PDMPs), where available, have been cited as effective ways to identify individuals who engage in such criminal activities [20-23,45].

Conclusion: The goal of this Model Policy is to provide state medical boards with an updated guideline for assessing physicians' management of pain, so as to determine whether opioid analgesics are used in a manner that is both medically appropriate and in compliance with applicable state and federal laws and regulations. The revised Model Policy makes it clear that the state medical board will consider inappropriate management of pain, particularly chronic pain, to be a departure from accepted best clinical practices, including, but not limited to the following:

- **Inadequate attention to initial assessment to determine if opioids are clinically indicated and to determine risks associated with their use in a particular individual with pain:** Not unlike many drugs used in medicine today, there are significant risks associated with opioids and therefore benefits must outweigh the risks.
- **Inadequate monitoring during the use of potentially abusable medications:** Opioids may be associated with addiction, drug abuse, aberrant behaviors, chemical coping and other dysfunctional

behavioral problems, and some patients may benefit from opioid dose reductions or tapering or weaning off the opioid.

- **Inadequate attention to patient education and informed consent:** The decision to begin opioid therapy for chronic pain should be a shared decision of the physician and patient after a discussion of the risks and a clear understanding that the clinical basis for the use of these medications for chronic pain is limited, that some pain may worsen with opioids, and taking opioids with other substances or certain condition (i.e. sleep apnea, mental illness, pre-existing substance use disorder) may increase risk.
- **Unjustified dose escalation without adequate attention to risks or alternative treatments:** Risks associated with opioids increase with escalating doses as well as in the setting of other comorbidities (i.e. mental illness, respiratory disorders, pre-existing substance use disorder and sleep apnea) and with concurrent use with respiratory depressants such as benzodiazepines or alcohol.
- **Excessive reliance on opioids, particularly high dose opioids for chronic pain management:** Prescribers should be prepared for risk management with opioids in advance of prescribing and should use opioid therapy for chronic non-cancer pain only when safer and reasonably effective options have failed. Maintain opioid dosage as low as possible and continue only if clear and objective outcomes are being met.
- **Not making use of available tools for risk mitigations:** When available, the state prescription drug monitoring program should be checked in advance of prescribing opioids and should be available for ongoing monitoring.

In addition, the Model Policy is designed to communicate to licensees that the state medical board views pain management as an important area of patient care that is integral to the practice of medicine; that opioid analgesics may be necessary for the relief of certain pain conditions; and that physicians will not be sanctioned solely for prescribing opioid analgesics or the dose (mg./mcg.) prescribed for legitimate medical purposes. However, prescribers must be held to a safe and best clinical practice. The federal Controlled Substances Act [25] defines a “lawful prescription” as one that is issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The use of opioids for other than legitimate medical purposes poses a threat to the individual and to the public health, thus imposing on physicians a responsibility to minimize the potential for misuse, abuse and diversion of opioids and all other controlled substances.

MODEL POLICY FOR THE USE OF OPIOID ANALGESICS IN THE TREATMENT OF CHRONIC PAIN

SECTION I: PREAMBLE

The (name of Board) is obligated under the laws of the State of (name of state) to protect the public health and safety. The (name of Board) recognizes that principles of high-quality medical practice dictate that the people of the State of (name of state) have access to appropriate, safe and effective pain management. The application of up-to-date knowledge and treatment modalities can help to restore function and thus improve the quality of life of patients who suffer from pain, particularly chronic pain [4,8,26].

This policy has been developed to articulate the Board's position on the use of controlled substances for pain, particularly the use of opioid analgesics and with special attention to the management of chronic pain. The policy thus is intended to encourage physicians to be knowledgeable about best clinical practices as regards the prescribing of opioids and be aware of associated risks. For the purposes of this policy, inappropriate treatment of pain includes non-treatment, inadequate treatment, overtreatment, and continued use of ineffective treatments.

The Board recognizes that opioid analgesics are useful and can be essential in the treatment of acute pain that results from trauma or surgery, as well as in the management of certain types of chronic pain, whether due to cancer or non-cancer causes [20,26,28]. The Board will refer to current clinical practice guidelines and expert reviews in approaching allegations of possible mismanagement of pain [8,10,12,14,26-41, 80].

Responsibility for Appropriate Pain Management: All physicians and other providers should be knowledgeable about assessing patients' pain and function, and familiar with methods of managing pain [4,16]. Physicians also need to understand and comply with federal and state requirements for prescribing opioid analgesics [3,12,19]. Whenever federal laws and regulations differ from those of a particular state, the more stringent rule is the one that should be followed [42].

Physicians should not fear disciplinary action from the Board for ordering, prescribing, dispensing or administering controlled substances, including opioid analgesics, for a legitimate medical purpose and in the course of professional practice, when current best clinical practices are met.

The Board will consider the use of opioids for pain management to be for a legitimate medical purpose if it is based on sound clinical judgment and current best clinical practices, is appropriately documented, and is of demonstrable benefit to the patient. To be within the usual course of professional practice, a legitimate physician-patient relationship must exist and the prescribing or administration of medications should be appropriate to the identified diagnosis, should be accompanied by careful follow-up monitoring of the patient's response to treatment as well as his or her safe use of the prescribed medication, and should demonstrate that the therapy has been adjusted as needed [7,38,43]. There should be documentation of appropriate referrals as necessary [36-37].

The medical management of pain should reflect current knowledge of evidence-based or best clinical practices for the use of pharmacologic and nonpharmacologic modalities, including the use of opioid analgesics and non-opioid therapies [14,16,27]. Such prescribing must be based on careful assessment of the patient and his or her pain (see the discussion on risk stratification, below) [33].

Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain

Pain should be assessed and treated promptly, and the selection of therapeutic modalities (including the quantity and frequency of medication doses) should be adjusted according to the nature of the pain, the patient's response to treatment, and the patient's risk level relative to the use of medications with abuse potential [8,10,12,14,26-38].

Preventing Opioid Diversion and Abuse: The Board also recognizes that individuals' use of opioid analgesics for other than legitimate medical purposes poses a significant threat to the health and safety of the individual as well as to the public health [3]. The Board further recognizes that inappropriate prescribing of controlled substances by physicians may contribute to drug misuse and diversion by individuals who seek opioids for other than legitimate medical purposes [5,19,44]. Accordingly, the Board expects physicians to incorporate safeguards into their practices to minimize the risk of misuse and diversion of opioid analgesics and other controlled substances [19-23,38,45-46].

Allegations of inappropriate pain management will be evaluated on an individual basis. The Board may use a variety of sources to determine the appropriateness of treatment including prescribing information obtained from the State Prescription Drug Monitoring Program. The Board will not take disciplinary action against a physician for deviating from this Model Policy when contemporaneous medical records show reasonable cause for such a deviation.

The Board will judge the validity of the physician's treatment of a patient on the basis of available documentation, rather than solely on the quantity and duration of medication administered. The goal is the management of the patient's pain while effectively addressing other aspects of the patient's functioning, including physical, psychological, social and work-related factors, and mitigating risk of misuse, abuse, diversion and overdose [4,29].

The Board will consider the unsafe or otherwise inappropriate treatment of pain to be a departure from best clinical practice, taking into account whether the treatment is appropriate to the diagnosis and the patient's level of risk.

SECTION II: GUIDELINES

The Board has adopted the following criteria for use in evaluating a physician's management of a patient with pain, including the physician's prescribing of opioid analgesics:

Understanding Pain: The diagnosis and treatment of pain is integral to the practice of medicine [4,34-37]. In order to cautiously prescribe opioids, physicians must understand the relevant pharmacologic and clinical issues in the use of such analgesics, and carefully structure a treatment plan that reflects the particular benefits and risks of opioid use for each individual patient. Such an approach should be employed in the care of every patient who receives chronic opioid therapy [4,8].

Patient Evaluation and Risk Stratification: The medical record should document the presence of one or more recognized medical indications for prescribing an opioid analgesic [7] and reflect an appropriately detailed patient evaluation [38]. Such an evaluation should be completed before a decision is made as to whether to prescribe an opioid analgesic.

The nature and extent of the evaluation depends on the type of pain and the context in which it occurs. For

Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain

example, meaningful assessment of chronic pain, including pain related to cancer or non-cancer origins, usually demands a more detailed evaluation than an assessment of acute pain. Assessment of the patient's pain typically would include the nature and intensity of the pain, past and current treatments for the pain, any underlying or co-occurring disorders and conditions, and the effect of the pain on the patient's physical and psychological functioning [31].

For every patient, the initial work-up should include a systems review and relevant physical examination, as well as laboratory investigations as indicated [33,36,48-53]. Such investigations help the physician address not only the nature and intensity of the pain, but also its secondary manifestations, such as its effects on the patient's sleep, mood, work, relationships, valued recreational activities, and alcohol and drug use.

Social and vocational assessment is useful in identifying supports and obstacles to treatment and rehabilitation; for example: Does the patient have good social supports, housing, and meaningful work? Is the home environment stressful or nurturing? [14].

Assessment of the patient's personal and family history of alcohol or drug abuse and relative risk for medication misuse or abuse also should be part of the initial evaluation [11,14,21-23,45], and ideally should be completed prior to a decision as to whether to prescribe opioid analgesics [56-58]. This can be done through a careful clinical interview, which also should inquire into any history of physical, emotional or sexual abuse, because those are risk factors for substance misuse [31]. Use of a validated screening tool (such as the Screener and Opioid Assessment for Patients with Pain [SOAPP-R; 48] or the Opioid Risk Tool [ORT; 49]), or other validated screening tools, can save time in collecting and evaluating the information and determining the patient's level of risk.

