



MEDICAL EXAMINING BOARD
Room 121A, 1400 East Washington Avenue, Madison
Contact: Tom Ryan (608) 266-2112
November 16, 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 October 19, 2016 – Review and Approval (5-9)**
- C) 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) Russel Yale – 07/01/2020
 - l) Robert Zoeller – 07/01/2019
 - m) 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
- D) Appointments, Reappointments, Confirmations, and Committee, Panel and Liaison Appointments**
- E) 8:00 A.M. Public Hearing: Clearinghouse Rule 15-087 – Med 24 Relating to Telemedicine (10-23)**
 - 1) Review and Respond to Public Comments and Legislative Reference Bureau Edits
- F) Legislation and Rule Matters – Discussion and Consideration (24-51)**
 - 1) Wisconsin Medical Examining Board Opioid Prescribing Guideline
 - a) Comments and Suggested Edits from June Dahl, Professor of Pharmacology, University of Wisconsin Medical School
 - b) Comments and Recommendation from Dr. James D. Lincer, President, American Board of Pain Medicine

- c) Comments and Recommendation from Nathan J. Rudin, Professor, Orthopedics and Rehabilitation Medicine
- 2) Update on Med 13 Relating to Continuing Medical Education for Prescribing Opioids
- 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

G) Pain Specialist Certification – Discussion (52-53)

H) Report From the Telemedicine Rule Committee

I) Prescription Drug Monitoring Program (PDMP) Report (54-83)

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

K) Federation of State Medical Boards (FSMB) Matters (84-160)

- 1) 2016 Annual Report on the USMLE
- 2) FSMB Workgroup on Team-Based Regulation –Request for Review and Comment
- 3) Call for Nominations for Elected Officers, 2017-2018
- 4) Call for Committee Appointment Recommendations, 2017-2018

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

M) Newsletter Matters (161)

- 1) Fall 2016 Newsletter Delivery and Reference Data

N) Screening Panel Report

O) Informational Items

P) Board Member Recusal

Q) 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

R) Future Agenda Items

S) 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.).

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

1) Administrative Warnings

- a) 15 MED 461 – L.K.K. **(162-163)**
- b) 16 MED 156 – R.G.J. **(164-165)**
- c) 16 MED 210 – I.I.S. **(166-167)**

2) Proposed Stipulations, Final Decisions and Orders

- a) Stipulation and Interim Order in the Matter of DLSC Case No. 15 MED 187 – Gregory McClain, M.D. **(168-172)**
- b) 15 MED 002 – Ronda Davis, M.D. **(173-179)**
- c) 15 MED 098 – Meenakshi Bhillakar, M.D. **(180-186)**
- d) 15 MED 128 – Gerald Paul Clarke, M.D. **(187-192)**

3) Case Closings

- a) 15 MED 371 **(193-202)**
- b) 15 MED 404 **(203-225)**
- c) 15 MED 427 **(226-232)**
- d) 16 MED 031 **(233-236)**
- e) 16 MED 080 **(237-267)**
- f) 16 MED 107 **(268-280)**
- g) 16 MED 147 **(281-287)**
- h) 16 MED 228 **(287-294)**
- i) 16 MED 256 **(295-297)**

4) Monitoring

5) Complaints

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

- 1) Timothy Lawler, D.O. **(298-325)**
- 2) Helen Manning, M.D. **(326-411)**
- 3) Bulent Mamikoglu, M.D. **(412-444)**

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 TWO (2) 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 two (2) Candidates for Licensure –Dr. Erickson & Dr. Roelke

NEXT MEETING DATE DECEMBER 21, 2016

**MEDICAL EXAMINING BOARD
MEETING MINUTES
October 19, 2016**

PRESENT: Mary Jo Capodice, D.O.; Michael Carton, (*via GoToMeeting*;) Rodney Erickson, M.D.; Bradley Kudick; Lee Ann Lau, M.D.; Carolyn Ogland Vukich, M.D. David Roelke, M.D.; Kenneth Simons, M.D. (*arrived via GoToMeeting at 9:36 a.m.*;) Timothy Westlake, M.D.; Robert Zoeller, M.D.

EXCUSED: Padmaja Doniparthi, M.D.; Russell Yale, M.D.; Robert Zondag

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

CALL TO ORDER

Timothy Westlake, Vice Chair, called the meeting to order at 8:00 a.m. A quorum of nine (9) members was confirmed.

ADOPTION OF AGENDA

Amendments to the Agenda:

- *Added one Oral Examination Candidate*
- *Added AAOE Meeting to Item K*
- *Removed duplicate Chapter from page 2 of Newsletter*

MOTION: David Roelke moved, seconded by Mary Jo Capodice, to adopt the agenda as amended. Motion carried unanimously.

MINUTES OF SEPTEMBER 21, 2016 – REVIEW AND APPROVAL

MOTION: Carolyn Ogland Vukich moved, seconded by Mary Jo Capodice, to approve the minutes of September 21, 2016 as published. Motion carried unanimously.

ADMINISTRATIVE UPDATES

Department and Staff Updates

MOTION: Carolyn Ogland Vukich moved, seconded by Mary Jo Capodice, to recognize Michael Phillips for his dedicated service to the Medical Examining Board and the State of Wisconsin. Motion carried unanimously.

**8:00 A.M. PUBLIC HEARING: CLEARINGHOUSE RULE 16-047 – MED 1 AND 14
RELATING TO GENERAL UPDATE AND CLEANUP OF RULES**

MOTION: Lee Ann Lau moved, seconded by David Roelke, to reject Clearinghouse comment numbers 2., 3.d., and 3.h., and to accept all remaining Clearinghouse comments for Clearinghouse Rule 16-047 relating to general update and cleanup of rules. Motion carried unanimously.

MOTION: Carolyn Ogland Vukich moved, seconded by Mary Jo Capodice, to appoint Kenneth Simons to approve the Legislative Report and Draft for Clearinghouse

Rule 16-047 relating to general update and cleanup of rules for submission to the Governor's Office and Legislature. Motion carried unanimously.

LEGISLATIVE/ADMINISTRATIVE RULE MATTERS

Review Revised Draft Language for Med 13 Relating to Continuing Medical Education for Prescribing Opioids

MOTION: David Roelke moved, seconded by Bradley Kudick, to approve the emergency rule draft of Wisconsin Administrative Code Ch. MED 13 relating to continuing medical education for prescribing opioids for submission to the Governor's Office and to authorize Timothy Westlake to approve the emergency rules for publication. Motion carried unanimously.

MOTION: Mary Jo Capodice moved, seconded by David Roelke, to approve the permanent rule draft of Wisconsin Administrative Code Ch. MED 13 relating to continuing medical education for prescribing opioids to solicit economic impact comments and submission to the Clearinghouse. Motion carried unanimously.

Med 24 Relating to Telemedicine

MOTION: Carolyn Ogland Vukich moved, seconded by Mary Jo Capodice, to approve the revised rule draft of Wisconsin Administrative Code Ch. MED 24 relating to telemedicine for posting to solicit public comment and request DSPS staff notice a public hearing on the revised rule draft for the Board's next meeting. Motion carried unanimously.

Review of Proposed Changes to DI 2 Relating to Credentials for Certification

MOTION: Mary Jo Capodice moved, seconded by Robert Zoeller, to affirm the Board has reviewed the proposed rule revising Wisconsin Administrative Code Ch. DI 2 relating to credentials for certification and has no comments for the Dietitians Affiliated Credentialing Board to consider. Motion carried unanimously.

SPEAKING ENGAGEMENTS, TRAVEL, OR PUBLIC RELATION REQUESTS, AND REPORTS

AAOE Annual Business Meeting on January 21, 2017 in Tampa, FL

MOTION: David Roelke moved, seconded by Lee Ann Lau, to designate Mary Jo Capodice to attend the AAOE Annual Business Meeting on January 19-21, 2017 in Tampa, FL and to authorize travel. Motion carried unanimously.

NEWSLETTER MATTERS

Fall 2016 Newsletter Draft

MOTION: Bradley Kudick moved, seconded by Carolyn Ogland Vukich, to approve the 2016 Newsletter Draft as amended and authorize Kenneth Simons to make any additional changes. Motion carried unanimously.

(Kenneth Simons arrived via GoToMeeting at 9:36 a.m.)

CLOSED SESSION

MOTION: Carolyn Ogland Vukich moved, seconded by Mary Jo Capodice, 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; Michael Carton – yes; Rodney Erickson – yes; Bradley Kudick – yes; Lee Ann Lau – yes; Carolyn Ogland Vukich – yes; David Roelke – yes; Timothy Westlake – yes; and Robert Zoeller – yes. Motion carried unanimously.

The Board convened into Closed Session at 9:34 a.m.

RECONVENE TO OPEN SESSION

MOTION: Mary Jo Capodice moved, seconded by David Roelke, to reconvene in Open Session at 11:07 a.m. Motion carried unanimously.

VOTE ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

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

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

Monitoring

Jonathan Thomas, M.D. – Requesting Voluntary Surrender of License

MOTION: David Roelke moved, seconded by Bradley Kudick, to offer the Respondent, Jonathan Thomas, M.D. a Stipulation and Order specifying the terms under which the Board would accept the surrender of his license to practice Medicine and Surgery in Wisconsin. Motion carried unanimously.

MOTION: Rodney Erickson moved, seconded by Robert Zoeller, to authorize the Executive Director, to sign on behalf of Mary Jo Capodice to execute the Board's offer to Respondent, Jonathan Thomas, M.D. to accept the surrender of his license to practice Medicine and Surgery in Wisconsin. Motion carried unanimously.

Ronald Rubin, M.D. – Requesting Modification of Limitations

MOTION: Robert Zoeller moved, seconded by Carolyn Ogland Vukich, to grant the request of Ronald Rubin, M.D. to remove the limitations described in ¶5, ¶6.a, ¶6.b.i, ¶7.d.iv, and ¶7.e of the order as Respondent completed the required continuing education and AODA assessment. Respondent shall withdraw the current application and shall not apply for or hold a DEA registration pursuant to ¶7.d.iii. Motion carried.

Complaints

15 MED 002 – D.H. – Amended Complaint

MOTION: Lee Ann Lau moved, seconded by Carolyn Ogland Vukich, to find probable cause to believe that David Houlihan, M.D. DLSC Case No. 15 MED 002 has committed unprofessional conduct, and therefore to issue the Complaint and hold a hearing on such conduct pursuant to Wis. Stat § 448.02(3)(b). Motion carried unanimously.

(Rodney Erickson recused himself and left the room for deliberation and voting in the matter concerning David Houlihan, DLSC Case No. 15 MED 002.)

Administrative Warnings

14 MED 577 – A.A.

MOTION: Rodney Erickson moved, seconded by David Roelke, to issue an Administrative Warning in the matter of DLSC Case No. 14 MED 577 against A.A. Motion carried unanimously.

(Lee Ann Lau and Mary Jo Capodice recused themselves and left the room for deliberation and voting in the matter concerning A.A., DLSC Case No. 14 MED 577.)

16 MED 233 – D.M.M.

MOTION: Rodney Erickson moved, seconded by Robert Zoeller, to issue an Administrative Warning in the matter of DLSC Case No. 16 MED 233 against D.M.M. Motion carried unanimously.

Proposed Stipulations, Final Decisions and Orders

14 MED 372 – Muhammad Khan, M.D.

MOTION: Rodney Erickson moved, seconded by Lee Ann Lau, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Muhammad Khan, M.D., DLSC Case No. 14 MED 372. Motion carried unanimously.

15 MED 177 – David Olson, M.D.

MOTION: Mary Jo Capodice moved, seconded by Robert Zoeller, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against David Olson, DLSC Case No. 15 MED 177. Motion carried unanimously.

15 MED 324 – Adetunji Adejumo, M.D.

MOTION: David Roelke moved, seconded by Lee Ann Lau, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Adetunji Adejumo, DLSC Case No. 15 MED 324. Motion carried unanimously.

15 MED 366 – Leonard Boras Jr.

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 Leonard Boras Jr., DLSC Case No. 15 MED 366. Motion carried unanimously.

16 MED 023 – James Turner III, M.D.

MOTION: Carolyn Ogland Vukich moved, seconded by Rodney Erickson, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against James Turner III, DLSC Case No. 16 MED 023. Motion carried unanimously.

Case Closings

CASE CLOSING(S)

MOTION: Mary Jo Capodice moved, seconded by David Roelke, to close the following cases according to the recommendations by the Division of Legal Services and Compliance:

1. 15 MED 397 (F.E. and W.M.) *Prosecutorial Discretion (P2)*
2. 16 MED 013 (K.C.D) *No Violation*
3. 16 MED 105 (W.J.B.) *Prosecutorial Discretion (P2)*

Motion carried unanimously.

16 MED 142 (K.W.L.) Insufficient Evidence

MOTION: Carolyn Ogland Vukich moved, seconded by Mary Jo Capodice, to not close DLSC Case No. 16 MED 142 against K.W.L. for *Insufficient Evidence*. Motion carried unanimously.

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

MOTION: Kenneth Simons moved, seconded by Mary Jo Capodice, to delegate ratification of examination results to DSPS staff and to ratify all licenses and certificates as issued. Motion carried unanimously.

ADJOURNMENT

MOTION: Mary Jo Capodice moved, seconded by Carolyn Ogland Vukich, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 11:09 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: 11/4/16 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: 11/16/16	5) Attachments: Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	6) How should the item be titled on the agenda page? 8:00 A.M. Public Hearing: Clearinghouse Rule 15-087 – Med 24 Relating to Telemedicine 1. Review and Respond to Public Comments and Legislative Reference Bureau Edits Legislative/Administrative Rule Matters: 1. Wisconsin Medical Examining Board Opioid Prescribing Guideline a. Comments and Suggested Edits from June Dahl, Professor of Pharmacology, University of Wisconsin Medical School b. Comments and Recommendation from Dr. James D. Lincer, President, American Board of Pain Medicine c. Comments and Recommendations from Nathan J. Rudin, Professor, Orthopedics and Rehabilitation Medicine 2. Update on Med 13 Relating to Continuing Medical Education for Prescribing Opioids 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	
<input checked="" type="checkbox"/> Place Item in: <input 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"/> <input checked="" type="checkbox"/> Yes (Fill out Board Appearance Request) No	9) Name of Case Advisor(s), if required:
10) Describe the issue and action that should be addressed:			
11) <i>Dale Kleven</i> Signature of person making this request		Authorization <i>November 4, 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	:	PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE	:	MEDICAL EXAMINING BOARD
MEDICAL EXAMINING	:	ADOPTING RULES
BOARD	:	(CLEARINGHOUSE RULE 15-087)

PROPOSED ORDER

An order of the Medical Examining Board to create ch. Med 24, relating to telemedicine.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted:

None.

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 current administrative code is silent with regards to telemedicine practice. The proposed rule will define telemedicine, explain how a valid physician-patient relationship can be established in a telemedicine setting, and identify technology requirements for

physicians who use electronic communications, information technology or other means of interaction with patients who are not physically present. The proposed rule will specify out-of-state physicians to hold a valid Wisconsin medical license in order to diagnose and treat patients located in Wisconsin.

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

2015 HR 691 - Telehealth Modernization Act of 2015 – the proposed bill seeks to establish a federal standard for telehealth and serve as guidance for states, subject to a number of specified conditions.