All patients should be screened for depression and other mental health disorders, as part of risk evaluation. Patients with untreated depression and other mental health problems are at increased risk for misuse or abuse of controlled medications, including addiction, as well as overdose.

Patients who have a history of substance use disorder (including alcohol) are at elevated risk for failure of opioid analgesic therapy to achieve the goals of improved comfort and function, and also are at high risk for experiencing harm from this therapy, since exposure to addictive substances often is a powerful trigger of relapse [11,31,45]. Therefore, treatment of a patient who has a history of substance use disorder should, if possible, involve consultation with an addiction specialist before opioid therapy is initiated (and follow-up as needed). Patients who have an active substance use disorder should not receive opioid therapy until they are established in a treatment/recovery program [31] or alternatives are established such as co-management with an addiction professional. Physicians who treat patients with chronic pain should be encouraged to also be knowledgeable about the treatment of addiction, including the role of replacement agonists such as methadone and buprenorphine. For some physicians, there may be advantages to becoming eligible to treat addiction using office-based buprenorphine treatment.

Information provided by the patient is a necessary but insufficient part of the evaluation process. Reports of previous evaluations and treatments should be confirmed by obtaining records from other providers, if possible. Patients have occasionally provided fraudulent records, so if there is any reason to question the truthfulness of a patient's report, it is best to request records directly from the other providers [54-55].

If possible, the patient evaluation should include information from family members and/or significant others [22-23,49-50]. Where available, the state prescription drug monitoring program (PDMP) should be consulted

Model Policy for the Use of Opioid Analgesics in the Treatment of Chronic Pain

to determine whether the patient is receiving prescriptions from any other physicians, and the results obtained from the PDMP should be documented in the patient record [34].

In dealing with a patient who is taking opioids prescribed by another physician—particularly a patient on high doses—the evaluation and risk stratification assume even greater importance [21-23]. With all patients, the physician’s decision as to whether to prescribe opioid analgesics should reflect the totality of the information collected, as well as the physician’s own knowledge and comfort level in prescribing such medications and the resources for patient support that are available in the community [21-23].

Development of a Treatment Plan and Goals: The goals of pain treatment include reasonably attainable improvement in pain and function; improvement in pain-associated symptoms such as sleep disturbance, depression, and anxiety; and avoidance of unnecessary or excessive use of medications [4,8]. Effective means of achieving these goals vary widely, depending on the type and causes of the patient’s pain, other concurrent issues, and the preferences of the physician and the patient.

The treatment plan and goals should be established as early as possible in the treatment process and revisited regularly, so as to provide clear-cut, individualized objectives to guide the choice of therapies [38]. The treatment plan should contain information supporting the selection of therapies, both pharmacologic (including medications other than opioids) and nonpharmacologic. It also should specify the objectives that will be used to evaluate treatment progress, such as relief of pain and improved physical and psychosocial function [14,36,47].

The plan should document any further diagnostic evaluations, consultations or referrals, or additional therapies that have been considered [21-23,45].

Informed Consent and Treatment Agreement: The decision to initiate opioid therapy should be a shared decision between the physician and the patient. The physician should discuss the risks and benefits of the treatment plan (including any proposed use of opioid analgesics) with the patient, with persons designated by the patient, or with the patient’s surrogate or guardian if the patient is without medical decision-making capacity [32,35]. If opioids are prescribed, the patient (and possibly family members) should be counseled on safe ways to store and dispose of medications [3,37].

Use of a written informed consent and treatment agreement (sometimes referred to as a “treatment contract”) is recommended [21-23,35,38].

Informed consent documents typically address:

- The potential risks and anticipated benefits of chronic opioid therapy.
- Potential side effects (both short- and long-term) of the medication, such as constipation and cognitive impairment.
- The likelihood that tolerance to and physical dependence on the medication will develop.
- The risk of drug interactions and over-sedation.
- The risk of impaired motor skills (affecting driving and other tasks).
- The risk of opioid misuse, dependence, addiction, and overdose.
- The limited evidence as to the benefit of long-term opioid therapy.
- The physician’s prescribing policies and expectations, including the number and frequency of prescription refills, as well as the physician’s policy on early refills and replacement of lost or stolen medications.
- Specific reasons for which drug therapy may be changed or discontinued (including violation of the policies and agreements spelled out in the treatment agreement).

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Treatment agreements outline the joint responsibilities of physician and patient [35-37] and are indicated for opioid or other abusable medications. They typically discuss:

- The goals of treatment, in terms of pain management, restoration of function, and safety.
- The patient's responsibility for safe medication use (e.g., by not using more medication than prescribed or using the opioid in combination with alcohol or other substances; storing medications in a secure location; and safe disposal of any unused medication).
- The patient's responsibility to obtain his or her prescribed opioids from only one physician or practice.
- The patient's agreement to periodic drug testing (as of blood, urine, hair, or saliva).
- The physician's responsibility to be available or to have a covering physician available to care for unforeseen problems and to prescribe scheduled refills.

Informed consent documents and treatment agreements can be part of one document for the sake of convenience.

Initiating an Opioid Trial: Generally, safer alternative treatments should be considered before initiating opioid therapy for chronic, non-malignant pain. Opioid therapy should be presented to the patient as a therapeutic trial or test for a defined period of time (usually no more than 90 days) and with specified evaluation points. The physician should explain that progress will be carefully monitored for both benefit and harm in terms of the effects of opioids on the patient's level of pain, function, and quality of life, as well as to identify any adverse events or risks to safety [51]. When initiating opioid therapy, the lowest dose possible should be given to an opioid naïve patient and titrate to affect. It is generally suggested to begin opioid therapy with a short acting opioid and rotate to a long acting/extended release if indicated.

A decision to continue opioid therapy beyond the trial period should reflect a careful evaluation of benefits versus adverse events [29]and/or potential risks.

Ongoing Monitoring and Adapting the Treatment Plan: The physician should regularly review the patient's progress, including any new information about the etiology of the pain or the patient's overall health and level of function [35,49-50]. When possible, collateral information about the patient's response to opioid therapy should be obtained from family members or other close contacts, and the state PDMP. The patient should be seen more frequently while the treatment plan is being initiated and the opioid dose adjusted [44-51]. As the patient is stabilized in the treatment regimen, follow-up visits may be scheduled less frequently. (However, if the patient is seen less than monthly and an opioid is prescribed, arrangements must be made for the patient to obtain a refill or new prescription when needed.)

At each visit, the results of chronic opioid therapy should be monitored by assessing what have been called the "5As" of chronic pain management; these involve a determination of whether the patient is experiencing a reduction in pain (Analgesia), has demonstrated an improvement in level of function (Activity), whether there are significant Adverse effects, whether there is evidence of Aberrant substance-related behaviors, and mood of the individual (Affect) [38,52]. Validated brief assessment tools that measure pain and function, such as the three-question "Pain, Enjoyment and General Activity" (PEG) scale [47] or other validated assessment tools, may be helpful and time effective.

Continuation, modification or termination of opioid therapy for pain should be contingent on the physician's evaluation of (1) evidence of the patient's progress toward treatment objectives and (2) the absence of substantial

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risks or adverse events, such as overdose or diversion [21-23,45]. A satisfactory response to treatment would be indicated by a reduced level of pain, increased level of function, and/or improved quality of life [29]. Information from family members or other caregivers should be considered in evaluating the patient's response to treatment [14,35-36]. Use of measurement tools to assess the patient's level of pain, function, and quality of life (such as a visual analog or numerical scale) can be helpful in documenting therapeutic outcomes [14,49].

Periodic Drug Testing: Periodic drug testing may be useful in monitoring adherence to the treatment plan, as well as in detecting the use of non-prescribed drugs [53-54]. Drug testing is an important monitoring tool because self-reports of medication use is not always reliable and behavioral observations may detect some problems but not others [55-59]. Patients being treated for addiction should be tested as frequently as necessary to ensure therapeutic adherence, but for patients being treated for pain, clinical judgment trumps recommendations for frequency of testing.

Urine may be the preferred biologic specimen for testing because of its ease of collection and storage and the cost-effectiveness of such testing [53]. When such testing is conducted as part of pain treatment, forensic standards are generally not necessary and not in place, so collection is not observed and chain-of-custody protocols are not followed. Initial testing may be done using class-specific immunoassay drug panels (point-of-care or laboratory-based), which typically do not identify particular drugs within a class unless the immunoassay is specific for that drug. If necessary, this can be followed up with a more specific technique, such as gas chromatography/mass spectrometry (GC/MS) or other chromatographic tests to confirm the presence or absence of a specific drug or its metabolites [53]. In drug testing in a pain practice, it is important to identify the specific drug not just the class of the drug.

Physicians need to be aware of the limitations of available tests (such as their limited sensitivity for many opioids) and take care to order tests appropriately [54]. For example, when a drug test is ordered, it is important to specify that it include the opioid being prescribed [53]. Because of the complexities involved in interpreting drug test results, it is advisable to confirm significant or unexpected results with the laboratory toxicologist or a clinical pathologist [59-60].

While immunoassay, point of care (POC) testing has its utility in the making of temporary and “on the spot” changes in clinical management, its limitations with regard to accuracy have recently been the subject of study. These limitations are such that the use of point of care testing for the making of more long term and permanent changes in management of people with the disease of addiction and other clinical situations may not be justified until the results of confirmatory testing with more accurate methods such as LC-MS/MS are obtained. A recent study on LC-MS/MS results following immunoassay POC testing in addiction treatment settings and found very high rates of “false negatives and positives” [53,81].

Test results that suggest opioid misuse should be discussed with the patient. It is helpful to approach such a discussion in a positive, supportive fashion, so as to strengthen the physician-patient relationship and encourage healthy behaviors (as well as behavioral change where that is needed). Both the test results and subsequent discussion with the patient should be documented in the medical record [53].

Periodic pill counting is also a useful strategy to confirm medication adherence and to minimize diversion (e.g., selling, sharing or giving away medications). As noted earlier and where available, consulting the state's PDMP before prescribing opioids for pain and during ongoing use is highly recommended. A PDMP can be useful in monitoring compliance with the treatment agreement as well as identifying individuals obtaining controlled substances from multiple prescribers [21-23,55,62].

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If the patient's progress is unsatisfactory, the physician must decide whether to revise or augment the treatment plan, whether other treatment modalities should be added to or substituted for the opioid therapy, or whether a different approach—possibly involving referral to a pain specialist or other health professional—should be employed [35-37,62-63].

Evidence of misuse of prescribed opioids demands prompt intervention by the physician [19,21-23,32,35]. Patient behaviors that require such intervention typically involve recurrent early requests for refills, multiple reports of lost or stolen prescriptions, obtaining controlled medications from multiple sources without the physician's knowledge, intoxication or impairment (either observed or reported), and pressuring or threatening behaviors [23]. The presence of illicit or unprescribed drugs, (drugs not prescribed by a physician) in drug tests similarly requires action on the part of the prescriber. Some aberrant behaviors are more closely associated with medication misuse than others [62-63]. Most worrisome is a pattern of behavior that suggests recurring misuse, such as unsanctioned dose escalations, deteriorating function, and failure to comply with the treatment plan [64].

Documented drug diversion or prescription forgery, obvious impairment, and abusive or assaultive behaviors require a firm, immediate response [22-23,38,46]. Indeed, failure to respond can place the patient and others at significant risk of adverse consequences, including accidental overdose, suicide attempts, arrests and incarceration, or even death [23,65-67]. For this reason, physicians who prescribe chronic opioid therapy should be knowledgeable in the diagnosis of substance use disorders and able to distinguish such disorders from physical dependence—which is expected in chronic therapy with opioids and many sedatives.

Consultation and Referral: The treating physician should seek a consultation with, or refer the patient to, a pain, psychiatry, addiction or mental health specialist as needed [37-38]. For example, a patient who has a history of substance use disorder or a co-occurring mental health disorder may require specialized assessment and treatment, if available [31,66].

Physicians who prescribe chronic opioid therapy should be familiar with treatment options for opioid addiction (including those available in licensed opioid treatment programs [OTPs]) and those offered by an appropriately credentialed and experienced physician through office-based opioid treatment [OBOT]), so as to make appropriate referrals when needed [23,31,37,39].

Discontinuing Opioid Therapy: Throughout the course of opioid therapy, the physician and patient should regularly weigh the potential benefits and risks of continued treatment and determine whether such treatment remains appropriate [46].

If opioid therapy is continued, the treatment plan may need to be adjusted to reflect the patient's changing physical status and needs, as well as to support safe and appropriate medication use [22-23].

Reasons for discontinuing opioid therapy include resolution of the underlying painful condition, emergence of intolerable side effects, inadequate analgesic effect, failure to improve the patient's quality of life despite reasonable titration, deteriorating function, or significant aberrant medication use [38, 45].

If opioid therapy is discontinued, the patient who has become physically dependent should be provided with a safely structured tapering regimen. Withdrawal can be managed either by the prescribing physician or by referring the patient to an addiction specialist [63]. The termination of opioid therapy should not mark the end of

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treatment, which should continue with other modalities, either through direct care or referral to other health care specialists, as appropriate [21-23].

Additionally, providers should not continue opioid treatment unless the patient has received a benefit, including demonstrated functional improvement.

Medical Records: Every physician who treats patients for chronic pain must maintain accurate and complete medical records. Information that should appear in the medical record includes the following [22-23,38,43-44]:

- Copies of the signed informed consent and treatment agreement.
- The patient's medical history.
- Results of the physical examination and all laboratory tests.
- Results of the risk assessment, including results of any screening instruments used.
- A description of the treatments provided, including all medications prescribed or administered (including the date, type, dose and quantity).
- Instructions to the patient, including discussions of risks and benefits with the patient and any significant others.
- Results of ongoing monitoring of patient progress (or lack of progress) in terms of pain management and functional improvement.
- Notes on evaluations by and consultations with specialists.
- Any other information used to support the initiation, continuation, revision, or termination of treatment and the steps taken in response to any aberrant medication use behaviors [21-23,30,38,45,68]. These may include actual copies of, or references to, medical records of past hospitalizations or treatments by other providers.
- Authorization for release of information to other treatment providers.

The medical record must include all prescription orders for opioid analgesics and other controlled substances, whether written or telephoned. In addition, written instructions for the use of all medications should be given to the patient and documented in the record [25]. The name, telephone number, and address of the patient's pharmacy also should be recorded to facilitate contact as needed [23]. Records should be up-to-date and maintained in an accessible manner so as to be readily available for review [25].

Good records demonstrate that a service was provided to the patient and establish that the service provided was medically necessary. Even if the outcome is less than optimal, thorough records protect the physician as well as the patient [23,38,45,68].

Compliance with Controlled Substance Laws and Regulations: To prescribe, dispense or administer controlled substances, the physician must be registered with the DEA, licensed by the state in which he or she practices, and comply with applicable federal and state regulations [25].

Physicians are referred to the *Physicians' Manual of the U.S. Drug Enforcement Administration* (and any relevant documents issued by the state medical Board) for specific rules and regulations governing the use of controlled substances. Additional resources are available on the DEA's website (at www.deadiversion.usdoj.gov), as well as from (*any relevant documents issued by the state medical board*).

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SECTION III: DEFINITIONS

For the purposes of this Model Policy, the following terms are defined as shown.

Aberrant Substance Use Behaviors: Behaviors that are outside the boundaries of the agreed-upon treatment plan may constitute aberrant substance use behaviors [22-23]. For example, obtaining prescriptions for the same or similar drugs from more than one physician or other health care provider without the treating physician's knowledge is aberrant behavior, as is use of illicit drugs.

Abuse: Abuse has been described as a maladaptive pattern of drug use that results in harm or places the individual at risk of harm [29]. Abuse of a prescription medication involves its use in a manner that deviates from approved medical, legal, and social standards, generally to achieve a euphoric state ("high") or to sustain opioid dependence that is opioid addiction or that is other than the purpose for which the medication was prescribed [28].

Addiction: A longstanding definition of addiction is that it is "a primary, chronic, neurobiologic disease, whose development and manifestations are influenced by genetic, psychosocial, and environmental factors" [28]. Addiction often is said to be characterized by behaviors that include impaired control over drug use, craving, compulsive use, and continued use despite harm [28].

A newer definition, adopted by the American Society of Addiction Medicine in 2011, describes addiction as "a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors. Addiction is characterized by inability to consistently abstain, impairment in behavioral control, craving, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death" [40].

(As discussed below, physical dependence and tolerance are expected physiological consequences of extended opioid therapy for pain and in this context do not indicate the presence of addiction.)

Controlled Substance: A controlled substance is a drug that is subject to special requirements under the federal Controlled Substances Act of 1970 (CSA) [25], which is designed to ensure both the availability and control of regulated substances. Under the CSA, availability of regulated drugs for medical purposes is accomplished through a system that establishes quotas for drug production and a distribution system that closely monitors the importation, manufacture, distribution, prescribing, dispensing, administering, and possession of controlled drugs. Civil and criminal sanctions for serious violations of the statute are part of the government's control apparatus. The Code of Federal Regulations (Title 21, Chapter 2) implements the CSA.

The CSA provides that responsibility for scheduling controlled substances is shared between the Food and Drug Administration (FDA) and the DEA. In granting regulatory authority to these agencies, the Congress noted that both public health and public safety needs are important and that neither takes primacy over the other. To accomplish this, the Congress provided guidance in the form of factors that must be considered by the FDA and DEA when assessing public health and safety issues related to a new drug or one that is being considered for rescheduling or removal from control.

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The CSA does *not* limit the amount of drug prescribed, the duration for which it is prescribed, or the period for which a prescription is valid (although some states do impose such limits).

Most potent opioid analgesics are classified in *Schedules II or III* under the CSA, indicating that they have a significant potential for abuse and a currently accepted medical use in treatment in the U.S. (with certain restrictions), and that abuse of the drug may lead to severe psychological or physical dependence. Although the scheduling system provides a rough guide to abuse potential, it should be recognized that all controlled medications have some potential for abuse.

Dependence: Physical dependence is a state of biologic adaptation that is evidenced by a class-specific withdrawal syndrome when the drug is abruptly discontinued or the dose rapidly reduced, and/or by the administration of an antagonist [28]. It is important to distinguish addiction from the type of physical dependence that can and does occur within the context of good medical care, as when a patient on long-term opioid analgesics for pain becomes physically dependent on the analgesic. This distinction is reflected in the two primary diagnostic classification systems used by health care professionals: the *International Classification of Mental and Behavioural Disorders, 10th Edition* (ICD-10) of the World Health Organization [70], and the *Diagnostic and Statistical Manual (DSM)* of the American Psychiatric Association [71]. In the DSM-IV-TR, a diagnosis of “substance dependence” meant addiction. In the upcoming DSM V, the term *dependence* is reestablished in its original meaning of physiological dependence. When symptoms are sufficient to meet criteria for substance misuse or addiction, the term “substance use disorder” is used, accompanied by severity ratings [69].