Comparison with rules in adjacent states:

Illinois: Illinois statutes require an individual who engages in telemedicine to hold a medical license issued by the state of Illinois. Telemedicine is defined as including but not limited to rendering written or oral opinions concerning diagnosis or treatment of a patient in Illinois by a person located outside the State of Illinois as a result of transmission of individual patient data by telephonic, electronic, or other means of communication from within this State. Telemedicine specifically does not include periodic consultations between a licensee and a person outside the State of Illinois, a second opinion provided to a licensee; and the diagnosis or treatment services provided to a patient in Illinois following care or treatment originally provided to the patient in the state in which the provider is licensed to practice medicine (225 Ill. Comp. Stat. Ann. s. 60/49.5). The telemedicine provisions are scheduled to be repealed on December 31, 2016.

Iowa: Iowa Administrative Code 653-13.11 establishes the standards of practices of physicians who use telemedicine. The rules define telemedicine, explain how a valid physician-patient relationship can be established in a telemedicine setting, and identify technology requirements for physicians who use electronic communications, information technology or other means of interaction with patients who are not physically present. The rules require out-of-state physicians to have a valid Iowa medical license in order to diagnose and treat patients located in Iowa.

Michigan: Michigan statutes and administrative code are silent with regards to the provision of telemedicine services. The standards are the same as in-person care.

Minnesota: Minnesota does not have any unique laws regulating the practice of telemedicine. Standards are the same as in person care (Minn. Stat. s. 147.032).

Summary of factual data and analytical methodologies:

Other states' requirements as well as the Federation of State Medical Boards model policy were reviewed when drafting the proposed rule change.

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

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

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis document is attached.

Effect on small business:

These 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 Dale2.Kleven@wisconsin.gov. Comments must be received on or before the public hearing on November 16, 2016 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Chapter Med 24 is created to read:

CHAPTER MED 24

TELEMEDICINE

Med 24.01 Authority and scope. The rules in this chapter are adopted by the medical examining board pursuant to the authority delegated by ss. 15.08 (5), 227.11, and 448.40, Stats., and govern the standards of the practice of medicine using telemedicine. The rules in this chapter may not be construed to prohibit:

(1) Consultations between physicians or the transmission and review of digital images, pathology specimens, test results, or other medical data by physicians related to the care of Wisconsin patients.

(2) Patient care in consultation with another physician who has an established physician-patient relationship with the patient.

(3) Patient care in on-call or cross-coverage situations in which the physician has access to patient records.

(4) Treating a patient with an emergency medical condition. In this subsection, “emergency medical condition” means a medical condition manifesting itself by acute symptoms of sufficient severity that the absence of immediate medical attention will result in serious jeopardy to patient health, serious impairment to bodily functions, or serious dysfunction of a body organ or part.

(5) Use of telemedicine by a Wisconsin licensed physician assistant to provide patient care, treatment, or services within the licensee’s scope of practice under s. Med 8.07.

Med 24.02 Definition of telemedicine. In this chapter, “telemedicine” means the practice of medicine where patient care, treatment, or services are provided through the use of medical information exchanged from one site to another via electronic communications. Telemedicine does not include the provision of health care services only through an audio-only telephone, email messages, text messages, facsimile transmission, mail or parcel service, or any combination thereof.

Med 24.03 Physician-patient relationship. A physician-patient relationship may be established through telemedicine.

Med 24.04 Wisconsin medical license required. A physician who uses telemedicine in the diagnosis and treatment of a patient located in Wisconsin shall hold an active Wisconsin medical license.

Med 24.05 Standards of practice and conduct. A Wisconsin licensed physician shall be held to the same standards of practice and conduct, including patient confidentiality and recordkeeping, regardless of whether health care services are provided in person or by telemedicine.

Med 24.06 Equipment and technology. A Wisconsin licensed physician providing health care services by telemedicine is responsible for the quality and safe use of equipment and technology that is integral to patient diagnosis and treatment. The equipment and technology used by a Wisconsin licensed physician to provide health care services by telemedicine shall be able to provide, at a minimum, information that will enable the physician to meet or exceed the standard of minimally competent medical practice.

Med 24.07 Internet diagnosis and treatment. (1) When a physician uses a website to communicate to a patient located in Wisconsin, the physician may not provide treatment recommendations, including issuing a prescription, unless the following requirements are met:

(a) The physician holds an active Wisconsin medical license as required under s. Med 24.04.

(b) The physician's name and contact information have been made available to the patient.

(c) Informed consent as required under s. 448.30, Stats., and ch. Med 18.

(d) A documented patient evaluation has been performed. A patient evaluation shall include a medical history and, to the extent required to meet or exceed the standard of minimally competent medical practice, an examination or evaluation, or both, and diagnostic tests.

(e) A patient health care record is prepared and maintained as required under ch. Med 21.

(2) Providing treatment recommendations, including issuing a prescription, based solely on a static electronic questionnaire does not meet the standard of minimally competent medical practice.

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

(END OF TEXT OF RULE)

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis

Original Updated Corrected

2. Administrative Rule Chapter, Title and Number

Med 24 Telemedicine

3. Subject

Relating to telemedicine

4. Fund Sources Affected

GPR FED PRO PRS SEG SEG-S

5. Chapter 20, Stats. Appropriations Affected

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 current administrative code is silent with regards to telemedicine practice. The proposed rule will define telemedicine, explain how a valid physician-patient relationship can be established in a telemedicine setting, and identify technology requirements for physicians who use electronic communications, information technology or other means of interaction with patients who are not physically present. The proposed rule will specify out-of-state physicians to hold a valid Wisconsin medical license in order to diagnose and treat patients located in Wisconsin.

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

This proposed rule was posted for a period of 14 days to solicit comments from the public. No businesses, business sectors, associations representing businesses, local governmental units, or individuals contacted the department about the proposed rule during that time period.

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

None. This rule does not affect local government units.

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)

The rule will not have an economic or fiscal impact on specific businesses, business sectors, public utility rate payers, local government units, or the state's economy as a whole.

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

Telemedicine is a rapidly growing practice. These rules will provide medical practitioners with necessary guidance with

ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

regards to the standards for telemedicine practice.

14. Long Range Implications of Implementing the Rule

This rule will allow medical practitioners to utilize telemedicine with the confidence of complying with clear requirements delineated in administrative code.

15. Compare With Approaches Being Used by Federal Government

2015 HR 691 - Telehealth Modernization Act of 2015 – the proposed bill seeks to establish a federal standard for telehealth and serve as guidance for states, subject to a number of specified conditions.

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

Illinois statutes require an individual who engages in telemedicine to hold a medical license issued by the state of Illinois. Telemedicine is defined as including but not limited to rendering written or oral opinions concerning diagnosis or treatment of a patient in Illinois by a person located outside the State of Illinois as a result of transmission of individual patient data by telephonic, electronic, or other means of communication from within this State. Telemedicine specifically does not include periodic consultations between a licensee and a person outside the State of Illinois, a second opinion provided to a licensee; and the diagnosis or treatment services provided to a patient in Illinois following care or treatment originally provided to the patient in the state in which the provider is licensed to practice medicine (225 Ill. Comp. Stat. Ann. s. 60/49.5). The telemedicine provisions are scheduled to be repealed on December 31, 2015.

Iowa Administrative Code 653-13.11 establishes the standards of practices of physicians who use telemedicine. Similar to the proposed rule, Iowa Administrative Code defines telemedicine, explains how a valid physician-patient relationship can be established in a telemedicine setting, and identifies technology requirements for physicians who use electronic communications, information technology or other means of interaction with patients who are not physically present. The rule requires out-of-state physicians to have a valid Iowa medical license in order to diagnose and treat patients located in Iowa.

Michigan statutes and administrative code are silent with regards to the provision of telemedicine services. The standards are the same as in-person care.

Minnesota does not have any unique laws regulating the practice of telemedicine. Standards are the same as in person care (Minn. Stat. s. 147.032).

17. Contact Name

Katie Vieira

18. Contact Phone Number

(608) 261-4472

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

STATE OF WISCONSIN
MEDICAL EXAMINING BOARD

IN THE MATTER OF RULEMAKING	:	PROPOSED ORDER OF THE
PROCEEDINGS BEFORE THE	:	MEDICAL EXAMINING BOARD
MEDICAL EXAMINING	:	ADOPTING RULES
BOARD	:	(CLEARINGHOUSE RULE 15-087)

PROPOSED ORDER

An order of the Medical Examining Board to create ch. Med 24, relating to telemedicine.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted:

None.

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 current administrative code is silent with regards to telemedicine practice. The proposed rule will define telemedicine, explain how a valid physician-patient relationship can be established in a telemedicine setting, and identify technology requirements for

physicians who use electronic communications, information technology or other means of interaction with patients who are not physically present. The proposed rule will specify out-of-state physicians to hold a valid Wisconsin medical license in order to diagnose and treat patients located in Wisconsin.

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

2015 HR 691 - Telehealth Modernization Act of 2015 – the proposed bill seeks to establish a federal standard for telehealth and serve as guidance for states, subject to a number of specified conditions.

Comparison with rules in adjacent states:

Illinois: Illinois statutes require an individual who engages in telemedicine to hold a medical license issued by the state of Illinois. Telemedicine is defined as including but not limited to rendering written or oral opinions concerning diagnosis or treatment of a patient in Illinois by a person located outside the State of Illinois as a result of transmission of individual patient data by telephonic, electronic, or other means of communication from within this State. Telemedicine specifically does not include periodic consultations between a licensee and a person outside the State of Illinois, a second opinion provided to a licensee; and the diagnosis or treatment services provided to a patient in Illinois following care or treatment originally provided to the patient in the state in which the provider is licensed to practice medicine (225 Ill. Comp. Stat. Ann. s. 60/49.5). The telemedicine provisions are scheduled to be repealed on December 31, 2016.

Iowa: Iowa Administrative Code 653-13.11 establishes the standards of practices of physicians who use telemedicine. The rules define telemedicine, explain how a valid physician-patient relationship can be established in a telemedicine setting, and identify technology requirements for physicians who use electronic communications, information technology or other means of interaction with patients who are not physically present. The rules require out-of-state physicians to have a valid Iowa medical license in order to diagnose and treat patients located in Iowa.

Michigan: Michigan statutes and administrative code are silent with regards to the provision of telemedicine services. The standards are the same as in-person care.

Minnesota: Minnesota does not have any unique laws regulating the practice of telemedicine. Standards are the same as in person care (Minn. Stat. s. 147.032).

Summary of factual data and analytical methodologies:

Other states' requirements as well as the Federation of State Medical Boards model policy were reviewed when drafting the proposed rule change.

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

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

Fiscal Estimate and Economic Impact Analysis:

The Fiscal Estimate and Economic Impact Analysis document is attached.

Effect on small business:

These 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 Dale2.Kleven@wisconsin.gov. Comments must be received on or before the public hearing on November 16, 2016 to be included in the record of rule-making proceedings.

TEXT OF RULE

SECTION 1. Chapter Med 24 is created to read:

CHAPTER MED 24

TELEMEDICINE

Med 24.01 Authority and scope. The rules in this chapter are adopted by the medical examining board pursuant to the authority delegated by ss. 15.08 (5), 227.11, and 448.40, Stats., and govern the standards of the practice of medicine using telemedicine.

The rules in this chapter may not be construed to prohibit any of the following:

(1) Consultations between physicians or the transmission and review of digital images, pathology specimens, test results, or other medical data by physicians related to the care of ~~Wisconsin~~ patients in this state.

Note: Statute drafting style is to use “in this state, rather than using Wisconsin as an adjective. In addition, in this case Wisconsin patient could create an ambiguity as whether it means any patient in the state, which I am assuming is the case, or Wisconsin residents who are patients.

(2) Patient care in consultation with another physician who has an established physician-patient relationship with the patient.

(3) Patient care in on-call or cross-coverage situations in which the physician has access to patient records.

(4) Treating a patient with an emergency medical condition. In this subsection, “emergency medical condition” means a medical condition manifesting itself by acute symptoms of sufficient severity that the absence of immediate medical attention will result in serious jeopardy to patient health, serious impairment to bodily functions, or serious dysfunction of a body organ or part.

(5) Use of telemedicine by a ~~Wisconsin licensed~~ physician assistant licensed by the medical examining board to provide patient care, treatment, or services within the licensee’s scope of practice under s. Med 8.07.

Note: Each place I say licensed by the medical examining board, licensed in this state would also probably be appropriate.

Med 24.02 Definition of telemedicine. In this chapter, “telemedicine” means the practice of medicine ~~when~~where patient care, treatment, or services are provided through the use of medical information exchanged from one site to another via electronic communications. Telemedicine does not include the provision of health care services only through an audio-only telephone, email messages, text messages, facsimile transmission, mail or parcel service, or any combination thereof.

NOTE: In statutory drafting style, “where” is limited to geographic references.

Med 24.03 Physician-patient relationship. A physician-patient relationship may be established through telemedicine.

Med 24.04 Wisconsin medical license required. A physician who uses telemedicine in the diagnosis and treatment of a patient located in this state Wisconsin shall ~~hold an~~be active Wisconsin medical licensed to practice medicine and surgery by the medical examining board.

Note: Inserts statutory terminology consistent with 448.03(1)(a), which reads: No person may practice medicine and surgery, or attempt to do so or make a representation as authorized to do so, without a license to practice medicine and surgery granted by the board.

Med 24.05 Standards of practice and conduct. A ~~Wisconsin licensed~~ physician licensed to practice medicine and surgery by the medical examining board shall be held to the same standards of practice and conduct, including patient confidentiality

and recordkeeping, regardless of whether health care services are provided in person or by telemedicine.

Med 24.06 Equipment and technology. A ~~Wisconsin licensed~~ physician licensed to practice medicine and surgery by the medical examining board who provides health care services by telemedicine is responsible for the quality and safe use of equipment and technology that is integral to patient diagnosis and treatment. The equipment and technology used by ~~thea Wisconsin licensed~~ physician to provide health care services by telemedicine shall ~~be able to~~ provide, at a minimum, information that will enable the physician to meet or exceed the standard of minimally competent medical practice.

Note: I removed “be able to” because I think it makes the standard “squishy.” Is it ok if the equipment is able to provide the information but does not actually provide it, for whatever reason? That is a comment on substance rather than form so not really in my domain.

Med 24.07 Internet diagnosis and treatment. (1) When a physician uses a website to communicate to a patient located in this state Wisconsin, the physician may not provide treatment recommendations, including issuing a prescription, unless the following requirements are met:

(a) The physician shall be holds an active Wisconsin medical licensed to practice medicine and surgery by the medical examining board as required under s. Med 24.04.

(b) The physician’s name and contact information have been made available to the patient.

(c) Informed consent as required under s. 448.30, Stats., and ch. Med 18.

(d) A documented patient evaluation has been performed. A patient evaluation shall include a medical history and, to the extent required to meet or exceed the standard of minimally competent medical practice, an examination or evaluation, or both, and diagnostic tests.

(e) A patient health care record is prepared and maintained as required under ch. Med 21.

(2) Providing treatment recommendations, including issuing a prescription, based solely only on a static electronic questionnaire does not meet the standard of minimally competent medical practice.

Note: Solely was incorrectly spelled, but only is generally used in statutory drafting.