It may be important to clarify this distinction during the informed consent process, so that the patient (and family) understands that physical dependence and tolerance are likely to occur if opioids are taken regularly over a period of time, but that the risk of addiction is relatively low, although estimates do vary. Discontinuing chronic opioid therapy may be difficult, even in the absence of addiction. According to the World Health Organization, “The development of tolerance and physical dependence denote normal physiologic adaptations of the body to the presence of an opioid” [70]. Consequently, physical dependence alone is neither necessary nor sufficient to diagnose addiction [71,72].

Diversion: Drug diversion is defined as the intentional transfer of a controlled substance from authorized to unauthorized possession or channels of distribution [73-74]. The federal Controlled Substances Act (21 U.S.C. §§ 801 et seq.) establishes a closed system of distribution for drugs that are classified as controlled substances. Records must be kept from the time a drug is manufactured to the time it is dispensed. Health care professionals who are authorized to prescribe, dispense, and otherwise control access to such drugs are required to register with the DEA [25,75].

Pharmaceuticals that make their way outside this closed distribution system are said to have been “diverted” [75], and the individuals responsible for the diversion (including patients) are in violation of federal law.

Experience shows that the degree to which a prescribed medication is misused depends in large part on how easily it is redirected (diverted) from the legitimate distribution system [17,19,74].

Misuse: The term *misuse* (also called *nonmedical use*) encompasses all uses of a prescription medication other than those that are directed by a physician and used by a patient within the law and the requirements of good medical practice [28].

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Opioid: An opioid is any compound that binds to an opioid receptor in the central nervous system (CNS) [4]. The class includes both naturally occurring and synthetic or semi-synthetic opioid drugs or medications, as well as endogenous opioid peptides [35].

Most physicians use the terms “opiate” and “opioid” interchangeably, but toxicologists (who perform and interpret drug tests) make a clear distinction between them. “Opioid” is the broader term because it includes the entire class of agents that act at opioid receptors in the CNS, whereas “opiates” refers to natural compounds derived from the opium plant but not semisynthetic opioid derivatives of opiates or completely synthetic agents. Thus, drug tests that are “positive for opiates” have detected one of these compounds or a metabolite of heroin, 6-monoacetyl morphine (MAM). Drug tests that are “negative for opiates” have found no detectable levels of opiates in the sample, even though other opioids that were not tested for—including the most common currently used and misused prescription opioids—may be present in the sample that was analyzed [53,59-260].

Pain: An unpleasant and potentially disabling sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage.

Acute pain is the normal, predictable physiological response to a noxious chemical, thermal or mechanical stimulus and typically is associated with invasive procedures, trauma and disease. Acute pain generally is time-limited, lasting six weeks or less [4].

Chronic pain is a state in which pain persists beyond the usual course of an acute disease or healing of an injury (e.g., more than three months). It may or may not be associated with an acute or chronic pathological process that causes continuous or intermittent pain over a period of months or years.

Chronic non-cancer related pain is chronic pain that is not associated with active cancer and does not occur at the end of life [4,76].

Opioid-induced hyperalgesia may develop as a result of long-term opioid use in the treatment of chronic pain. *Primary hyperalgesia* is pain sensitivity that occurs directly in the damaged tissues, while *secondary hyperalgesia* occurs in surrounding undamaged tissues. Human and animal studies have demonstrated that primary or secondary hyperalgesia can develop in response to both chronic and acute exposure to opioids. Hyperalgesia can be severe enough to warrant discontinuation of opioid treatment [77].

Prescription Drug Monitoring Program: Almost all states have enacted laws that establish prescription drug monitoring programs (PDMPs) to facilitate the collection, analysis, and reporting of information on the prescribing and dispensing of controlled substances. Most such programs employ electronic data transfer systems, under which prescription information is transmitted from the dispensing pharmacy to a state agency, which collates and analyzes the information [3,24].

After analyzing the efficacy of PDMPs, the GAO concluded that such programs have the potential to help law enforcement and regulatory agencies rapidly identify and investigate activities that may involve illegal prescribing, dispensing or consumption of controlled substances. Where real-time data are available, PDMPs also can help to prevent prescription drug misuse and diversion by allowing physicians to determine whether a patient is receiving prescriptions for controlled substances from other physicians, as well as whether the patient has filled or refilled an order for an opioid the physician has prescribed [24,78-79].

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Tolerance: Tolerance is a state of physiologic adaptation in which exposure to a drug induces changes that result in diminution of one or more of the drug's effects over time. Tolerance is common in opioid treatment, has been demonstrated following a single dose of opioids, and is not the same as addiction [28].

Trial Period: A period of time during which the efficacy of an opioid for treatment of an individual's pain is tested to determine whether the treatment goals can be met in terms of reduction of pain and restoration of function. If the goals are not met, the opioid dose may be adjusted, a different opioid substituted, an adjunctive therapy added, or use of opioids discontinued and an alternative approach to pain management selected [36].

Universal Precautions: The concept of *universal precautions* is borrowed from an infectious disease model of the same name to underscore its comparability to practices in other areas of medicine. The concept recognizes that all patients have a level of risk that can only be estimated initially, with the estimate modified over time as more information is obtained. The 10 essential steps of universal precautions can be summarized as follows [38]:

1. Make a diagnosis with an appropriate differential.
2. Conduct a patient assessment, including risk for substance use disorders.
3. Discuss the proposed treatment plan with the patient and obtain informed consent.
4. Have a written treatment agreement that sets forth the expectations and obligations of both the patient and the treating physician.
5. Initiate an appropriate trial of opioid therapy, with or without adjunctive medications.
6. Perform regular assessments of pain and function.
7. Reassess the patient's pain score and level of function.
8. Regularly evaluate the patient in terms of the "5 A's": Analgesia, Activity, Adverse effects, Aberrant behaviors, and Affect.
9. Periodically review the pain diagnosis and any comorbid conditions, including substance use disorders, and adjust the treatment regimen accordingly.
10. Keep careful and complete records of the initial evaluation and each follow-up visit.

By acknowledging the fact that there are no signs that invariably point to substance use disorder [41], the universal precautions encourage a consistent and respectful approach to the assessment and management of pain patients, thereby minimizing stigma, improving patient care, and reducing overall risk [38].

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Attn: State of Wisconsin Medical Examining Board:

The current revision of Chapter N6 specifies a “provider” as: “a physician, podiatrist, dentist, optometrist or advanced practice nurse provider”. With the addition of “advanced practice nurse provider” I asked the Wisconsin Board of Nursing: 1. How does this effect physician assistant (PA) delegation to an RN, LPN or unlicensed assistive personnel (UAP) – i.e. medical assistants? 2. Did you intend with the update that the current N6 would read that PA’s cannot delegate to RNs, LPNs, UAPs? The response that I received back from the WI Board of Nursing was (italicized below):

The Board intended to not include physician assistants in the definition of provider in order to not be in conflict with the Medical Examining Board rule. Med 8.07 Practice.(1) SCOPE AND LIMITATIONS. In providing medical care, the entire practice of any physician assistant shall be under the supervision of one or more licensed physicians or physicians exempt from licensure requirements pursuant to s. 448.03 (2) (b), Stats. The scope of practice is limited to providing medical care as specified in sub. (2). A physician assistant’s practice may not exceed his or her educational training or experience and may not exceed the scope of practice of the physician providing supervision. A medical care task assigned by the supervising physician to a physician assistant may not be delegated by the physician assistant to another person. **(emphasis added)**

The Board of Nursing then directed me to the WI Medical Examining Board, where I received the following response (italicized below from DSPS):

Credential holders are responsible for their own professional practice and for compliance with the law. The Department is unable to answer questions regarding: • Potential or ongoing litigation • Billing issues • Business advice • Employer/employee disputes • Legal opinions • Scope of practice • Questions involving professional judgment or discretion The Department’s website provides a wide range of materials to assist credential holders, as well as the public, in answering questions about the practice of the various professions. These materials include the relevant Wisconsin Statutes, Wisconsin Administrative Code, formal disciplinary orders, meeting minutes, and frequently asked practice questions (Position Statements) developed for many of the professions. The address for the Department’s website is <http://dsps.wi.gov>. To find the resources available on this website, please select the Board you are inquiring about from this list, then look for the Statutes and Administrative Codes and/or Position Statements: Board Council Listing If after reviewing the website and materials you still have questions, you may submit an item for consideration at a Board or Council meeting by using the following link and filling in the form: Public Board Agenda Item

Upon review of the above information, it is not clearly stated within the statutes, administrative codes, or position statements if/what a PA can delegate to RNs/LPNs/unlicensed assistive personnel (UAP) – i.e. medical assistants. Judging by what is currently provided in Chapter N6 and Chapter Med 8, the delegation from PA to RN/LPN/UAP is questionable. For some of us, this would be a great change in practice – so I have continued to seek **clarification**. I have attached copies of both Chapter N6 and Chapter Med 8 highlighting the recent changes or pieces in question. Can you please provide **clarification** on this matter?

Thank you for your time and attention, Morgen Johnson, MSN, RN

Chapter N 6

STANDARDS OF PRACTICE FOR REGISTERED NURSES AND LICENSED PRACTICAL NURSES

N 6.01 Authority and intent.

N 6.02 Definitions.

N 6.03 Standards of practice for registered nurses.

N 6.04 Standards of practice for licensed practical nurses.

N 6.05 Violations of standards.

Note: Chapter N 10 as it existed on September 30, 1985 was renumbered Chapter N 6, effective 10–1–85.

N 6.01 Authority and intent. (1) This chapter is adopted pursuant to authority of ss. 15.08 (5) (b), 227.11 and 441.001 (3) and (4), Stats., and interprets the statutory definitions of professional and practical nursing.