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

(END OF TEXT OF RULE)

Kenneth Simons
Chairperson

Timothy Westlake
Vice Chairperson

Mary Jo Capodice
Secretary

WISCONSIN MEDICAL EXAMINING BOARD



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Wisconsin Medical Examining Board Opioid Prescribing Guideline – July 20, 2016

Scope and purpose of the guideline: To help providers make informed decisions about acute and chronic pain treatment -pain lasting longer than three months or past the time of normal tissue healing. The guideline is not intended for patients who are in active cancer treatment, palliative care, or end-of-life care. Although not specifically designed for pediatric pain, many of the principals upon which they are based could be applied there, as well.

Opioids pose a potential risk to all patients. The guideline encourages providers to implement best practices for responsible prescribing which includes prescribing the lowest effective dose for the shortest possible duration for post-operative care and acutely-injured patients.

1) Identify and treat the cause of the pain, use non-opioid therapies

Use non-pharmacologic therapies (such as yoga, exercise, cognitive behavioral therapy and complementary/alternative medical therapies) and non-opioid pharmacologic therapies (such as acetaminophen and anti-inflammatories) for acute and chronic pain. Don't use opioids routinely for chronic pain. When opioids are used, combine them with non-pharmacologic or non-opioid pharmacologic therapy, as appropriate, to provide greater benefits.

2) Start low and go slow

When opioids are used, prescribe the lowest possible effective dosage and start with immediate-release opioids instead of extended-release/long-acting opioids. Only provide the quantity needed for the expected duration of pain.

3) Close follow-up

Regularly monitor patients to make sure opioids are improving pain and function without causing harm. If benefits do not outweigh harms, optimize other therapies and work with patients to taper or discontinue opioids, if needed.

What's included in the guideline?

The guideline addresses patient-centered clinical practices including conducting thorough assessments, considering all possible treatments, treating the cause of the pain, closely monitoring risks, and safely discontinuing opioids. The three main focus areas in the guideline include:

1) Determining when to initiate or continue opioids

- Selection of non-pharmacologic therapy, non-opioid pharmacologic therapy, opioid therapy
- Establishment of treatment goals
- Discussion of risks and benefits of therapy with patients

2) Opioid selection, dosage, duration, follow-up and discontinuation

- Selection of immediate-release or extended-release and long-acting opioids
- Dosage considerations
- Duration of treatment
- Considerations for follow-up and discontinuation of opioid therapy

3) Assessing risk and addressing harms of opioid use

- Evaluation of risk factors for opioid-related harms and ways to mitigate/reduce patient risk
- Review of prescription drug monitoring program (PDMP) data
- Use of urine drug testing
- Considerations for co-prescribing benzodiazepines
- Arrangement of treatment for opioid use disorder

Prescription Opioid Guideline

1. Pain is a subjective experience and at present, physicians lack options to objectively quantify pain severity other than by patient reported measures including pain intensity. While accepting the patient's report of pain, the clinician must simultaneously decide if the magnitude of the pain complaint is commensurate with causative factors and if these have been adequately evaluated and addressed with non-opioid therapy.

2. In treating acute pain, if opioids are at all indicated, the lowest dose and fewest number of opioid pills needed should be prescribed. In most cases, less than 3 days' worth are necessary, and rarely more than 5 days' worth. Left-over pills in medicine cabinets are often the source for illicit opioid abuse in teens and young adults. When prescribing opioids, physicians should consider writing two separate prescriptions for smaller amounts of opioids with specific refill dates, rather than a single large prescription. Most patients do not fill the second prescription, thus limiting opioid excess in a patient's home and potential misuse.

3. A practitioner's first priority in treating a patient in pain is to identify the cause of the pain and, if possible, to treat it. While keeping the patient comfortable during this treatment is important, it is critical to address to the extent possible the underlying condition as the primary objective of care.

a. Patients unwilling to obtain definitive treatment for the condition causing their pain should be considered questionable candidates for opioids. If opioids are prescribed to such patients, documentation of clear clinical rationale should exist.

b. Opioids should not be prescribed unless there is a medical condition present which would reasonably be expected to cause pain severe enough to require an opioid. For conditions where this is questionable, use of other treatments instead of opioids should be strongly considered.

c. Consultation should be considered if diagnosis of and/or treatment for the condition causing the pain is outside of the scope of the prescribing practitioner.

4. Opioids should not necessarily be the first choice in treating acute or chronic pain.

a. Acute pain: Evidence for opioids is weak. Other treatments such as acetaminophen, anti-inflammatories, and non-pharmacologic treatments should be attempted prior to initiating opioid

therapy. Although opioids could be simultaneously prescribed if it is apparent from the patient's condition that he/she will need opioids in addition to these. Don't use opioids routinely for chronic pain. When opioids are used, combine them with non-pharmacologic or non-opioid pharmacologic therapy, as appropriate, to provide greater benefits.

b. Acute pain lasting beyond the expected duration: A complication of the acute pain issue (surgical complication, nonunion of fracture, etc.) should be ruled out. If complications are ruled out, a transition to non-opioid therapy (tricyclic antidepressant, serotonin/norepinephrine reuptake inhibitor, anticonvulsant, etc.) should be attempted.

c. Chronic pain: Evidence for opioids is poor. Other treatments such as acetaminophen, anti-inflammatories, and non-pharmacologic treatments (such as yoga, exercise, cognitive behavioral therapy and complementary/alternative medical therapies) should be utilized. Multiple meta-analyses demonstrate that the benefits of opioids are slight, while annualized mortality rates dramatically increased. There are few if any treatments in medicine with this poor a risk/benefit ratio, and there should be adequate clinical indication to indicate why chronic opioid therapy was chosen in a given patient. **Note:** There is no high-quality evidence to support opioid therapy longer than 6 months in duration. Despite this fact, it is considered acceptable although not preferable to continue patients on treatment who have been on chronic opioid therapy prior to this Guideline's release and who have shown no evidence of aberrant behavior.

d. Patients unwilling to accept non-pharmacological and/or nonnarcotic treatments (or those providing questionably credible justifications for not using them) should not be considered candidates for opioid therapy.

5. Patients should not receive opioid prescriptions from multiple physicians. There should be a dedicated provider such as a primary care or pain specialist to provide all opioids used in treating any patient's chronic pain, with existing pain contracts being honored. Physicians should avoid prescribing controlled substances for patients who have run out of previously prescribed medication or have had previous prescriptions lost or stolen.

6. Physicians should avoid using intravenous or intramuscular opioid injections for patients with exacerbations of chronic non-cancer pain in the emergency department or urgent care setting.

7. Physicians are encouraged to review the patient's history of controlled substance prescriptions using the Wisconsin Prescription Drug Monitoring Program (PDMP) data to determine whether the patient is receiving opioid dosages or dangerous combinations that put him or her at high risk for overdose. As of April, 2017, Wisconsin state law requires prescribers to review the PDMP before prescribing any controlled substance for greater than a three-day supply.

8. Pain from acute trauma or chronic degenerative diseases can oftentimes be managed without opioids prior to surgery. Surgical patients using opioids preoperatively have higher complications rates, require more narcotics postoperatively, and have lower satisfaction rates with poorer outcomes following surgery.

9. Prescribing of opioids is not encouraged in patients concurrently taking benzodiazepines or other respiratory depressants. Benzodiazepines triple the already high increases in annual mortality rates from opioids. If they are used concurrently, clear clinical rationale must exist.

10. The use of oxycodone is discouraged. There is no evidence to support that oxycodone is more effective than other oral opioids, while there are multiple studies indicating that oxycodone is more abused and has qualities that would promote addiction to a greater degree than other opioids. As a result, oxycodone should not be considered first-line and should be used only in patients who cannot tolerate other opioids and who have been evaluated for and found not to demonstrate increased risk of abuse.

11. Patients presenting for chronic pain treatment should have a thorough evaluation, which may include the following:

a. Medical history and physical examination targeted to the pain condition

b. Nature and intensity of the pain

c. Current and past treatments, with response to each treatment

d. Underlying or co-existing diseases or conditions, including those which could complicate treatment (i.e., renal disease, sleep apnea, COPD, etc.)

e. Effect of pain on physical and psychological functioning

f. Personal and family history of substance abuse

g. History of psychiatric disorders associated with opioid abuse (bipolar, ADD/ADHD, sociopathic, borderline, untreated/severe depression)

h. Medical indication(s) for use of opioids.

12. Initiation of opioids for chronic pain should be considered on a trial basis. Prior to starting opioids, objective symptomatic and functional goals should be established with the patient. If after a reasonable trial these goals are not met, then opioids should be weaned or discontinued.

13. Practitioners should always consider the risk-benefit ratio when deciding whether to start or continue opioids. Risks and benefits should be discussed with patients prior to initiating chronic opioid therapy, and continue to be reassessed during that therapy. If evidence of increased risk develops, weaning or discontinuation of opioids should be considered. If evidence emerges that indicates that the opioids put a patient at the risk of imminent danger (overdose, addiction, etc.), or that they are being diverted, opioids should be discontinued and the patient should be treated for withdrawal, if needed.

a. Exceptions to this include patients with unstable angina and pregnant patients, especially in the 3rd trimester (withdrawal could precipitate pre-term labor).

b. Components of ongoing assessment of risk include:

i. Review of the Prescription Drug Monitoring Program (PDMP) information

ii. Periodic urine drug testing (including chromatography) – at least yearly in low risk cases, more frequently with evidence of increased risk

iii. Periodic pill counts – at least yearly in low risk cases, more frequently if evidence of increased risk

iiii. Violations of the opioid agreement

- 14.** All patients on chronic opioid therapy should have informed consent consisting of:
- a.** Specifically detailing significant possible adverse effects of opioids, including (but not limited to) addiction, overdose, and death
 - b.** Treatment agreement, documenting the behaviors required of the patient by the prescribing practitioner to ensure that they are remaining safe from these adverse effects
- 15.** Initial dose titration for both acute and chronic pain should be with short-acting opioids. For chronic therapy, it would be appropriate once an effective dose is established to consider long-acting agents for a majority of the daily dose.
- 16.** Opioids should be prescribed in the lowest effective dose. This includes prescribing the lowest effective dose for the shortest possible duration for post-operative care and acutely-injured patients. If daily doses for chronic pain reach 50 morphine milligram equivalents (MMEs), additional precautions should be implemented (see #13.b. above). Given that there is no evidence base to support efficacy of doses over 90 MMEs, with dramatically increased risks, dosing above this level is strongly discouraged, and appropriate documentation to support such dosing should be present on the chart.
- 17.** The use of methadone is not encouraged unless the practitioner has extensive training or experience in its use. Individual responses to methadone vary widely; a given dose may have no effect on one patient while causing overdose in another. Metabolism also varies widely and is highly sensitive to multiple drug interactions, which can cause accumulation in the body and overdose. For a given analgesic effect, the respiratory depressant effect is much stronger compared to other opioids. Finally, methadone can have a potent effect on prolonging the QTc, predisposing susceptible patients to potentially fatal arrhythmias.
- 18.** Prescribing of opioids is strongly discouraged for patients abusing illicit drugs. These patients are at extremely high risk for abuse, overdose, and death. If opioids are prescribed to such patients, a clear and compelling justification should be present.
- 19.** During initial opioid titration, practitioners should re-evaluate patients every 1-4 weeks. During chronic therapy, patients should be seen at least every 3 months, more frequently if they demonstrate higher risk.
- 20.** Practitioners should consider prescribing naloxone for home use in case of overdose for patients at higher risk, including:
- a.** History of overdose (a relative contraindication to chronic opioid therapy)
 - b.** Opioid doses over 50 MMEs/day
 - c.** Clinical depression
 - d.** Evidence of increased risk by other measures (behaviors, family history, PDMP, UDS, risk questionnaires, etc.)

The recommended dose is 0.4 mg for IM or intranasal use, with a second dose available if the first is ineffective or wears off before EMS arrives. Family members can be prescribed naloxone for use with the patient.

21. All practitioners are expected to provide care for potential complications of the treatments they provide, including opioid use disorder. As a result, if a patient receiving opioids develops behaviors indicative of opioid use disorder, the practitioner should be able to assist the patient in obtaining addiction treatment, either by providing it directly (buprenorphine, naltrexone, etc. plus behavioral therapy) or referring them to an addiction treatment center which is willing to accept the patient. Simply discharging a patient from the provider's practice after prescribing the medication that led to the complication of opioid use disorder is not considered acceptable.

22. Discontinuing Opioid Therapy

A. If lack of efficacy of opioid therapy is determined, discontinuation of therapy should be performed.

1. Opioid weaning can be performed by reducing the MED by 10% weekly until 5-10mg MED remain at which time the opioid can be fully discontinued.

2. Prescription of clonidine 0.2 mg po BID or tizanidine 2mg po TID can be provided to patients complaining of opioid withdrawal related symptoms.

B. If evidence of increased risk develops, weaning or discontinuation of opioid should be considered.

1. Opioid weaning can be performed by reducing the MED by 25% weekly until 5-10mg MED remain at which time the opioid can be fully discontinued.

2. Prescription of clonidine 0.2 mg po BID or tizanidine 2mg po TID can be provided to patients complaining of opioid withdrawal related symptoms.

3. Physicians can consider weekly or bi-monthly follow-up during the weaning process.

C. If evidence emerges that indicates that the opioids put a patient at the risk of imminent danger (overdose, addiction, etc.), or that they are being diverted, opioids should be immediately discontinued and the patient should be treated for withdrawal, if needed.

1. Exceptions to abrupt opioid discontinuation include patients with unstable angina and pregnant patients. These patients should be weaned from the opioid medications in a gradual manner with close follow-up.

Resources

CDC Guideline for Prescribing Opioids for Chronic Pain--United States 2016. Dowell D1, Haegerich TM1, Chou R1., JAMA. 2016 Apr 19;315(15):1624-45. doi:10.1001/jama.2016.1464.

Chronic Opioid Clinical Management Guidelines for Wisconsin Worker's Compensation Patient Care. <https://dwd.wisconsin.gov/wc/medical/pdf/CHRONIC%20OPIOID%20CLINICAL%20MANAGEMENT%20GUIDELINES%20.pdf>

Within-subject comparison of the psychopharmacological profiles of oral oxycodone and oral morphine in non-drug-abusing volunteers. Zacny, James, & Lichtor, Stephanie. Psychopharmacology (2008) 196:105-116

Subjective, Psychomotor, and Physiological Effects Profile of Hydrocodone/Acetaminophen and Oxycodone/Acetaminophen Combination Products. Zachny, James, & Gutierrez, Sandra. Pain Medicine (2008) Vol 9, No 4: 433-443

Positive and Negative Subjective Effects of Extended-Release Oxymorphone versus Controlled-Release Oxycodone in Recreational Opioid Users. Schoedel, Kerri et. al. Journal of Opioid Management 7:3 May/June 2011. 179-192

Tapentadol Abuse Potential: A Postmarketing Evaluation Using a Sample of Individuals Evaluated for Substance Abuse Treatment. Stephen F. Butler, PhD et. al., Pain Medicine 2015; 16: 119–130

Methadone Safety: A Clinical Practice Guideline from the American Pain Society and College on Problems of Drug Dependence, in collaboration with the Heart Rhythm Society. Chou R1, et. al., J Pain. 2014 Apr;15(4):321-37

Emerging Issues in the Use of Methadone. SAMHSA Substance Abuse Treatment Advisory, Spring 2009, Volume 8, Issue 1, available at <http://store.samhsa.gov/shin/content//SMA09-4368/SMA09-4368.pdf>

Opioid Use, Misuse, and Abuse in Orthopedic Practice. American Academy of Orthopedic Surgeons, Information Statement 1045, October, 2015, available at <http://www.aaos.org/PositionStatements/Statement1045/?ssopc=1>

Wisconsin Medical Society Opioid Prescribing Principles. <https://www.wisconsinmedicalsociety.org/advocacy/boards-councils/society-initiatives/opioid-task-force/opioid-prescribing-principles/>

Comments from June Dahl, Professor of Pharmacology, University of Wisconsin Medical School

1. I question the accuracy of the statement in 4a that *Evidence for opioids for acute pain is weak*. Opioids would be the drugs of choice for severe acute pain so am puzzled about the origins of that comment.
2. Am puzzled by the statement in 4b that tricyclics, SRNIs, and anticonvulsants would be used to for treatment of acute pain in the situation described. Those drugs are used in the treatment of neuropathic pain. It is true that gabapentin is used in the treatment of acute postoperative pain but that's not the focus of this statement.
3. Paragraph 8 is puzzling. The management of acute pain in persons who are on chronic opioids is very challenging. They will need higher than "typical" doses of opioids and they may go through withdrawal if the dose used to manage acute pain is less than the dose they were receiving chronically. This section doesn't address that optimally.
4. Paragraph 9. Co-prescribing of opioids and benzodiazepines is very dangerous - I think this risk could be emphasized even more strongly.
5. Paragraph 10. The dangers associated with oxycodone have decreased with reformulation of Oxycontin. I provide a reference from the New England Journal of Medicine that provides the data about abuse. Hydrocodone was moved to Schedule II in October, 2014 because of its abuse. I can't find the data from 2010-2012, but I thought it was more abused than oxycodone. Of course, the short-acting formulation is only available with acetaminophen; that increases the risk of hepatotoxicity. Codeine is a problematic opioid. It is not recommended for the treatment of pain in children. That's an opioid to avoid.