(2) The intent of the board of nursing in adopting this chapter is to specify minimum practice standards for which R.N.s and L.P.N.s are responsible, and to clarify the scope of practice for R.N.s and L.P.N.s.

History: Cr. Register, May, 1983, No. 329, eff. 6–1–83; correction in (1) made under s. 13.93 (2m) (b) 7., Stats., Register, May, 1990, No. 413; correction in (1) made under s. 13.93 (2m) (b) 7., Stats., Register June 2006 No. 606.

N 6.02 Definitions. As used in this chapter,

(1) “Advanced practice nurse prescriber” means a registered nurse who holds an advance practice nurse prescriber certificate under s. 441.16, Stats.

(1m) “Basic nursing care” means care that can be performed following a defined nursing procedure with minimal modification in which the responses of the patient to the nursing care are predictable.

(2) “Basic patient situation” as determined by an R.N., physician, podiatrist, dentist or optometrist means the following 3 conditions prevail at the same time in a given situation:

- (a) The patient’s clinical condition is predictable;
- (b) Medical or nursing orders are not changing frequently and do not contain complex modifications; and,
- (c) The patient’s clinical condition requires only basic nursing care.

(3) “Complex patient situation” as determined by an R.N., physician, podiatrist, dentist or optometrist means any one or more of the following conditions exist in a given situation:

- (a) The patient’s clinical condition is not predictable;
- (b) Medical or nursing orders are likely to involve frequent changes or complex modifications; or,
- (c) The patient’s clinical condition indicates care that is likely to require modification of nursing procedures in which the responses of the patient to the nursing care are not predictable.

(5) “Delegated act” means acts delegated to a registered nurse or licensed practical nurse.

(6) “Direct supervision” means immediate availability to continually coordinate, direct and inspect at first hand the practice of another.

(7) “General supervision” means regularly to coordinate, direct and inspect the practice of another.

(8) “Nursing diagnosis” means a judgment made by an R.N. following a nursing assessment of a patient’s actual or potential health needs for the purpose of establishing a nursing care plan.

(9) “Patient” means a person receiving nursing care by an R.N. or L.P.N. performing nursing services for compensation.

(10) “Protocol” means a precise and detailed written plan for a regimen of therapy.

(10m) “Provider” means a physician, podiatrist, dentist, optometrist or advanced practice nurse provider.

(11) “R.N.” means a registered nurse licensed under ch. 441, Stats., or a nurse who has a privilege to practice in Wisconsin under s. 441.50, Stats.

(12) “L.P.N.” means a licensed practical nurse licensed under ch. 441, Stats., or a nurse who has a privilege to practice in Wisconsin under s. 441.50, Stats.

History: Cr. Register, May, 1983, No. 329, eff. 6–1–83; reprinted to correct error in (7), Register, July, 1983, No. 331; am. (5) and (12), Register, May, 1990, No. 413, eff. 6–1–90; CR 00–167: am. (2) (intro.), (3) (intro.) and (4), Register August 2001 No. 548, eff. 9–1–01; CR 15–099: renum. (1) to (1m), cr. (1) r. (4), r. and recr. (5), cr. (10m), am. (11), (12) Register August 2016 No. 728, eff. 9–1–16; correction in (1) made under s. 35.17, Stats., Register August 2016 No. 728, eff. 9–1–16.

N 6.03 Standards of practice for registered nurses.

(1) GENERAL NURSING PROCEDURES. An R.N. shall utilize the nursing process in the execution of general nursing procedures in the maintenance of health, prevention of illness or care of the ill. The nursing process consists of the steps of assessment, planning, intervention and evaluation. This standard is met through performance of each of the following steps of the nursing process:

(a) *Assessment.* Assessment is the systematic and continual collection and analysis of data about the health status of a patient culminating in the formulation of a nursing diagnosis.

(b) *Planning.* Planning is developing a nursing plan of care for a patient which includes goals and priorities derived from the nursing diagnosis.

(c) *Intervention.* Intervention is the nursing action to implement the plan of care by directly administering care or by directing and supervising nursing acts delegated to L.P.N.’s or less skilled assistants.

(d) *Evaluation.* Evaluation is the determination of a patient’s progress or lack of progress toward goal achievement which may lead to modification of the nursing diagnosis.

(2) PERFORMANCE OF DELEGATED ACTS. In the performance of delegated acts an R.N. shall do all of the following:

(a) Accept only those delegated acts for which there are protocols or written or verbal orders.

(b) Accept only those delegated acts for which the R.N. is competent to perform based on his or her nursing education, training or experience.

(c) Consult with a provider in cases where the R.N. knows or should know a delegated act may harm a patient.

(d) Perform delegated acts under the general supervision or direction of provider.

(3) SUPERVISION AND DIRECTION OF DELEGATED ACTS. In the supervision and direction of delegated acts an R.N. shall do all of the following:

(a) Delegate tasks commensurate with educational preparation and demonstrated abilities of the person supervised.

(b) Provide direction and assistance to those supervised.

(c) Observe and monitor the activities of those supervised.

(d) Evaluate the effectiveness of acts performed under supervision.

History: Cr. Register, May, 1983, No. 329, eff. 6-1-83; am. (1) (c) and (2) (intro.), Register, May, 1990, No. 413, eff. 6-1-90; CR 00-167: am. (2) (c) and (d), Register August 2001 No. 548, eff. 9-1-01; CR 15-099: am. (2), (3) (intro.), (a) to (c) Register August 2016 No. 728, eff. 9-1-16.

N 6.04 Standards of practice for licensed practical nurses. (1) PERFORMANCE OF ACTS IN BASIC PATIENT SITUATIONS. In the performance of acts in basic patient situations, the L.P.N. shall, under the general supervision of an R.N. or the direction of a provider:

- (a) Accept only patient care assignments which the L.P.N. is competent to perform.
- (b) Provide basic nursing care.
- (c) Record nursing care given and report to the appropriate person changes in the condition of a patient.
- (d) Consult with a provider in cases where an L.P.N. knows or should know a delegated act may harm a patient.
- (e) Perform the following other acts when applicable:
 1. Assist with the collection of data.
 2. Assist with the development and revision of a nursing care plan.
 3. Reinforce the teaching provided by an R.N. provider and provide basic health care instruction.
 4. Participate with other health team members in meeting basic patient needs.

(2) PERFORMANCE OF ACTS IN COMPLEX PATIENT SITUATIONS. In the performance of acts in complex patient situations the L.P.N. shall do all of the following:

- (a) Meet standards under sub. (1) under the general supervision of an R.N., physician, podiatrist, dentist or optometrist.

(b) Perform delegated acts beyond basic nursing care under the direct supervision of an R.N. or provider. An L.P.N. shall, upon request of the board, provide documentation of his or her nursing education, training or experience which prepares the L.P.N. to competently perform these assignments.

(3) ASSUMPTION OF CHARGE NURSE POSITION IN NURSING HOMES. In assuming the position of charge nurse in a nursing home as defined in s. 50.04 (2) (b), Stats., an L.P.N. shall do all of the following:

- (a) Follow written protocols and procedures developed and approved by an R.N.
- (b) Manage and direct the nursing care and other activities of L.P.N.s and nursing support personnel under the general supervision of an R.N.
- (c) Accept the charge nurse position only if prepared for the responsibilities of charge nurse based upon education, training and experience beyond the practical nurse curriculum. The L.P.N. shall, upon request of the board, provide documentation of the nursing education, training or experience which prepared the L.P.N. to competently assume the position of charge nurse.

History: Cr. Register, May, 1983, No. 329, eff. 6-1-83; CR 00-167: am. (1) (intro.), (d), (e) 3., (2) (a) and (b), Register August 2001 No. 548, eff. 9-1-01; CR 15-099: am. (1) (intro.), (a) to (d), (e) (intro.), 1. to 3., am. (2) (intro.), (b), (3) (intro.), (a), (b), r. and recr. (3) Register August 2016 No. 728.

N 6.05 Violations of standards. A violation of the standards of practice constitutes unprofessional conduct or misconduct and may result in the board limiting, suspending, revoking or denying renewal of the license or in the board reprimanding an R.N. or L.P.N.

History: Cr. Register, May, 1983, No. 329, eff. 6-1-83; am. Register, May, 1990, No. 413, eff. 6-1-90.

Chapter Med 8

PHYSICIAN ASSISTANTS

<p>Med 8.01 Authority and purpose. Med 8.02 Definitions. Med 8.03 Council. Med 8.04 Educational program approval. Med 8.05 Panel review of applications; examinations required. Med 8.053 Examination review by applicant.</p>	<p>Med 8.056 Board review of examination error claim. Med 8.06 Temporary license. Med 8.07 Practice. Med 8.09 Employee status. Med 8.10 Physician to physician assistant ratio.</p>
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Note: Chapter Med 8 as it existed on October 31, 1976 was repealed and a new chapter Med 8 was created effective November 1, 1976. Sections Med 8.03 to 8.10 as they existed on July 31, 1984 were repealed and recreated effective August 1, 1984.

Med 8.01 Authority and purpose. (1) The rules in this chapter are adopted by the medical examining board pursuant to authority in ss. 15.08 (5), 227.11, 448.04 (1) (f) and 448.40, Stats., and govern the licensure and regulation of physician assistants.

(2) Physician assistants provide health care services as part of physician-led teams, the objectives of which include safe, efficient, and economical health care. The realities of the modern practice of medicine and surgery require supervising physicians and physician assistants to use discretion in delivering health care services, typically at the level of general supervision. The constant physical presence of a supervising physician is often unnecessary. The supervising physician and the physician assistant are jointly responsible for employing more intensive supervision when circumstances require direct observation or hands-on assistance from the supervising physician.