Although this Guideline and the CDC guideline focus on opioids, one can not ignore the risks associated with the use of NSAIDs. Hospitalizations and deaths associated with the use of those drugs have decreased significantly in the last dozen years. Recent guidelines promote the use of NSAIDs; I am concerned that there may be an increase in adverse events associated with the use of those agents.

Kenneth Simons
Chairperson

Timothy Westlake
Vice Chairperson

Mary Jo Capodice
Secretary

WISCONSIN MEDICAL EXAMINING BOARD



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Wisconsin Medical Examining Board Opioid Prescribing Guideline

Scope and purpose of the guideline: To help providers make informed decisions about acute and chronic pain treatment -pain lasting longer than three months or past the time of normal tissue healing. The guideline is not intended for patients who are in active cancer treatment, palliative care, or end-of-life care. Although not specifically designed for pediatric pain, many of the principals upon which they are based could be applied there, as well.

Opioids pose a potential risk to all patients. The guideline encourages providers to implement best practices for responsible prescribing which includes prescribing the lowest effective dose for the shortest possible duration for post-operative care and acutely-injured patients.

1) Identify and treat the cause of the pain, use non-opioid therapies

Use non-pharmacologic therapies (such as yoga, exercise, cognitive behavioral therapy and complementary/alternative medical therapies) and non-opioid pharmacologic therapies (such as acetaminophen and **anti-inflammatories** [does this mean NSAIDs?](#)) for acute and chronic pain. Don't use opioids routinely for chronic pain. When opioids are used, combine them with non-pharmacologic or non-opioid pharmacologic therapy, as appropriate, to provide greater benefits.

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2) Start low and go slow

When opioids are used, prescribe the lowest ~~possible~~ effective dosage and start with ~~immediate-release-short-acting~~ opioids instead of extended-release/long-acting opioids. Only provide the quantity needed for the expected duration of pain. [Correct term is used in item 15. Immediate release is a drug company creation that has no clear meaning.](#)

3) Close follow-up

Regularly monitor patients to make sure opioids are improving pain and function without causing harm. If benefits do not outweigh harms, optimize other therapies and work with patients to taper or discontinue opioids, if needed.

What's included in the guideline?

The guideline addresses patient-centered clinical practices including conducting thorough assessments, considering all possible treatments, treating the cause of the pain, closely monitoring risks, and safely discontinuing opioids. The three main focus areas in the guideline include:

1) Determining when to initiate or continue opioids

- Selection of non-pharmacologic therapy, non-opioid pharmacologic therapy, opioid therapy
- Establishment of treatment goals
- Discussion of risks and benefits of therapy with patients

2) Opioid selection, dosage, duration, follow-up and discontinuation

- Selection of ~~immediate-release~~[short-acting](#) or extended-release and long-acting opioids
- Dosage considerations
- Duration of treatment
- Considerations for follow-up and discontinuation of opioid therapy

3) Assessing risk and addressing harms of opioid use

- Evaluation of risk factors for opioid-related harms and ways to mitigate/reduce [patient](#)-risk
- Review of prescription drug monitoring program (PDMP) data
- Use of urine drug testing
- Considerations for co-prescribing benzodiazepines
- Arrangement of treatment for opioid use disorder?[Treatment of opioid use disorder](#)

Prescription Opioid Guideline

1. Pain is a subjective experience and at present, physicians lack options to objectively quantify pain severity other than by patient reported measures including pain intensity. While accepting the patient's report of pain, the clinician must simultaneously decide if the magnitude of the pain complaint is commensurate with causative factors and if these have been adequately evaluated and addressed with non-opioid therapy.

2. In treating acute pain, if opioids are ~~at all~~-indicated, the lowest dose and fewest number of ~~opioid pills~~ [tablets](#) needed should be prescribed. In most cases, less than 3 days' worth are necessary~~???~~ [evidence for this?](#), and rarely more than 5 days' worth. Left-over pills in medicine cabinets are often the source for illicit opioid abuse in teens and young adults. [This is really important.](#) When prescribing opioids, physicians should consider writing two separate prescriptions for smaller amounts of opioids with specific refill dates, rather than a single large prescription. Most patients do not fill the second prescription, thus limiting opioid excess in a patient's home and potential misuse.

3. A practitioner's first priority in treating a patient in pain is to identify the cause of the pain and, if possible, to treat it. While keeping the patient comfortable during this treatment is important, it is critical to address to the extent possible the underlying condition as the primary objective of care.

a. Patients unwilling to obtain definitive treatment for the condition causing their pain should be considered questionable candidates for opioids. If opioids are prescribed to such patients, documentation of clear clinical rationale should exist.

b. Opioids should not be prescribed unless there is a medical condition present which would reasonably be expected to cause pain severe enough to require an opioid. For conditions where this is questionable, use of other treatments instead of opioids should be strongly considered.

c. Consultation should be considered if diagnosis of and/or treatment for the condition causing the pain is outside of the scope of the prescribing practitioner.

4. Opioids should not necessarily be the first choice in treating acute or chronic pain.

a. Acute pain: ~~Evidence for opioids is weak.~~ [What is the evidence for this statement? Opioids would be the drugs of choice for severe acute pain.](#) Other treatments such as acetaminophen, ~~anti-inflammatory~~ [NSAIDs?](#), and non-pharmacologic treatments should be attempted prior to initiating opioid

therapy. Although opioids could be simultaneously prescribed if it is apparent from the patient's condition that he/she will need opioids in addition to these. Don't use opioids routinely for chronic pain. When opioids are used, combine them with non-pharmacologic or non-opioid pharmacologic therapy, as appropriate, to provide greater benefits.

b. Acute pain lasting beyond the expected duration: A complication of the acute pain issue (surgical complication, nonunion of fracture, etc.) should be ruled out. If complications are ruled out, a transition to non-opioid therapy (~~tricyclic antidepressant, serotonin/norepinephrine re-uptake inhibitor, anticonvulsant, etc.~~) should be attempted. Such drugs would only be appropriate if the patient has neuropathic pain.

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c. Chronic pain: ~~Evidence for opioids is poor. Don't think this is true; the evidence is lacking. There is insufficient evidence to determine the effectiveness of long-term opioid therapy OR The safety and efficacy of long-term opioid therapy hasn't been determined.~~ Other treatments such as acetaminophen, ~~anti-inflammatories,~~ does this mean NSAIDs? and non-pharmacologic treatments (such as yoga, exercise, cognitive behavioral therapy and complementary/alternative medical therapies) should be utilized. Multiple meta- analyses demonstrate that the benefits of opioids are slight, while annualized mortality rates dramatically increased. There are few if any treatments in medicine with this poor a risk/benefit ratio, and there should be adequate clinical indication to indicate why chronic opioid therapy was chosen in a given patient. **Note:** There is no high-quality evidence to support opioid therapy longer than 6 months in duration. Despite this fact, it is considered acceptable although not preferable to continue patients on treatment who have been on chronic opioid therapy prior to this Guideline's release and who have shown no evidence of aberrant behavior. There are significant risks associated with the use of NSAIDs, especially in the elderly.

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d. Patients unwilling what about patients whose insurance will not pay for non-pharmacological therapies? to accept non-pharmacological and/or ~~nonnarcotic non-opioid~~ treatments (or those providing questionably credible justifications for not using them) should not be considered candidates for opioid therapy.

5. Patients should not receive opioid prescriptions from multiple physicians. There should be a dedicated provider such as a primary care or pain specialist to provide all opioids used in treating any patient's chronic pain, with existing pain ~~contracts agreements~~ being honored. Physicians should avoid prescribing ~~controlled substances- opioids?~~ for patients who have run out of previously prescribed medication or have had previous prescriptions lost or stolen. Is it the prescriptions that are lost or stolen or the medications?

6. Physicians should avoid using intravenous or ~~intramuscular~~ shouldn't IM injections always be avoided? opioid injections for patients with exacerbations of chronic non-cancer pain in the emergency department or urgent care setting.

7. Physicians are encouraged to review the patient's history of controlled substance prescriptions using the Wisconsin Prescription Drug Monitoring Program (PDMP) data to determine whether the patient is receiving opioids ~~dosages~~ or dangerous combinations that put him or her at high risk for overdose. As of April, 2017, Wisconsin state law requires prescribers to review the PDMP before prescribing more than a three-day supply of any controlled ~~substance~~ substance. ~~for greater than a three-day supply.~~

~~8-8.~~ Pain from acute trauma or chronic degenerative diseases can oftentimes be managed without opioids prior to surgery. Is it really true that pain from acute trauma can often be managed without opioids? Surgical patients using opioids preoperatively have higher complications rates, require more ~~narcotics~~ opioids postoperatively, and have lower

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satisfaction rates with poorer outcomes following surgery. The second sentence is confusing. The impact of opioid use preoperatively would depend on how long the drugs were used. Of course, patients would require more opioids after surgery if they had needed opioids before – they might have developed tolerance and would likely have developed physical dependence. They would experience withdrawal if their opioid dose after surgery were smaller than the dose they were receiving prior to surgery. Think this point needs to be revisited because the management of postoperative pain in persons who have been on opioid therapy is very challenging.

9.9. Prescribing of opioids is not encouraged in patients concurrently taking benzodiazepines or other respiratory depressants. Believe this point needs to be made more strongly. Opioids and bzs are a lethal combination. Benzodiazepines triple the already high increases in annual mortality rates from opioids. If they are used concurrently, clear clinical rationale must exist.

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10. The use of oxycodone is discouraged. There is no evidence to support that oxycodone is more effective than other oral opioids, while there are multiple studies indicating that oxycodone is more abused and has qualities that would promote addiction to a greater degree than other opioids. As a result, oxycodone should not be considered first-line and should be used only in patients who cannot tolerate other opioids and who have been evaluated for and found not to demonstrate increased risk of abuse. [Don't understand the rationale for this paragraph. The abuse of oxycodone has decreased since the reformulation of Oxycontin.NEJM, 2015, 372\(3\), 241-248. Codeine is the opioid whose use should be discouraged. Morphine has active metabolites; oxycodone does not.](#)

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11. Patients presenting for chronic pain treatment should have a thorough evaluation, which may include the following:

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- a. Medical history and physical examination targeted to the pain condition
- b. Nature and intensity of the pain
- c. Current and past treatments, with response to each treatment
- d. Underlying or co-existing diseases or conditions, including those which could complicate treatment (i.e., renal disease, sleep apnea, COPD, etc.)
- e. Effect of pain on physical and psychological functioning
- f. Personal and family history of substance abuse?? [should the term substance use disorder be used?](#)
- g. History of psychiatric disorders associated with opioid abuse (bipolar, ADD/ADHD, sociopathic, borderline, untreated/severe depression) [What about a psychiatric history not associated with opioid abuse?](#)
- h. Medical indication(s) for use of opioids.

12. Initiation of opioids for chronic pain should be considered on a trial basis. Prior to starting opioids, objective symptomatic and functional goals should be established with the patient. If after a reasonable trial these goals are not met, then opioids should be ~~weaned-tapered~~ or discontinued. [The patient is weaned, the drugs are tapered.](#)

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13. Practitioners should always consider the risk-benefit ratio when deciding whether to start or continue opioids. Risks and benefits should be discussed with patients prior to initiating ~~chronic~~ opioid therapy, and continue to be reassessed during that therapy. If evidence of increased risk develops, weaning or discontinuation of opioids should be considered. If evidence emerges that indicates that the opioids put a patient at the risk of imminent danger (overdose, addiction, etc.), or that they are being diverted, opioids should be discontinued and the patient should be treated for withdrawal, if needed.

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- a. Exceptions to this include patients with unstable angina and pregnant patients, especially in the 3rd trimester (withdrawal could precipitate pre-term labor).
- b. Components of ongoing assessment of risk include:
 - i. Review of the Prescription Drug Monitoring Program (PDMP) information
 - ii. Periodic urine drug testing ~~(including chromatography) ???~~ – at least yearly in low risk cases, more frequently with evidence of increased risk
 - iii. Periodic pill counts – at least yearly in low risk cases, more frequently if evidence of increased risk

iv. Violations of the opioid agreement

14. 14.All patients on chronic opioid therapy should have informed consent consisting of:

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a. Specifically detailing significant possible adverse effects of opioids, including (but not limited to) addiction, overdose, and death

b. Treatment agreement, documenting the behaviors required of the patient by the prescribing practitioner to ensure that they are remaining safe from these adverse effects

~~15.8.~~ 15.Initial dose titration for both acute and chronic pain should be with short-acting opioids. For chronic therapy, it would be appropriate once an effective dose is established to consider long- acting agents for a majority of the daily dose.

~~16.9.~~ 16.Opioids should be prescribed in the lowest effective dose. This includes prescribing the lowest effective dose for the shortest possible duration for post-operative care and acutely-injured patients. If daily doses for chronic pain reach 50 morphine milligram equivalents (MMEs), additional precautions should be implemented (see #13.b. above). Given that there is no evidence base to support efficacy of doses over 90 MMEs, with dramatically increased risks, dosing above this level is strongly discouraged, and appropriate documentation to support such dosing should be present on the chart.

17. 17.The use of methadone is not encouraged unless the practitioner has extensive training or experience in its use. Very important! Individual responses to methadone vary widely; a given dose may have no effect on one patient while causing overdose in another. Metabolism also varies widely and is highly sensitive to multiple drug interactions, which can cause accumulation in the body and overdose. For a given analgesic effect, the respiratory depressant effect is much stronger compared to other opioids. ?? is the preceding sentence really true? What is the evidence? Finally, methadone can ~~have a potent effect on prolonging the~~prolong the QTc, predisposing susceptible patients to potentially fatal arrhythmias.

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18. 18.Prescribing of opioids is strongly discouraged for patients who are abusing illicit drugs.Why would one ever prescribe opioids for such patients? Such prescribing would seem to be contraindicated. These patients are at extremely high risk for abuse, overdose, and death. If opioids are prescribed to such patients, a clear and compelling justification should be present.

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19. 19.During initial opioid titration, practitioners should re-evaluate patients every 1-4 weeks. During chronic therapy, patients should be seen at least every 3 months, more frequently if they demonstrate higher risk.

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20. 20.Practitioners should consider prescribing naloxone for home use in case of overdose for patients at higher risk, including:

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a. History of overdose (a relative contraindication to chronic opioid therapy)

b. Opioid doses over 50 MMEs/day

c. Clinical depression

d. Evidence of increased risk ~~by other measures~~ ???? sorry don't understand; the introductory sentence refers to higher risk. Aren't these already cited in 13 above? (behaviors, family history, PDMP, UDS, risk questionnaires, etc.)

The recommended dose is 0.4 mg for IM or intranasal use, with a second dose available if the first is ineffective or wears off before EMS arrives. Family members can be prescribed naloxone for use with the patient.

~~21.~~ 21. All practitioners are expected to provide care for potential complications of the treatments they provide, including opioid use disorder. As a result, if a patient receiving opioids develops behaviors indicative of opioid use disorder, the practitioner should be able to assist the patient in obtaining addiction treatment, either by providing it directly (buprenorphine, naltrexone, etc. plus behavioral therapy) or referring them to an **addiction treatment center** what kind of center? a methadone maintenance program or something else? which is willing to accept the patient. **Simply discharging a patient from the provider's practice after prescribing the medication that led to the complication of opioid use disorder is not considered acceptable.** Is it unacceptable or is it considered to be in the realm of malpractice?

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~~22.~~ 22. Discontinuing Opioid Therapy This section needs to be revised: unusual/unclear wording

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A. If lack of efficacy of opioid therapy is determined, discontinuation of therapy should be performed. Unusual wording, e.g., don't think one performs discontinuation.

1. Opioid weaning-tapering can be performed by reducing the MED what is MED? by 10% weekly until 5-10mg MED remain at which time the opioid can be fully discontinued. don't literally perform weaning.

2. Prescription of clonidine 0.2 mg po BID or tizanidine 2mg po TID can be provided to patients complaining of opioid withdrawal related symptoms. don't literally provide prescription to patients

B. If evidence of increased risk develops, weaning or discontinuation of opioid should be considered. again question wording

1. Opioid weaning can be performed by reducing the MED by 25% weekly until 5-10mg MED remain at which time the opioid can be fully discontinued.

2. Prescription of clonidine 0.2 mg po BID or tizanidine 2mg po TID can be provided to patients **complaining** better to write that patients report rather than that they complain of opioid withdrawal related symptoms.

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3. Physicians can consider weekly or bi-monthly follow-up during the weaning process. what does this mean?

C. If evidence emerges that indicates If there is evidence that.... that the opioids put a patient at the risk of imminent danger (overdose, addiction, etc.), or that they are being diverted, opioids should be immediately discontinued and the patient should be treated for withdrawal, if needed. how does one treat for withdrawal and how does one decide if treatment is needed?

1. Exceptions to abrupt opioid discontinuation include patients with unstable angina and pregnant patients. These patients should be weaned from the opioid medications in a gradual manner with close follow-up.

Resources [There are more recent relevant references](#)

CDC Guideline for Prescribing Opioids for Chronic Pain--United States 2016. Dowell D1, Haegerich TM1, Chou R1., JAMA. 2016 Apr 19;315(15):1624-45. doi:10.1001/jama.2016.1464.

Chronic Opioid Clinical Management Guidelines for Wisconsin Worker's Compensation Patient Care. <https://dwd.wisconsin.gov/wc/medical/pdf/CHRONIC%20OPIOID%20CLINICAL%20MANAGEMENT%20GUIDELINES%20.pdf>

Within-subject comparison of the psychopharmacological profiles of oral oxycodone and oral morphine in non-drug-abusing volunteers. Zaczny, James, & Lichtor, Stephanie. Psychopharmacology (2008) 196:105-116

Subjective, Psychomotor, and Physiological Effects Profile of Hydrocodone/Acetaminophen and Oxycodone/Acetaminophen Combination Products. Zaczny, James, & Gutierrez, Sandra. Pain Medicine (2008) Vol 9, No 4: 433-443

Positive and Negative Subjective Effects of Extended-Release Oxymorphone versus Controlled-Release Oxycodone in Recreational Opioid Users. Schoedel, Kerri et. al. Journal of Opioid Management 7:3 May/June 2011. 179-192

Tapentadol Abuse Potential: A Postmarketing Evaluation Using a Sample of Individuals Evaluated for Substance Abuse Treatment. Stephen F. Butler, PhD et. al., Pain Medicine 2015; 16: 119-130

Methadone Safety: A Clinical Practice Guideline from the American Pain Society and College on Problems of Drug Dependence, in collaboration with the Heart Rhythm Society. Chou R1, et. al., J Pain. 2014 Apr;15(4):321-37

Emerging Issues in the Use of Methadone. SAMHSA Substance Abuse Treatment Advisory, Spring 2009, Volume 8, Issue 1, available at <http://store.samhsa.gov/shin/content//SMA09-4368/SMA09-4368.pdf>

Opioid Use, Misuse, and Abuse in Orthopedic Practice. American Academy of Orthopedic Surgeons, Information Statement 1045, October, 2015, available at <http://www.aaos.org/PositionStatements/Statement1045/?ssopc=1>

Wisconsin Medical Society Opioid Prescribing Principles. <https://www.wisconsinmedicalsociety.org/advocacy/boards-councils/society-initiatives/opioid-task-force/opioid-prescribing-principles/>

From: james LINCER [<mailto:lincer5@aol.com>]
Sent: Thursday, June 09, 2016 1:14 PM
To: Dernbach, BJ - DWD
Cc: O'Malley, Jim T - DWD; Mike Slawny; Nancy Bratanow, MD
Subject: Re: Pain Specialist

Dear BJ Dernbach,

Thank you for your response to my concern regarding lack of definition of who is a pain medicine specialist. This is a topic that has gathered a significant amount of attention lately, in part due to the opioid problem and in part from the Institute of Medicine report regarding the problem of pain and pain treatment in America. There are now eleven states and the United States Veterans Health Administration that have specifically identified Diplomates of the American Board of Pain Medicine (ABPM) as meeting criteria to be designated as Pain specialists. The eleven states are Alabama, California, Florida, Georgia, Kentucky, Michigan, Ohio, Rhode Island, Tennessee, Texas, Washington and most recent - West Virginia. As you can see, ABPM diplomates are widely considered as experts in pain medicine and recognized as such by the VA and the three largest states in the nation (as well as other states). There are states that have not yet defined who is a Pain Medicine practitioner. It is believed the Wisconsin should join in the effort to protect the health and safety of the population by defining who is a pain doctor.

I invite you to visit the website of the American Board of Pain Medicine (ABPM.org) to review our standards and mission. Please note the Recognition area which details the state recognition legislation.

I request that the Wisconsin Work Comp. guidelines clearly stipulate that a pain medicine physician is one that holds certification from the ABPM or subspecialty certification from the American Board of Medical Specialties. This will help to clarify the guidelines and help protect the public by identifying those physicians that are recognized by reputable institutions as qualified pain physicians.

I will enclose ABPM literature for your review.

Feel free to contact me with any questions.

James D. Lincer, MD

President, American Board of Pain Medicine



A Call for State Action: **Provide Guidance on Qualifications Needed to Serve as Pain Medicine Specialists**

In the interest of improving the quality of medical care for the 100 million patients in the U.S. who suffer from pain, the American Board of Pain Medicine calls on state policymakers to more clearly define the credentials of physicians who have demonstrated training, skills and clinical experience needed to provide specialist-level medical care for those patients who suffer from acute or persistent pain. Clearer definitions are needed within laws or regulations that establish protocols for opioid prescribing, standards for owning or operating pain clinics and advertising restrictions that protect the public from misleading statements by health care practitioners claiming to be “pain specialists.”



About the ABPM and our Mission

The mission of the American Board of Pain Medicine (ABPM) is to serve the public by improving access to comprehensive, high quality pain care in the U.S. through a rigorous certification process for Pain Medicine physician specialists. Since 1992, ABPM has offered qualified candidates an eight-hour, comprehensive, psychometrically valid examination in the field of Pain Medicine. Certified ABPM Diplomates now number over 2,300 physicians. ABPM believes in an integrated approach to comprehensive pain care that includes demonstrated clinical experience and substantive expertise in the full spectrum of pain treatment therapies, including pharmacologic, psychological, interventional and complimentary therapies. Successfully passing our examination demands that applicants demonstrate thorough knowledge in all areas of Pain Medicine, including but in no way limited to expertise in safe and appropriate prescribing of opioids, which are often over-prescribed by practitioners who do not understand the additional modalities of effective pain treatment.

ABPM's Credentialing Standards

ABPM's Credentials Committee carefully reviews every candidate's application in order to determine eligibility to sit for the examination based on meeting all the following requirements:

- 1) Satisfactory completion of an ACGME-accredited residency-training program relevant to pain medicine, primarily in anesthesiology, neurological surgery, neurology, psychiatry or physical medicine and rehabilitation. The applicant must otherwise demonstrate satisfactory completion of an ACGME-accredited training program with substantial, identifiable training in Pain Medicine with equivalent scope, content and duration to one of these five specialties.
- 2) Possession of a current, valid, unrestricted US license to practice allopathic or osteopathic medicine as well as a valid and unrestricted DEA number.
- 3) Current certification by an ABMS member board in a medical specialty with training relevant to pain medicine.
- 4) Substantial, recent and comprehensive clinical practice experience in Pain Medicine. ABPM's Credentials Committee carefully assesses every applicant's clinical experience and applies strict criteria related thereto in judging an applicant's standing to sit for the examination.
- 5) Completion of a minimum of 50 hours of Category I Continuing Medical Education in Pain Medicine within the two years prior to the initial examination, and
- 6) Documentation that he or she adheres to ethical and professional standards and has a good practice performance record.

Applicants who meet all of these criteria and pass our examination are granted Diplomate status (DABPM). Once certified, ABPM requires recertification every 10 years through our "MOC" process, which involves satisfactory assessment by our Credentials Committee relating to a Diplomate's professional standing, completion of CME requirements (300 hours of pertinent CME within the ten years, with at least 100 of those in the three years preceding recertification).



I. Overview

Our nation's policymakers have focused considerable attention on how to address the public health crisis stemming from rampant opioid abuse and diversion. At the same time, there is growing understanding of the need to improve the way our nation's health care system delivers care to the over 100 million Americans suffering from pain. Given these twin challenges, government and physician leaders alike must work to devise a system that provide more comprehensive, effective pain care to this enormous population of patients and also protect them from unqualified or unscrupulous practitioners who engage in prescribing practices that contribute to opioid abuse. States have been on the forefront of efforts to accomplish these goals by adopting a range of regulatory initiatives, including:

- **Opioid Prescribing Protocols** – In an effort to improve prescribing practices of all health care providers, states are adopting regulations to establish medical practice protocols for prescribers to follow when treating patients who require prescriptions for opioid analgesics, including when to refer or consult with a pain specialist. This effort aligns with physician organizations' work to educate all prescribers on appropriate standards of practice when prescribing opioids.
- **Pain Clinic or Anti "Pill Mill" Regulations** – Several states have addressed inappropriate prescribing by certain health care providers with substandard prescribing practices, seen in regulations designed to halt the influx of "pill mills" that churn patients seeking prescriptions for opioids established regulations that establish restrictions over the ownership/operation of pain clinics. Including a clear definition of "pain specialists" in the Model Policy will provide another weapon in states' arsenal in the battle against the operators of these establishments.
- **Advertising Restrictions** – State medical boards in some states have restricted the ability of health care practitioners from advertising themselves as "board-certified" unless the state recognizes the medical specialty board that issued the practitioner's certification. In the context of Pain Medicine specialists, ABPM supports this approach as a way to combat overstated claims of expertise in pain management by practitioners, including those representing themselves as holding some level of certification from entities with standards that are much less rigorous than those employed by ABMS boards or by ABPM.
- **Continuing Medical Education requirements** – Some states are considering continuing medical education requirements specific to safe and effective prescribing practices.
- **Prescription Drug Monitoring Programs ("PDMPs")** – States have established these databases to improve communications between prescribers and protect patients from prescriptions for multiple opioids, which can occur inadvertently or through active "physician shopping" by patients.

While there is general agreement regarding many of these policies, there is legitimate concern among physician organizations that government efforts to combat these problems will have a chilling effect on appropriate use of opioid analgesics in caring for patients who suffer from chronic or acute pain. Striking the appropriate balance is critical.



This paper shares the ABPM's perspectives on one under-examined aspect of this policy discussion: **the need for states to more clearly define the qualifications of physicians who have demonstrated training, skills and clinical experience needed to provide specialty-level medical care, own or oversee a "pain clinic" or advertise their qualifications to the public as a "pain medicine specialist."**

II. System Problems

All too often, the current health care system's approach to treating pain produces uneven, fragmented and poorly coordinated delivery of care. This has contributed to the rampant abuse of opioid analgesics, over-use of expensive procedures, and an unacceptably wide variation in the quality and breadth of pain care. In our view, a better system would have the following key characteristics:

- Deliver pain care through a multi-disciplinary, team-based approach;
- Provide better training for all physicians in how to most effectively treat pain;
- Increase research on effective treatments to inform evidence-based treatment protocols for treating pain; and
- Establish comprehensive, coherent and accredited graduate medical education programs in pain medicine, which would increase the supply of Pain Medicine specialists and establish more consistent training and qualifications within this field.

❖ *Inadequate training*

Threading state policy discussions is a legitimate concern regarding the adequacy of training for physicians and other health care providers who prescribe opioid analgesics while treating patients with pain. There is wide agreement among state policymakers and physician organizations, including ABPM, regarding the need for enhanced education and more consistent clinical guidance to inform patient care. In our view, it is important that physicians and physician organizations play a lead role in addressing system-wide shortcomings that contribute to substandard pain care and aggravate the prescription drug abuse problem. Physician organizations must enhance the curricula relating to effective pain care in medical education and graduate medical education programs to improve training for all physicians and work to develop and implement effective clinical pain treatment protocols for specific medical conditions.

❖ *Inadequate access to specialists*

The 2011 Institute of Medicine report "Pain in America: A Blueprint for Transforming Prevention, Care, Education and Research," details how access to high quality, cost-effective care continues to prove elusive for many of the 116 million-plus Americans who suffer from chronic pain. The IOM report reflects that there is only one certified Pain Medicine specialist for every 28,500 people with pain. This severe shortage of pain medicine specialists impedes efforts to develop efficient, cost-effective health care delivery models for treating this vast population of patients with chronic pain. With the undersupply of competent pain medicine consultation options, primary care physicians often have difficulty referring patients with complex pain problems to specialists.



❖ ***Confusion about who qualifies as a “pain medicine specialist”***

Currently, the term “pain medicine specialist” is confusing for all health system stakeholders, including:

- Policymakers seeking to protect the public from unqualified practitioners, regulate pain clinics and establish opioid prescribing protocols;
- Patients seeking specialty-level care;
- Treating physicians looking for consultations to help manage patients’ pain; and
- Hospitals and payers seeking to credential physicians

Although no silver bullet to this problem, states that clearly define “pain specialist” will help establish a standard for identifying physicians who are qualified to provide comprehensive, advanced pain management care to patients with persistent pain. As a credentialing board for pain medicine specialists, we are keenly aware of the need to protect the interests of patients with acute or intractable pain, as they are often particularly susceptible to representations that their pain can be alleviated quickly and easily. Patients with pain often will spend considerable resources and subject themselves to untested treatments in a quest for relief.