History: Cr. Register, October, 1976, No. 250, eff. 11-1-76; am. Register, April, 1981, No. 304, eff. 5-1-81; am. Register, July, 1984, No. 343, eff. 8-1-84; correction made under s. 13.93 (2m) (b) 7., Stats., Register, May, 1989, No. 401; am. Register, October, 1996, No. 490, eff. 11-1-96; am. Register, December, 1999, No. 528, eff. 1-1-00; CR 12-005; renum. to (1), cr. (2) Register February 2014 No. 698, eff. 3-1-14.

Med 8.02 Definitions. (1) “Board” means the medical examining board.

(2) “Council” means the council on physician assistants.

(3m) “DEA” means the United States drug enforcement administration.

(4) “Educational program” means a program for educating and preparing physician assistants which is approved by the board.

(5) “Individual” means a natural person, and does not include the terms firm, corporation, association, partnership, institution, public body, joint stock association, or any other group of individuals.

(5m) “License” means documentary evidence issued by the board to applicants for licensure as a physician assistant who meet all of the requirements of the board.

(6) “Supervision” means to coordinate, direct, and inspect the accomplishments of another, or to oversee with powers of direction and decision the implementation of one’s own or another’s intentions.

History: Cr. Register, October, 1976, No. 250, eff. 11-1-76; am. (6) and (7) (b) to (e), Register, June, 1980, No. 294, eff. 7-1-80; r. (7), Register, July, 1984, No. 343, eff. 8-1-84; am. (2), (3) and (4) and cr. (3m), Register, October, 1996, No. 490, eff. 11-1-96; renum. (3) to be (5m) and am., am. (6), Register, December, 1999, No. 528, eff. 1-1-00.

Med 8.03 Council. As specified in s. 15.407 (2), Stats., the council shall advise the board on the formulation of rules on the education, examination, licensure and practice of a physician assistant.

History: Cr. Register, July, 1984, No. 343, eff. 8-1-84; am. Register, October, 1996, No. 490, eff. 11-1-96; am. Register, December, 1999, No. 528, eff. 1-1-00; correction made under s. 13.92 (4) (b) 7., Stats., Register August 2009 No. 644.

Med 8.04 Educational program approval. The board shall approve only educational programs accredited and approved by the committee on allied health education and accreditation of the American medical association, the commission for accreditation of allied health education programs, or its successor agency.

History: Cr. Register, July, 1984, No. 343, eff. 8-1-84; am. Register, October, 1994, No. 466, eff. 11-1-94; am. Register, December, 1999, No. 528, eff. 1-1-00.

Med 8.05 Panel review of applications; examinations required. The board may use a written examination prepared, administered and scored by the national commission on certification of physician assistants or its successor agency, or a written examination from other professional testing services as approved by the board.

(1) APPLICATION. An applicant for examination for licensure as a physician assistant shall submit to the board:

(a) An application on a form prescribed by the board.

Note: An application form may be obtained upon request to the Department of Safety and Professional Services office located at 1400 East Washington Avenue, P.O. Box 8935, Madison, Wisconsin 53708.

(b) After July 1, 1993, proof of successful completion of an educational program, as defined in ss. Med 8.02 (4) and 8.04.

(c) Proof of successful completion of the national certifying examination.

(cm) Proof that the applicant is currently certified by the national commission on certification of physician assistants or its successor agency.

(d) The fee specified in s. 440.05 (1), Stats.

(e) An unmounted photograph, approximately 8 by 12 cm., of the applicant taken no more than 60 days prior to the date of application which has on the reverse side a statement of a notary public that the photograph is a true likeness of the applicant.

(2) EXAMINATIONS, PANEL REVIEW OF APPLICATIONS. (a) All applicants shall complete the written examination under this section, and an open book examination on statutes and rules governing the practice of physician assistants in Wisconsin.

(b) An applicant may be required to complete an oral examination if the applicant:

1. Has a medical condition which in any way impairs or limits the applicant’s ability to practice as a physician assistant with reasonable skill and safety.

2. Uses chemical substances so as to impair in any way the applicant’s ability to practice as a physician assistant with reasonable skill and safety.

3. Has been disciplined or had certification denied by a licensing or regulatory authority in Wisconsin or another jurisdiction.

4. Has been convicted of a crime, the circumstances of which substantially relate to the practice of physician assistants.

5. Has not practiced as a physician assistant for a period of 3 years prior to application, unless the applicant has been graduated from an approved educational program for physician assistants within that period.

6. Has been found to have been negligent in the practice as a physician assistant or has been a party in a lawsuit in which it was

alleged that the applicant has been negligent in the practice of medicine.

7. Has been diagnosed with any condition that may create a risk of harm to a patient or the public.

8. Has within the past 2 years engaged in the illegal use of controlled substances.

9. Has been subject to adverse formal action during the course of physician assistant education, postgraduate training, hospital practice, or other physician assistant employment.

(c) An application filed under this chapter shall be reviewed by an application review panel of at least 2 council members designated by the chairperson of the board to determine whether an applicant is required to complete an oral examination or a personal appearance or both under par. (b). If the application review panel is not able to reach unanimous agreement on whether an applicant is eligible for licensure without completing an oral examination or a personal appearance or both, the application shall be referred to the board for a final determination.

(d) Where both written and oral examinations are required they shall be scored separately and the applicant shall achieve a passing grade on both examinations to qualify for a license.

(e) The board may require an applicant to complete a personal appearance for purposes of interview or review of credentials or both. An applicant's performance at a personal appearance is satisfactory if the applicant establishes to the board's satisfaction that the applicant has met requirements for licensure and is minimally competent to practice as a physician assistant.

(3) EXAMINATION FAILURE. An applicant who fails to receive a passing score on an examination may reapply by payment of the fee specified in sub. (1) (d). An applicant may reapply twice at not less than 4-month intervals. If an applicant fails the examination 3 times, he or she may not be admitted to an examination unless the applicant submits proof of having completed further professional training or education as the board may prescribe.

Note: There is no provision for waiver of examination nor reciprocity under rules in s. Med 8.05.

(4) LICENSURE; RENEWAL. At the time of licensure and each biennial registration of licensure thereafter, a physician assistant shall list with the board the name and address of the supervising physician and shall notify the board within 20 days of any change of a supervising physician.

History: Cr. Register, July, 1984, No. 343, eff. 8-1-84; am. (intro.), r. and recr. (2), Register, October, 1989, No. 406, eff. 11-1-89; am. (1) (b), cr. (1) (cm), Register, July, 1993, No. 451, eff. 8-1-93; am. (intro.), (1) (intro), (cm), (2) (b) 4., 5., 6., (c) and (4), Register, October, 1996, No. 490, eff. 11-1-96; am. (2) (a), (b) (intro.) and 3. to 5., r. and recr. (2) (b) 1. and 2., cr. (2) (b) 7. to 11., Register, February, 1997, No. 494, eff. 3-1-97; am. (intro.), (1) (intro.) and (cm), (2) (b) 5., (c), (d) and (4), r. (2) (b) 10. and 11., Register, December, 1999, No. 528, eff. 1-1-00; CR 12-005: am. (2) (b) 7., (c), cr. (2) (e) Register February 2014 No. 698, eff. 3-1-14.

Med 8.053 Examination review by applicant. (1) An applicant who fails the oral or statutes and rules examination may request a review of that examination by filing a written request and required fee with the board within 30 days of the date on which examination results were mailed.

(2) Examination reviews are by appointment only.

(3) An applicant may review the statutes and rules examination for not more than one hour.

(4) An applicant may review the oral examination for not more than 2 hours.

(5) The applicant may not be accompanied during the review by any person other than the proctor.

(6) At the beginning of the review, the applicant shall be provided with a copy of the questions, a copy of the applicant's answer sheet or oral tape and a copy of the master answer sheet.

(7) The applicant may review the examination in the presence of a proctor. The applicant shall be provided with a form on which to write comments, questions or claims of error regarding any items in the examination. Bound reference books shall be per-

mitted. Applicants shall not remove any notes from the area. Notes shall be retained by the proctor and made available to the applicant for use at a hearing, if desired. The proctor shall not defend the examination nor attempt to refute claims of error during the review.

(8) An applicant may not review the examination more than once.

History: Cr. Register, February, 1997, No. 494, eff. 3-1-97.

Med 8.056 Board review of examination error claim.

(1) An applicant claiming examination error shall file a written request for board review in the board office within 30 days of the date the examination was reviewed. The request shall include all of the following:

(a) The applicant's name and address.

(b) The type of license for which the applicant applied.

(c) A description of the mistakes the applicant believes were made in the examination content, procedures, or scoring, including the specific questions or procedures claimed to be in error.

(d) The facts which the applicant intends to prove, including reference text citations or other supporting evidence for the applicant's claim.

(2) The board shall review the claim, make a determination of the validity of the objections and notify the applicant in writing of the board's decision and any resulting grade changes.

(3) If the decision does not result in the applicant passing the examination, a notice of denial of license shall be issued. If the board issues a notice of denial following its review, the applicant may request a hearing under s. SPS 1.05.

Note: The board office is located at 1400 East Washington Avenue, P.O. Box 8935, Madison, Wisconsin 53708.

History: Cr. Register, February, 1997, No. 494, eff. 3-1-97; correction in (3) made under s. 13.92 (4) (b) 7., Stats., Register November 2011 No. 671.