❖ ***Pill Mills***

The current vacuum has created an easy market for non-experts to claim to be pain specialists or set up pain clinics that all too often simply serve as “pill mills.” Owner-operators of these sham clinics reap financial reward for services that involve little more than writing prescriptions. Defining this term will also help states better guard against truly unscrupulous actors. Patients with addiction problems often will “physician shop” to secure prescriptions when their treating physicians decline. This has been the source of considerable concern in states that have experienced an influx of these entities, which serve primarily as ready sources for opioid prescriptions rather than centers that provide comprehensive pain care to patients. These operators thrive off the problems of patients suffering from pain and/or addiction and do not provide anything akin to specialty level pain care. States are stepping in to address this problem with stricter qualifications for pain clinic operators and “truth in advertising” regulations.

❖ ***Proliferation of credentialing for health care practitioners in “pain management”***

In our view, state medical boards or other appropriate state agencies should carefully consider the process and standards employed by any credentialing entity or board before allowing the certification to be used for advertising purposes. We are very concerned about the growth of “credentialing” of practitioners by entities whose standards fall far short of those of the American Board of Medical Specialties (ABMS) or the ABPM for certifying pain medicine specialists. In some instances, this credentialing is open to “all clinicians” (including MDs, DOs, RNs, NPs, PAs, etc.), who after passing a two-hour test can be “credentialed” as Diplomates, Fellows or Clinical Associates. Membership in the credentialing entity/professional association is one criterion for becoming credentialed.¹

¹ American Academy of Pain Management “Credential in Pain Management Program” booklet, available at www.aapainmanage.org.



❖ **Lack of a Consistent Pathway for Training Pain Medicine Specialists**

In addition to the emergence of under-qualified professionals claiming expertise in pain management, this widespread confusion occurs in part because there is no consistent pathway for training physicians as pain medicine specialists. Unlike other medical specialties (e.g., pediatrics, cardiology and emergency medicine), there are no independent residency training programs for the specialty of Pain Medicine. To become Board-certified in Pain Medicine, a physician must complete an ACGME-accredited residency training program in a different primary medical specialty whose core training varies considerably, typically Anesthesiology, Neurology, Neurosurgery, Psychiatry, or Physical Medicine & Rehabilitation. After completing this residency program, a physician must complete either a one-year fellowship in Pain Medicine (through the American Board of Anesthesiology or another ABMS board) or provide proof of substantial training in pain medicine related-topics, and actively practice comprehensive Pain Medicine for a significant amount of time to demonstrate competence to qualify to apply for Board certification (through the ABPM). The physician must then successfully pass an examination offered by either ABPM or an ABMS recognized Board.

The ABPM has long advocated for fundamental changes to how our medical education system trains physicians in pain medicine at both the specialist and primary care levels. We are working to build the case for the ABMS to endorse Pain Medicine as a primary medical specialty, which would include developing ACGME-accredited pain residency programs to provide four years of concentrated, comprehensive training in Pain Medicine. Currently, the ABMS's policies support Pain Medicine only as a subspecialty of other primary medical specialties, not as a primary and independent medical specialty. While the subspecialty pathway is appropriate and should be preserved, in our view, this approach is inadequate to meet the demands of this patient population.

As states define "pain specialist" for the purpose of state regulations, it is important that both existing pathways – the subspecialty pathway offered by several ABMS and AOA Boards and the training-based pathway offered by ABPM – be recognized.

III. Federal and State Recognition of ABPM in Definitions of Pain Specialists

A growing number of states have adopted definitions of "pain specialist" or "pain management specialist" that recognize ABPM certification in addition to certification by an ABMS and AOA Board. We are confident that a thorough review of ABPM's certification process will support recognition of ABPM certification by additional states, in keeping with the following federal and state policies:

- **The U.S. Veterans Health Administration recognizes ABPM specialty certification along with ABMS subspecialty certification when defining qualified Pain Medicine specialists.**
- **The Boards of Medicine in California, Florida and Texas specifically recognize ABPM as having "equivalent" certification requirements as ABMS Boards, allowing ABPM Diplomates to advertise as board-certified Pain Medicine specialists.**
- **Several states, including Washington, Alabama, Florida, Kentucky, Georgia, Ohio and Tennessee specifically recognize ABPM along with ABMS certification in state regulations to establish a prescribing protocol or define standards for pain clinics.**



IV. Opioid Prescribing Protocols

States are working to encourage best treatment practices for patients with pain and discourage inappropriate or ineffective practices of some health care practitioners. For instance, several states have adopted medical practice guidelines for physicians and other health care providers to follow when prescribing opioid analgesics. These protocols typically include requirements for consultation or referral to pain medicine specialists as needed for patients with complex pain conditions.

The Federation of State Medical Boards (FSMB) led this effort to establish practice protocols for prescribing practitioners. In 2013, FSMB amended its longstanding “Model Policy on the Appropriate Use of Opioid Analgesics in the Treatment of Chronic Pain” (“Model Policy”) to define with greater specificity the standard of medical practice for physicians who prescribe opioid analgesics to patients with pain. FSMB has urged state medical boards to adopt the Model Policy, which establishes a detailed protocol for physicians to follow when prescribing opioid analgesics that includes patient evaluation, risk stratification, ongoing monitoring, consultation and referral and other processes that comprise high quality, comprehensive pain management care. These are all important steps for achieving the best possible outcomes with fewer problems for patients with pain.

In its section entitled “Ongoing Monitoring and Adapting the Treatment Plan,” the Model Policy advises the treating physician to consider each patient’s progress continually and assess whether “other modalities” of pain care and/or referral to a “pain specialist” are in order. Similarly, the “Consultation and Referral” section specifically directs a treating physician to refer patients with complex problems to a “pain or addiction specialist as needed” for “specialized assessment and treatment, if available.” We view this guidance as a critical aspect of the FSMB’s effort to improve outcomes for patients who need specialty-level pain management care.

Notwithstanding the important role the Model Policy ascribes to “pain specialists” within its well-considered protocol for comprehensive, integrated pain care, there is no definition of the term. The ABPM urges FSMB to provide clearer guidance on this definition to states as they consider the Model Policy. Explicitly defining “pain specialist” will help clarify for treating physicians which specialists they can turn to for consultations or referrals when a patient’s condition so requires. States that are developing opioid prescribing protocols are faced with the challenge of defining this term, and ABPM will continue to provide information regarding its credentialing process to demonstrate that our Diplomates are highly qualified to provide specialty level consultation and care for these patients.

V. ABPM Recommendations

For the reasons outlined in this paper, the ABPM urges states to define “pain specialist” or a similar term explicitly within the state regulations designed to improve the quality of pain care or protect the public from under-qualified or predatory practitioners.

ABPM offers the following model language:



Proposed Language to define “Pain specialist” in State Regulations

For the purpose of this regulation, “Pain Medicine Specialist” includes physicians who are certified in Pain Medicine by a member Board of the American Board of Medical Specialties (ABMS), American Osteopathic Association (AOA) or by the American Board of Pain Medicine (ABPM).

Some states have established a process by which medical specialty boards can apply for recognition by a state (typically through the state board of medicine) establishing the validity of their credentialing processes. This would enable the state to review a board’s credentialing process and qualifications required of applicants (including GME training and clinical experience in comprehensive pain management), to determine if the state will recognize the board’s certification for the purpose of demonstrating competency as a pain medicine medical specialty credentialing board.

Proposed Language for Physician/Practitioner Advertising Rules

No physician shall advertise or otherwise represent his or her credentials as a “Board-certified pain medicine/management specialist,” or a “pain medicine/management specialist” unless certified by an ABMS or AOA member board, by the American Board of Pain Medicine or by a medical specialty board approved by this state medical board.

The ABPM welcomes the opportunity to work with state policymakers as they address the issues outlined in this paper. For more information, please contact Kelly Kenney, ABPM Counsel at k2strategiesllc@gmail.com.



October 29, 2016

Wisconsin Medical Examining Board
1400 E Washington Avenue
PO Box 8935
Madison, WI 53708-8935

Dear Members of the Wisconsin Medical Examining Board:

I am a specialist in physical medicine and rehabilitation, with a primary subspecialty in the management of chronic pain. I have practiced academic pain management for 21 years and have had a front-row seat for the twists and turns of opioid medication use to treat chronic noncancer pain. My own emphasis has always been to pursue non-opioid treatments whenever possible and to emphasize functional restoration over pain relief. I encounter numerous patients who are on high doses of opioid analgesics without good results, and spend considerable time on counseling and dose reduction. I do have a small, carefully supervised cohort of patients who successfully use opioids as part of a multimodal plan to treat refractory chronic pain.

Given my interests, I looked forward to the release of the Medical Examining Board's general guideline for opioid prescribing. I congratulate the Board on tackling such a complex and controversial topic with the aim of helping the public and the medical community. The guideline contains much important information and sound advice. However, it is nevertheless inaccurate and misleading in places. I would like to politely provide some suggestions for ways the guideline might be improved, add a stronger evidence base, and become more useful to its audience.

- It would help to re-order the recommendations in the order the prescriber should follow; for example, discuss diagnosis, medical contraindications, and risk screening in detail earlier.
- A clearer statement is needed regarding potential medical INDICATIONS for opioid use.
- Section 4a: "Evidence for opioids in acute pain is weak." No, it isn't! It's STRONG! Opioids are the drug of choice for conditions such as major trauma, fracture, intraabdominal hemorrhage or ischemia (where NSAIDs could worsen the clinical situation), and many others. If I were to break my leg, I would certainly want an opioid. I think your intention was to tell physicians not to use opioids as a first choice for more minor conditions, such as ankle sprains. The current statement, however, would seem to imply that even a compound fracture might be most safely treated with, for example, an NSAID and acupuncture. This whole paragraph needs an overhaul.

- Section 4b: If acute pain lasts beyond the expected duration and complications are ruled out, certainly it is preferable to take the patient off of opioids. However, there are still variations in rates of healing, and not all patients are the same. Ruling out obvious complications does not mean that we have ruled them all out, nor that persistent severe pain is no longer amenable to opioid treatment. Again, I understand the intention but the wording should be changed.
- Section 4c: I suggest taking the Note at the end of the paragraph and putting it higher up in the guideline, since it summarizes an important point of guidance for the practitioner.
- I recommend further emphasis on the importance of the combination of opioids and benzodiazepines, which markedly increases the morbidity/mortality experienced by users.
- Clearly state what your recommendations are intended to accomplish. I agree with the recommendation to use opioid agreements/"contracts" but they are not known to reduce substance abuse; rather, they specify goals and rules for patients, and protect providers.
- I agree with the recommendation for checking the PDMP website, but it is not known to reduce substance abuse; rather, it helps to control prescribing, reveal potential aberrant drug-related behavior, and trigger referral for treatment.
- I agree with the recommendations for the use of behavioral therapies and addiction treatment. Unfortunately, in Wisconsin, these treatments are in miserably short supply. If you recommend the use of such treatment, parallel effort is required to improve treatment availability, or no one can truly follow the recommendation.
- The potential for morbidity/mortality associated with opioids is multifactorial. Higher doses are more dangerous, but other vital considerations include patient behavior, concurrent illicit or prescribed drug use, environmental influences on behavior, and comorbid medical issues. In other words, it's not all about the dose. This should be emphasized.
- The emphasis on setting a dosage limit, while it dovetails with the CDC guideline recommendation, is misleading. Practitioners should use the same amount of caution no matter what the dose. The only reason to prescribe is to reduce pain and to improve function. If those goals are not being achieved, opioids should be discontinued. There is no solid evidence for the 50- and 90-mg thresholds specified by the CDC, just as there is no solid evidence for the efficacy of opioids in chronic noncancer pain. If an "extra caution" threshold dose must be specified, 90 mg is reasonable, but again is unsupported in the literature. It is also worth noting that the concept of "morphine equivalent daily dose" is not precisely defined. In fact, there is vast disagreement between websites, textbook tables, and individual practitioners regarding how to make such calculations, or even whether they are valid between individuals.

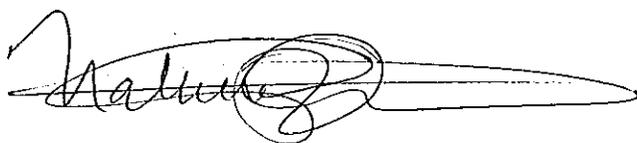
- As a whole, extended-release opioids do not cause more deaths than short-acting opioids, and short-acting opioids are much more likely to be left unconsumed and potentially misused or diverted.
- There is *not* any convincing evidence that oxycodone is more addictive or liable to abuse than other opioids. The articles you cited, small trials showing small differences, do not support this argument. If you have stronger evidence, please present it (I couldn't find any); if not, the paragraph discouraging oxycodone use should be excised. By contrast, the methadone cautions are reasonable and appropriate.
- You need a much stronger and more extensive set of citations to back up your assertions. The current references do not sufficiently support your assertions, nor do they reflect the amount of time and effort that undoubtedly went into this document.

While it's easy to complain, it's harder to help effect change. I therefore offer my services in assisting the Board to revise the Wisconsin opioid guideline. I have coauthored clinical guidelines in the past; please see my attached curriculum vitae for details. I can provide citations to support the observations I've made above. It's been my pleasure to assist DSPS in the past as an expert witness in complex cases of irresponsible prescribing; it would be an honor to assist in this new capacity.

Other than less than \$300 of stock in a pharmaceutical startup which has no involvement in opioids, I have no past or present affiliations or financial interest in any corporate entity connected to pain management or medication.

I appreciate your time and consideration, and look forward to your response.

Sincerely yours,



Nathan J. Rudin, MD, MA, FAAPMR
Professor, Orthopedics and Rehabilitation Medicine
University of Wisconsin School of Medicine and Public Health
Past President, Midwest Pain Society
Past President, Medical Staff Board, UW Hospital and Clinics
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**State of Wisconsin
Department of Safety & Professional Services**

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Nifty Lynn Dio, Bureau Assistant On behalf of Tom Ryan, Executive Director		2) Date When Request Submitted: 11/07/2016 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: 11/17/2016	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? Pain Specialist Certification - Discussion	
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: Thomas, I received an email from Dr. Lincer regarding the lack of definition of who is a pain medicine specialist. This is not an area where the Division of Worker's Compensation has jurisdiction. We felt this should be forwarded to Dr. Simons of the MEB since this is the likely place for discussion. As I cannot find Dr. Simon's contact information, would you be able to forward this email, including the attachments, as a professional courtesy? Thank you. BJ Dernbach Division Administrator, Workers Compensation Department of Workforce Development 201 E. Washington Ave. PO Box 7901 Madison, WI 53707-7901			
11) Authorization			
Nifty Lynn Dio		11/07/2016	
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: 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
Department of Safety & Professional Services**

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4) Meeting Date: 11/17/2016	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? PDMP Report	
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: N/A	
10) Describe the issue and action that should be addressed: <div style="text-align: center;">  <h2 style="margin: 0;">SCOTT WALKER</h2> <p style="margin: 0;">OFFICE OF THE GOVERNOR</p> </div> <hr style="border: 1px solid black; margin: 10px 0;"/> <p>FOR IMMEDIATE RELEASE</p> <p>November 1, 2016</p> <p>Contact: Tom Evenson, (608) 266-2839</p> <p style="text-align: center;">Governor Walker Highlights Efforts to End Drug Abuse in Wisconsin, Applauds Findings of First Report by the Controlled Substances Board</p> <p style="text-align: center;"><i>Number of opioid prescription doses dispensed decreases by 8.2 million</i></p> <p>Madison – Governor Walker joins the Department of Safety and Professional Services (DSPS) in announcing the findings of the first report from the Controlled Substances Board, which highlights the success of the Wisconsin Prescription Drug Monitoring Program (PDMP). The report indicates that between July 1 and September 30, 2016, the number of opioid prescriptions dispensed decreased by 8.2 million as compared to the same time period in 2015.</p> <p>“We continue to take steps to fight the opioid epidemic in Wisconsin,” Governor Walker said. “The statistics released in this report are very encouraging and indicate the efforts we’re putting forth to combat</p>			

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

prescription drug abuse and misuse are steps in the right direction. This decrease of 8.2 million fewer doses dispensed means there are fewer doses that may sit in medicine cabinets with the potential of being misused.”

The number of opioid prescriptions dispensed in Wisconsin between July 1 and September 30, 2015 was 1,280,367, which is equivalent to 83,233,662 drug doses. Numbers released in the Controlled Substances Board report show that between July 1 and September 30 of this year, there was a 9.63 percent reduction in opioid prescriptions and a 9.89 percent reduction in drug doses when compared to the same time period in 2015.

Additional information in the report includes the number of requests for data about their patients made by health care professionals, the number of law enforcement reports submitted to the PDMP, and the quantity of prescriptions dispensed by Wisconsin dispensers located in Wisconsin versus out-of-state dispensers. It also provides data on doctor shopping, pharmacy hopping, and the number of individuals receiving both opioids and benzodiazepine prescriptions.

“We are proud that this program is making inroads in our fight against opioid abuse,” said DSPPS Secretary Dave Ross. “We expect the report will continue to provide improved results, especially given our upcoming rollout of the enhanced program, which will launch in early 2017.”

The Wisconsin PDMP was deployed in June 2013 and is administered by DSPPS. Since its inception, the PDMP has been a tool to help health care professionals make more informed decisions about prescribing and dispensing controlled substance prescriptions to patients and discloses data as authorized by law to governmental and law enforcement agencies. It stores over 40 million prescription records submitted by over 2,000 pharmacies and dispensing practitioners.

A copy of the report is attached.

###

- [PDMP Report.pdf](#)

Office of the Governor Scott Walker
115 East Capitol • Madison, WI 53702

Press Office: (608) 266-2839
Email: govpress@wisconsin.gov

11)	Authorization
Nifty Lynn Dio	11/07/2016
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	

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

Directions for including supporting documents:

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3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

Doug Englebert
Chairperson

Alan Bloom
Vice Chairperson

Yvonne Bellay
Secretary

CONTROLLED SUBSTANCES BOARD



1400 E Washington Ave
PO Box 8935
Madison WI 53708-8935

Email: dsps@wisconsin.gov
Voice: 608-266-2112
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October 24, 2016

The Honorable Dave Ross
Secretary, Department of Safety and Professional Services
State of Wisconsin
Department of Safety and Professional Services
PO Box 8935
Madison, WI 53708-8935

Dear Secretary Ross,

On March 17, 2016, 2015 Wisconsin Act 267 was enacted providing reporting requirements for the Prescription Drug Monitoring Program (PDMP). On behalf of the Controlled Substance Board, I am pleased to provide you and the Department with a copy of the first quarterly report.

The Controlled Substance Board expects the report to continue to improve, especially as we move to the new enhanced PDMP and have greater functionality for reporting. On behalf of the Controlled Substance Board, I would like to thank Department staff for their extensive work to create the current report and look forward to working with staff as we continue to improve the PDMP functionality and reporting.

This report will be a valuable tool for those around the state who are interested in promoting the health, safety and well-being of Wisconsin residents. If you receive any questions or comments about the report please forward them to the Controlled Substance Board so we can improve the report as necessary.

Sincerely,

A handwritten signature in black ink, appearing to read 'Doug Englebert', with a large, sweeping flourish extending to the right.

Doug Englebert
Chair, Wisconsin Controlled Substance Board



Controlled Substances Board



Report 1

July 1 – September 30, 2016

Contact Information

Wisconsin Controlled Substances Board

Chairperson: Doug Englebert

Members:

Englebert, Doug, Chairperson
Bloom, Alan, Vice Chairperson
Bellay, Yvonne M., Secretary
LaDien, Franklin "Rocky"
Larson, Gunnar
Miller, Jeffrey G.
Pietz, Wendy M.
Smith, Jason
Westlake, Timothy W.

DHS Designated Member
Pharmacologist
DATCP Designated Member
Pharmacy Board Representative
Psychiatrist
Board of Nursing Representative
Dentistry Board Representative
Attorney General Designee
Medical Board Representative

Wisconsin Department of Safety and Professional Services

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Wisconsin Prescription Drug Monitoring Program

PDMP@wisconsin.gov

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Introduction

The Wisconsin Prescription Drug Monitoring Program (PDMP) was deployed in June 2013. It is administered by the Wisconsin Department of Safety and Professional Services (DSPA) pursuant to the regulations and policies established by the Wisconsin Controlled Substances Board (CSB). Since being deployed, the PDMP primarily has been a tool to help healthcare professionals make more informed decisions about prescribing and dispensing controlled substance prescription drugs to patients. It also discloses data as authorized by law to governmental and law enforcement agencies.

The PDMP currently stores over 40 million prescription records submitted by over 2,000 pharmacies and dispensing practitioners. Over 15,000 prescribers, pharmacists, and their delegates have performed over 3 million queries for patient prescription reports. The number of queries performed by healthcare users per day has steadily risen, with an average of over 4,500 queries performed each day.

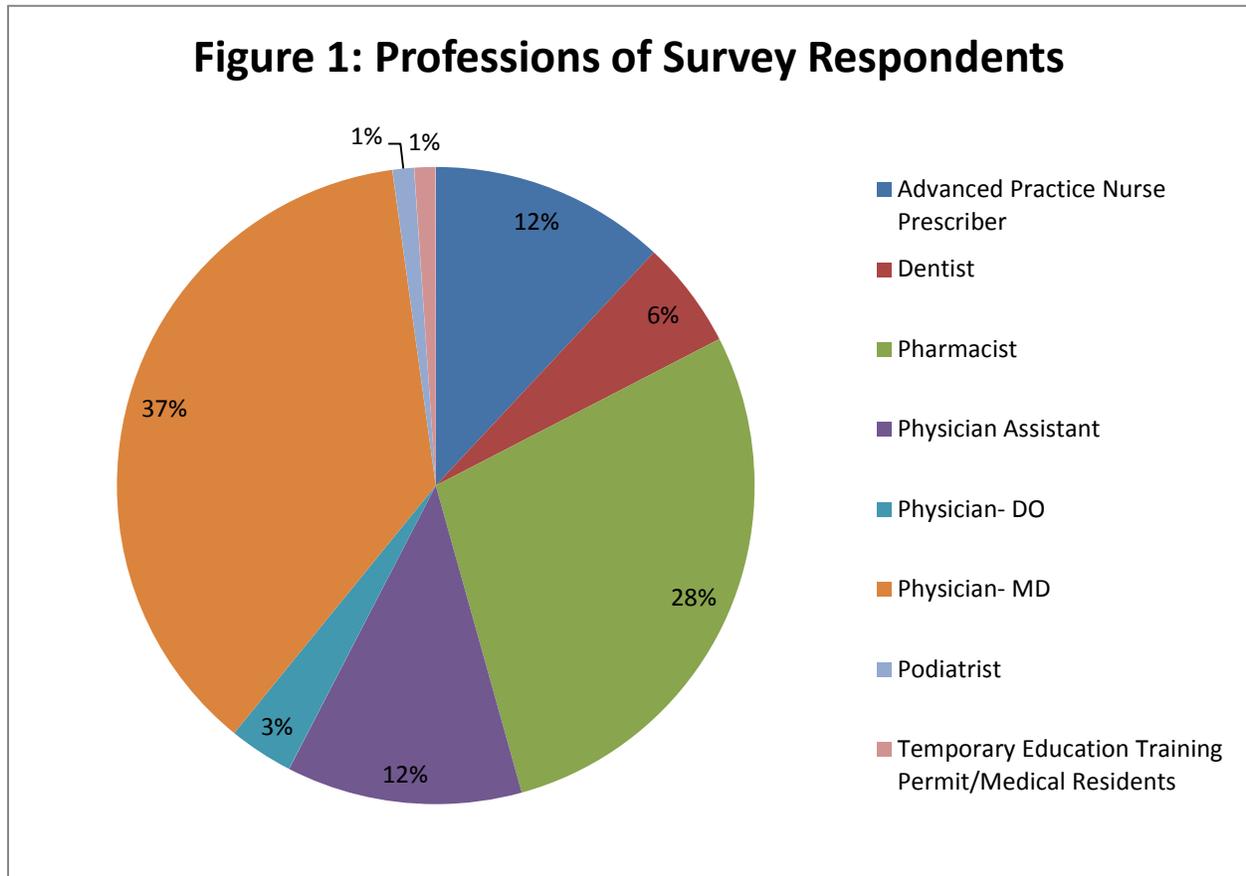
Pursuant to ss. 961.385 (5) – (6), Wis. Stats., the CSB is required to submit a report to DSPA about the PDMP. This report is the first report intended to satisfy that requirement. It includes information related to each of the following topics identified in the law:

- The satisfaction with the program of pharmacists, pharmacies, practitioners, and other users of the program.
- The program's impact on referrals of pharmacists, pharmacies, and practitioners to licensing or regulatory boards for discipline and to law enforcement agencies for investigation and possible prosecution.
- An assessment of the trends and changes in the use of monitored prescription drugs in this state.
- The number of practitioners, by profession, and pharmacies submitting records to the board under the program in the previous quarter.
- A description of the number, frequency, and nature of submissions by law enforcement agencies under s. 961.37 (3) (a) in the previous quarter.
- A description of the number, frequency, and nature of requests made in the previous quarter for disclosure of records generated under the program.
- The number of individuals receiving prescription orders from 5 or more practitioners or having monitored prescription drugs dispensed by 5 or more pharmacies within the same 90-day period at any time over the course of the program.
- The number of individuals receiving daily morphine milligram equivalents of 1 to 19 milligrams, 20 to 49 milligrams, 50 to 99 milligrams, and 100 or more milligrams in the previous quarter.
- The number of individuals to whom both opioids and benzodiazepines were dispensed within the same 90-day period at any time over the course of the program.

Currently, DSPS is developing an enhanced PDMP (ePDMP) system that will be deployed no later than the first quarter of 2017. The primary emphasis of the new system's design is value-added clinical workflow integration, improved data quality capabilities for both searching and reporting, and maximized public health and public safety use. It will also be capable of compiling all of the data required for future reports.

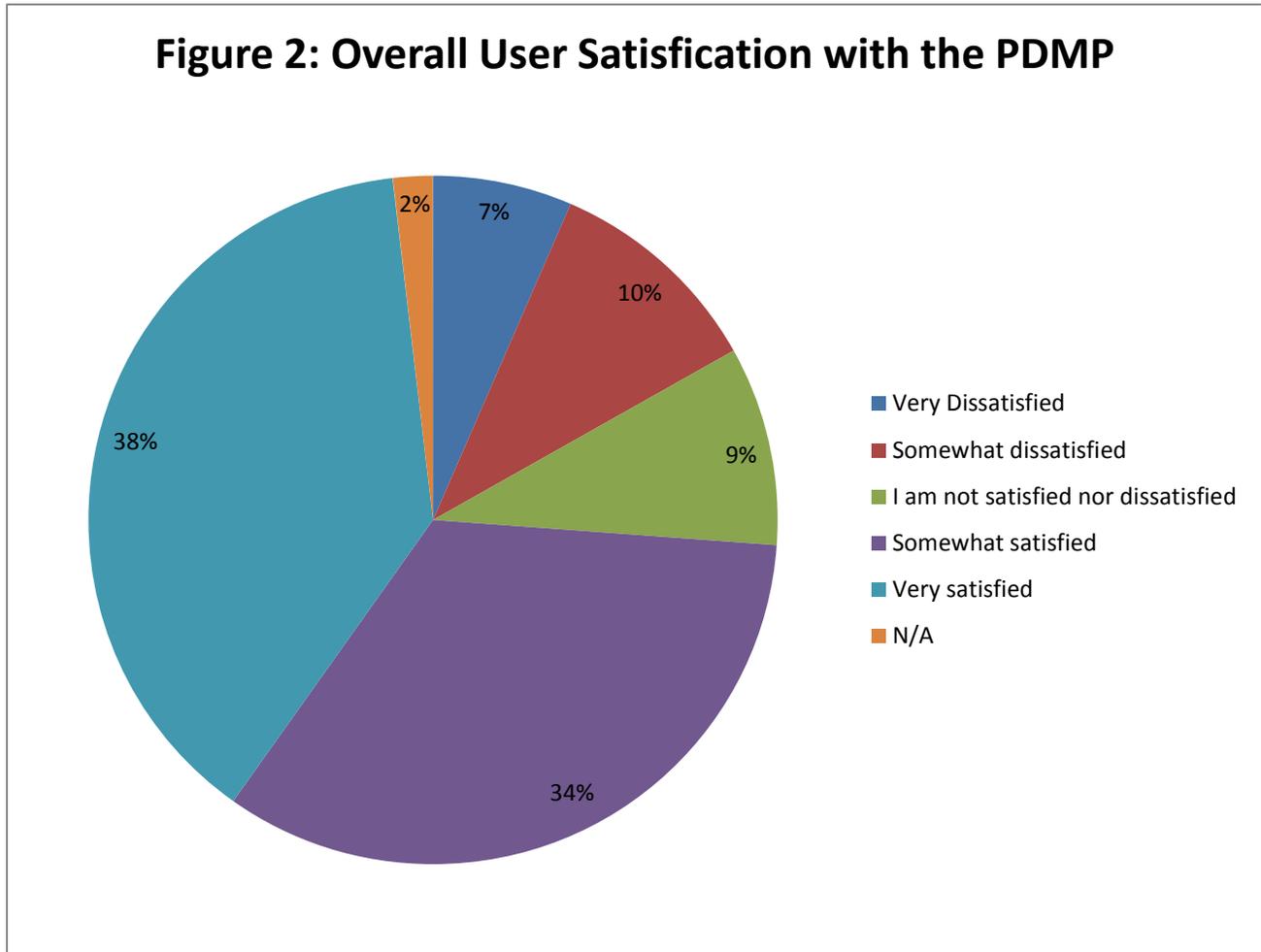
User Satisfaction

DSPS conducted an online survey between August 22 and September 14, 2016. During that time, DSPS emailed the user satisfaction survey attached to this report to 398 random current users of the PDMP. During the survey period, 109 current users of the PDMP completed the survey. Figure 1 shows the profession of the survey respondents.



While 109 users responded to the survey, only 92 users indicated their profession. The most common profession with 34 individuals is physician – MD. The second most common profession of survey respondents is pharmacist with 26 individuals. Besides optometrists, very few of whom are current PDMP users, and anesthesiologist assistants, none of whom are current PDMP users, all professions granted access to the PDMP are represented in the survey results.