Med 8.06 Temporary license. (1) An applicant for licensure may apply to the board for a temporary license to practice as a physician assistant if the applicant:

(a) Remits the fee specified in s. 440.05 (6), Stats.

(b) Is a graduate of an approved school and is scheduled to take the examination for physician assistants required by s. Med 8.05 (1) or has taken the examination and is awaiting the results; or

(c) Submits proof of successful completion of the examination required by s. Med 8.05 (1) and applies for a temporary license no later than 30 days prior to the date scheduled for the next oral examination.

(2) (a) Except as specified in par. (b), a temporary license expires on the date the board grants or denies an applicant permanent licensure. Permanent licensure to practice as a physician assistant is deemed denied by the board on the date the applicant is sent notice from the board that he or she has failed the examination required by s. Med 8.05 (1) (c).

(b) A temporary license expires on the first day of the next regularly scheduled oral examination for permanent licensure if the applicant is required to take, but failed to apply for, the examination.

(3) A temporary license may not be renewed.

(4) An applicant holding a temporary license may apply for one transfer of supervising physician and location during the term of the temporary license.

History: Cr. Register, July, 1984, No. 343, eff. 8-1-84; am. (1) (b) and (c), Register, October, 1989, No. 406, eff. 11-1-89; am. (2) (a), Register, January, 1994, No. 457, eff. 2-1-94; am. (1) (intro.) and (2) (a), Register, October, 1996, No. 490, eff. 11-1-96; am. (1) (intro.) and (b) to (3), cr. (4), Register, December, 1999, No. 528, eff. 1-1-00.

Med 8.07 Practice. (1) SCOPE AND LIMITATIONS. In providing medical care, the entire practice of any physician assistant shall be under the supervision of one or more licensed physicians or physicians exempt from licensure requirements pursuant to s. 448.03 (2) (b), Stats. The scope of practice is limited to providing

medical care as specified in sub. (2). A physician assistant's practice may not exceed his or her educational training or experience and may not exceed the scope of practice of the physician providing supervision. A medical care task assigned by the supervising physician to a physician assistant may not be delegated by the physician assistant to another person.

(2) MEDICAL CARE. Medical care a physician assistant may provide include:

(a) Attending initially a patient of any age in any setting to obtain a personal medical history, perform an appropriate physical examination, and record and present pertinent data concerning the patient.

(b) Performing, or assisting in performing, routine diagnostic studies as appropriate for a specific practice setting.

(c) Performing routine therapeutic procedures, including, but not limited to, injections, immunizations, and the suturing and care of wounds.

(d) Instructing and counseling a patient on physical and mental health, including diet, disease, treatment, and normal growth and development.

(e) Assisting the supervising physician in a hospital or facility, as defined in s. 50.01 (1m), Stats., by assisting in surgery, making patient rounds, recording patient progress notes, compiling and recording detailed narrative case summaries, and accurately writing or executing orders.

(f) Assisting in the delivery of medical care to a patient by reviewing and monitoring treatment and therapy plans.

(g) Performing independently evaluative and treatment procedures necessary to provide an appropriate response to life-threatening emergency situations.

(h) Facilitating referral of patients to other appropriate community health-care facilities, agencies and resources.

(i) Issuing written prescription orders for drugs provided the physician assistant has had an initial and at least annual thereafter,

review of the physician assistant's prescriptive practices by a physician providing supervision. Such reviews shall be documented in writing, signed by the reviewing physician and physician assistant, and made available to the Board for inspection upon reasonable request.

(3) IDENTIFYING SUPERVISING PHYSICIAN. The physician providing supervision must be readily identifiable by the physician assistant through procedures commonly employed in the physician assistant's practice.

History: Cr. Register, July, 1984, No. 343, eff. 8-1-84; am. (2) (i), Register, July, 1994, No. 463, eff. 8-1-94; am. (1) and (2) (intro.), Register, October, 1996, No. 490, eff. 11-1-96; am. (1), (2) (intro.), (c), (e), (f) and (i), Register, December, 1999, No. 528, eff. 1-1-00; CR 12-005: am. (1), (2) (a), (e), (i), cr. (3) Register February 2014 No. 698, eff. 3-1-14.

Med 8.09 Employee status. No physician assistant may be self-employed. If the employer of a physician assistant is other than a licensed physician, the employer shall provide for, and may not interfere with, the supervisory responsibilities of the physician, as defined in s. Med 8.02 (6) and required in ss. Med 8.07 (1) and 8.10.

History: Cr. Register, July, 1984, No. 343, eff. 8-1-84; am. Register, October, 1996, No. 490, eff. 11-1-96.

Med 8.10 Physician to physician assistant ratio.

(1) No physician may supervise more than 4 on-duty physician assistants at any time unless a written plan to do so has been submitted to and approved by the board. Nothing herein shall limit the number of physician assistants for whom a physician may provide supervision over time. A physician assistant may be supervised by more than one physician while on duty.

(2) A supervising physician shall be available to the physician assistant at all times for consultation either in person or within 15 minutes of contact by telecommunication or other means.

History: Cr. Register, July, 1984, No. 343, eff. 8-1-84; am. (1), Register, December, 1999, No. 528, eff. 1-1-00; CR 09-006: am. (3) Register August 2009 No. 644, eff. 9-1-09; CR 12-005: r. and recr. Register February 2014 No. 698, eff. 3-1-14.

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Kimberly Wood, Program Assistant Supervisor-Advanced		2) Date When Request Submitted: 12/8/2016 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Medical Examining Board			
4) Meeting Date: 12/21/2016	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Discussion and Consideration of Council Appointment Methods 1) Review of the Proposed Medical Examining Board Application for Council Member Appointment	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input checked="" type="checkbox"/> Yes – Kimberly Wood <input type="checkbox"/> No	9) Name of Case Advisor(s), if required: N/A	
10) Describe the issue and action that should be addressed: MEB Council Appointment Considerations: <ol style="list-style-type: none"> 1) <u>New Applicants</u>: Following discussion in September an application for appointment to the Councils under the purview of the Medical Examining Board was further developed as a result of the direction provided by the Board. Please review the attached application and identify whether to approve the application for use or advise regarding and additional edits required. 2) <u>Reappointments</u>: Please determine whether to require the submission of a new application for existing Council members who are eligible and interested in reappointment. MEB Councils: <ol style="list-style-type: none"> 1) Respiratory Care Practitioners Examining Council 15.407(1m) 2) Council on Physician Assistants 15.407(2) 3) Perfusionists Examining Council 15.407(2m) 4) Council on Anesthesiologist Assistants 15.407(7) 			
11) Authorization			
Kimberly Wood		12/8/2016	
Signature of person making this request		Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date			
Directions for including supporting documents: <ol style="list-style-type: none"> 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting. 			

Kenneth Simons
Chairperson

Timothy Westlake
Vice Chairperson

Mary Jo Capodice
Secretary

WISCONSIN MEDICAL EXAMINING BOARD



1400 E Washington Ave
PO Box 8366
Madison WI 53708-8366

Email: dsps@wisconsin.gov
Voice: 608-266-2112
FAX: 608-251-3032

APPLICATION FOR APPOINTMENT

INSTRUCTIONS

Thank you for expressing an interest in serving Wisconsin. Councils attached to the Medical Examining Board serve an integral role in protecting the public and in creating licensing standards for professionals in related fields. To be considered for appointment to a Council, please complete the application below.

PART I – Personal Information

Name (First, Middle Initial, Last):			
Home Address 1:			
Address Line 2:			
City:		ZIP Code:	
Home Phone:		Cell Phone:	
E-mail Address:		Date of Birth:	
Job Title, Company:			
Work Address 1:			
Address Line 2:			
City:		ZIP Code:	
Work Phone:		Fax Number:	
Preferred Mailing Address (please check one):	<input type="checkbox"/> Home <input type="checkbox"/> Work		
What is your state of residence?			
Are you a state employee?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
If yes, list your Department and Division.			
Are you an elected official?	<input type="checkbox"/> Yes <input type="checkbox"/> No		
If yes, what is your position?			
Are you a licensed/certified professional? If so, please specify.			
Do you belong to any professional groups? If so, please specify.			

*Demographic Information – Optional			
Disability:		Veteran:	
Gender:	<input type="checkbox"/> Female <input type="checkbox"/> Male	Ethnicity:	

Part II – Social Media

Provide a link to the profile page of any social media accounts you maintain.

Social Media Type	Link(s)
Facebook:	
Twitter:	
LinkedIn:	
Google+:	
YouTube:	
Instagram:	
Pinterest:	
Tumblr:	
Vine:	
Flickr:	
Miscellaneous	
:	
:	

Part III – Council(s) Sought

Please list in order of preference and specify member type, if known.

1.	
2.	
3.	
4.	

Part IV – References

In the space provided below, please list the names of three people who are willing to serve as references. Please also include phone numbers and their relationship to you.

Name	Phone Number	Relationship to You
1.		
2.		
3.		

Did anyone refer you to this council? If so, who?

1.	
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Part V – Supporting Documentation and Submission

Please attach a resume and cover letter to this application.

Resume:

Please include relevant work experience, education, community involvement, government or military service, honors, awards, and other talents.

Cover Letter:

Please describe why you are interested in working for a Medical Examining Board council. Your cover letter should include any information that is relevant for the Board to know as they consider your appointment.

- By submitting this application you are affirming that all the statements you have made in this document are true and that you understand that a background check may be conducted if you are considered for appointment.
- Under Wisconsin Statutes 19.36(7)(b), as an applicant for this position, you have the limited right to request that your identity be kept in confidence. If you wish to prefer this right, you must attach to our application a letter requesting confidentiality of your identity with respect to this application.
- This right prevents your identity from being released in response to a public records request unless; you are appointed to the position or you are a finalist for the position as defined by Wisconsin Statute 19.36(7)(a).

Applications should be faxed to:	Applications should be emailed to:	Applications should be mailed to:
608-251-3032	DSPSAppointments@wisconsin.gov	Department of Safety & Professional Services Division of Policy Development MEB Appointments P.O. Box 8366 Madison, WI 53708-8366

Council	Number of Members	Statutory Citation	Term Length	Term Limits	Appointing Authority	Oath of Office Required	Senate Confirmation Required
Respiratory Care Practitioners Examining Council	5	15.407(1m)	3 years	None			
3 Certified Respiratory Care Practitioners					MEB	Yes	
1 Physician Member					MEB	Yes	
1 Public Member					GOV	Yes	Yes
Council on Physician Assistants	5	15.407(2)	4 Years	2 Years			
1 Public Member					GOV		Yes
3 Physician Assistants					MEB		
1 Physician Assistant Educator					MEB		
Perfusionists Examining Council	5	15.407(2m)	3 years	2 Years			
3 Perfusionist Members					MEB	Yes	
1 Physician Member					MEB	Yes	
1 Public Member					GOV	Yes	Yes
Council on Anesthesiologist Assistants	5	15.407(7)	3 years	2 Years			
1 MEB member					MEB Chair		
1 Licensed Anesthesiologist Assistant					MEB		
2 Anesthesiologists					MEB		
1 Public Member					GOV		Yes

**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Dr. Mary Jo Capodice		2) Date When Request Submitted: 11/21/2016 <small>Items will be considered late if submitted after 4:30 p.m. and less than:</small> <ul style="list-style-type: none"> ▪ 10 work days before the meeting for Medical Board ▪ 14 work days before the meeting for all others 	
3) Name of Board, Committee, Council, Sections: Medical Examining Board			
4) Meeting Date: 12/21/2016	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? American Association of Osteopathic Examiners Call for Nominations (Dr. Capodice to Inform Board of Candidacy)	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	8) Is an appearance before the Board being scheduled? If yes, who is appearing? No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed: The AAOE Nominating Committee is seeking nominations for the upcoming AAOE elections in April 2017. There are three openings, President, Vice-President and Secretary-Treasurer. The Board will consider approving and supporting Dr. Capodice's candidacy for an open office within AAOE leadership. A letter from Dr. Simons would be sent supporting her candidacy.			
11) Authorization			
Signature of person making this request		Date	
Supervisor (if required)		Date	
Bureau Director signature (indicates approval to add post agenda deadline item to agenda)		Date	

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:		2) Date When Request Submitted: 12/7/2016	
		Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Wisconsin Medical Examining Board			
4) Meeting Date: 12/21/2016	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? FSMB Matters: Consideration of Nominations for Elective Office and Committee Appointments	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes (Fill out Board Appearance Request) <input checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed: To consider Board member and/or Executive Director interest in elective positions and committee appointments through the FSMB.			
11) Authorization			
Signature of person making this request			Date
Supervisor (if required)			Date
Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date			
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:		2) Date When Request Submitted: 12/7/2016	
		Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Medical Examining Board			
4) Meeting Date: 12/21/2016	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? FSMB Matters: April 20-22, 2017 Annual Meeting, Public Member Scholarship Award – Board Consideration	
7) Place Item in: <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes (Fill out Board Appearance Request) <input checked="" type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed: Wisconsin has been granted one scholarship for a public member who has never attended an FSMB meeting for full reimbursement of expenses, in compliance with State of Wisconsin reimbursement rules.			
11) Authorization			
Signature of person making this request		Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date			
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Rodney Erickson		2) Date When Request Submitted: 12/16/2016 <small>Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting</small>	
3) Name of Board, Committee, Council, Sections: Medical Examining Board			
4) Meeting Date: 12/21/2016	5) Attachments: <input type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Informational Item - Final AHRQ technical brief on Medication-Assisted Treatment Models of Care for Opioid Use Disorder in Primary Care Settings	
7) Place Item in: <input type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes (Fill out Board Appearance Request) <input type="checkbox"/> No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed: Dr. Erickson asked that the Final AHRQ technical brief on Medication-Assisted Treatment Models of Care for Opioid Use Disorder in Primary Care Settings was recently published. https://www.effectivehealthcare.ahrq.gov/ehc/products/636/2350/opioid-use-disorder-report-161123.pdf			
11) Authorization			
Signature of person making this request		Date	
Supervisor (if required)		Date	
Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date			
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request:		2) Date When Request Submitted: 12/5/2016	
		Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting	
3) Name of Board, Committee, Council, Sections: Wisconsin Medical Examining Board			
4) Meeting Date: 12/21/2016	5) Attachments: x Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? 2016 Report from Interim Meeting of the American Medical Association	
7) Place Item in: x Open Session <input type="checkbox"/> Closed Session	8) Is an appearance before the Board being scheduled? <input type="checkbox"/> Yes (Fill out Board Appearance Request) x No	9) Name of Case Advisor(s), if required:	
10) Describe the issue and action that should be addressed: Report Review.			
11) Authorization			
Signature of person making this request			Date
Supervisor (if required)			Date
Executive Director signature (indicates approval to add post agenda deadline item to agenda) Date			
Directions for including supporting documents: 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

MEMORANDUM

Date : December 5, 2016
To : Executive Directors, FSMB Member Boards
From : Lisa Robin, Chief Advocacy Officer
Re : 2016 Interim Meeting of the American Medical Association

The interim meeting of the American Medical Association (AMA) was held November 12-15, 2016 in Orlando, Florida. The Federation of State Medical Boards (FSMB) maintains its official observer status at the AMA House of Delegates and monitors, and may provide testimony, on resolutions and reports pertinent to state medical and osteopathic boards and the FSMB. Representing the FSMB this year were FSMB President/CEO, Humayun J. Chaudhry, DO, MACP, Claudette Dalton, MD and FSMB staff, Frances Cain. The reports and resolutions of interest to state medical and osteopathic boards were as follows:

Report of the Council on Medical Education, Access to Confidential Health Services for Medical Students and Physicians (Resolution 901-I-15, Resolution 913-I-15, Resolution 304-A-16). This report addressed the importance of the provision of mental health services to physicians, and the confidentiality of this care throughout medical education, training, and practice. The Report offers recommendations as to how medical students and resident/fellow physicians can receive appropriate care without fear of stigma or repercussions. The FSMB offered no testimony on the report's recommendation but the consensus of testimony before the reference committee was that resident and fellow physicians often forego their own health needs due to a variety of stressors, including future career concerns and the potential impact on medical licensure. Accordingly, one of the recommendations adopted by the House of Delegates calls for the AMA to urge state medical boards to refrain from asking applicants about past history of mental health or substance use disorder diagnosis or treatment, and only focus on current impairment by mental illness or addiction, and to accept "safe haven" non-reporting for physicians seeking licensure or relicensure who are undergoing treatment for mental health or addiction issues, to help ensure confidentiality of such treatment for the individual physician while providing assurance of patient safety. An additional recommendation adopted urges a more proactive approach by medical schools to create effective mental health awareness and suicide prevention screening programs.

Council on Ethical and Judicial Affairs Report 01, Collaborative Care. This report examines key ethical considerations for health care teams engaged in providing care collaboratively and provides guidance for physicians as leader-members of care teams. The report states that within collaborative care teams, physicians and other health care professional must work in concert to provide high quality patient-centered care, establish mutual respect and trust throughout the team, maintain avenues of communication, and uphold accountability for all team members. The report outlines the types of leadership physicians should consider in leading such teams, the variety of challenges collaborative care teams frequently encounter, and offers ethical guidance on how physician leaders can promote and encourage the many qualities that constitute an effective collaborative care team.

Council on Ethical and Judicial Affairs Report 02, Competence, Self-Assessment and Self-Awareness. This report addresses the benefits and limits of physician self-assessment, what it means for a physician to maintain expertise in their specialty and general medical knowledge, and the implicit and explicit influences that can shape a physician's competence and self-awareness. The report offers ethical guidance on how individual physicians (at all career stages) can engage in greater self-reflection, and how the medical profession itself can refine the mechanisms it uses to meaningfully assess physician competence. Testimony before the reference committee was mixed in that some testimony argued the guidance could stigmatize aging physicians and did not account for periods in a physician's life where s/he is not in peak condition but may still be able to provide quality care to patients. The reference committee recommended the report be adopted; however, the House of Delegates voted to refer the report back to the Council.

Resolution 219, Protect Individualized Compounding in Physicians' Offices. This resolution called for the AMA to "strongly request" that the US Food and Drug Administration (FDA) withdraw its draft guidance "Insanitary Conditions at Compounding Facilities" and that no further action be taken by the agency until revisions to the USP Chapter 797 on Sterile Compounding, are finalized. The Resolution also called on the AMA to work with the US Congress to adopt legislation that would preserve physician office-based compounding as the practice of medicine and be codified in law that physicians compounding medications in their offices for immediate or subsequent use in the management of their patients not be considered compounding facilities under the FDA's jurisdiction. Testimony before the reference committee was mixed focusing on concerns about patient access if low-level in-office compounding were to be eliminated and the impact of the FDA's draft guidance on the practice of medicine. Other testimony recommended referral. The USP representative testified that revisions to USP Chapter 797 may not be finalized for a number of years. Ultimately, the reference committee recommended, and the House of Delegates adopted, a resolution in lieu of Resolution 219 that calls for the AMA to advocate that the FDA remove physician offices and ambulatory surgery centers from its definition of a compounding facility.