Overall, current users of the PDMP are satisfied with the PDMP system. In fact, 72% of current users surveyed describe their satisfaction with the PDMP as “somewhat satisfied” or “very satisfied.” For the purposes of the survey, current users were defined as users who had registered with the PDMP and had an active PDMP account at the time the survey began. Figure 2 shows the 107 responses collected as part of the survey from current users about their satisfaction with the PDMP system.

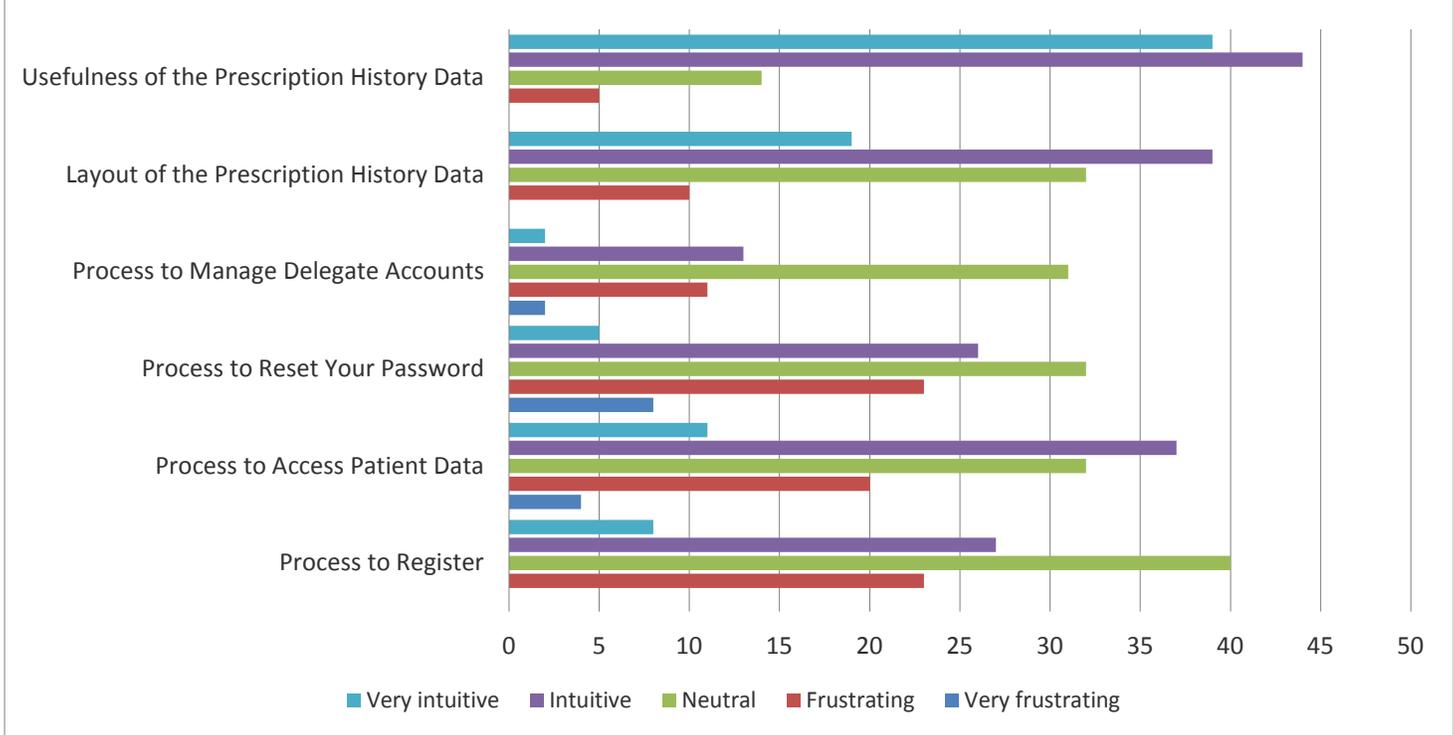


The survey also asked users to rate specific qualities of the PDMP system. The qualities of the PDMP in the survey are:

- Process to Register
- Process to Access Patient Data
- Process to Reset Your Password
- Process to Manage Delegate Accounts
- Layout of the Prescription History Data
- Usefulness of the Prescription History Data

Figure 3 shows the results from the survey.

Figure 3: Rating Qualities of the PDMP System

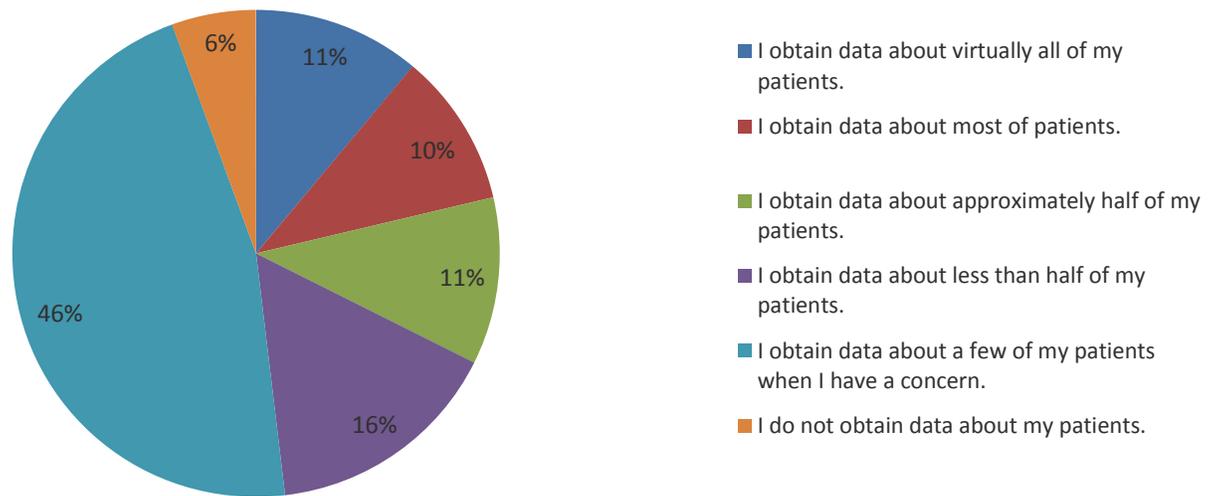


The most positive responses related to the usefulness of the prescription history data. Almost 80% of current users highly rated the usefulness of the data as intuitive or very intuitive. However, only 55% of current users describe the layout of the prescription history data as intuitive or very intuitive. So, while current users find the data useful, less find it laid out in an intuitive manner.

There is significantly more variation in the responses to the ratings for the processes. The most negative ratings regard the process to reset a password in the PDMP system. While approximately 29% of current users rate the process to reset their passwords as intuitive or very intuitive, an equal percentage of current users, 29%, rate the process as frustrating or very frustrating.

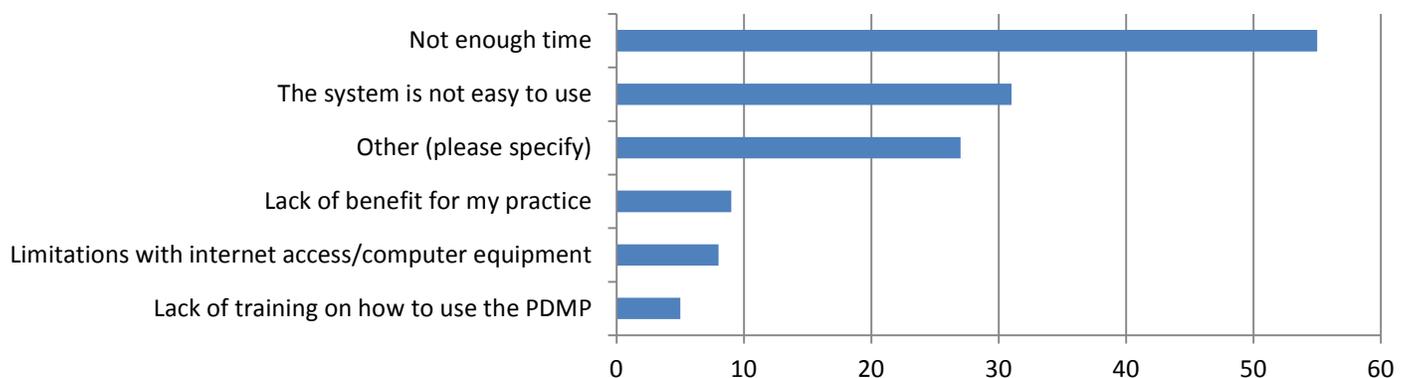
In addition to asking about satisfaction with the PDMP, the survey asked users about how often the current users or someone to whom they have delegated their authority to access PDMP data actually access PDMP data about a patient. Approximately 46% of the survey respondents only access PDMP data about “a few of my patients when I have a concern.” Nearly 28% of survey respondents accessed data about half of their patients or less. Over 5% of survey respondents do not access PDMP data about their patients. Taken together, almost 79% of current users only access data about half of their patients or less. Figure 4 shows the results from the survey.

Figure 4: Frequency of Accessing PDMP Data About Patients



Current users most often cited not having enough time to access PDMP data as a barrier to using the PDMP more. In fact, approximately 55% of current users identified it as a barrier in the survey. The second most cited barrier, identified by 31% of current users, is that the current users do not find the PDMP system easy to use. Figure 5 shows the results of the survey.

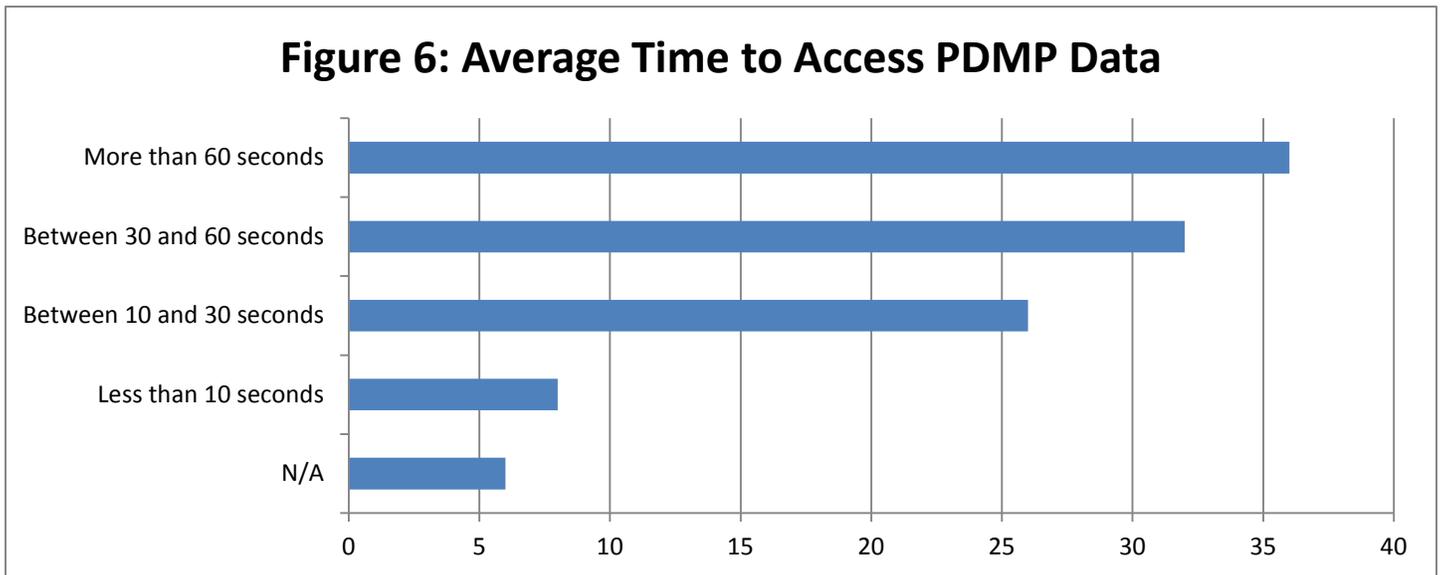
Figure 5: Barriers to Using the PDMP More



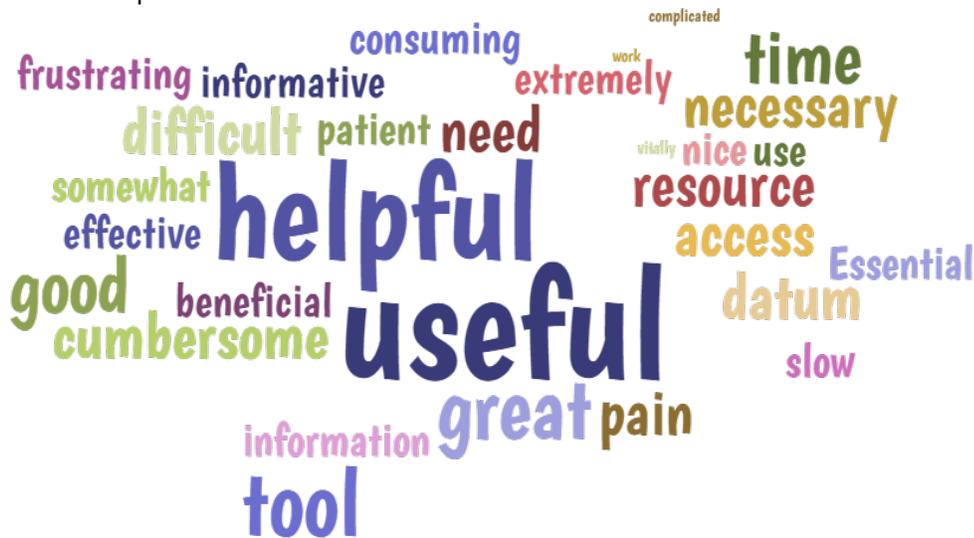
In the survey, 27% of the current users said that other barriers prevent them from using the PDMP more. There were two prevailing themes in the responses: passwords expire too often and are difficult to remember, and the PDMP system is cumbersome and requires too many clicks to access PDMP data. One response succinctly summed up the frustrations with both commonly cited barriers:

“frequent cumbersome [sic] passwords that change frequently resulting in forgotten password; a MILLION clicks to finally get to the screen to look someone up.”

The survey also asked the current users to judge the average amount of time it takes them to access PDMP data about a patient. The results are in Figure 6.



Finally, the survey asked current users to describe the PDMP in three or fewer words. The below word cloud was built using WordSift.org. It visualizes the cumulative responses. Words that appear larger in the word cloud were used in more responses than the words that appear smaller. The words most commonly used were “helpful” and “useful.”



Impact on Referrals for Investigation

Between July 1 and September 30, 2016, the Controlled Substances Board referred two pharmacists to the Pharmacy Examining Board for possible investigation and disciplinary action pursuant to s. 961.385 (2) (f), Wis. Stats. The referrals were made for suspected improper use of the PDMP. Prior to referring the pharmacists, the Controlled Substances Board suspended the pharmacists' access to PDMP data pursuant to s. CSB 4.09 (3) (a), Wis. Admin. Code.

Monitored Prescription Drug Use Trend¹

The amount of monitored prescription drugs, and opioids in particular, dispensed between July 1 and September 30, 2016 is less than the amount dispensed during the same period in 2015. During the third quarter 2016, the total number of prescriptions dispensed was 2,494,577, and the number of doses dispensed was 146,531,257. During the third quarter 2015, the total number of prescriptions dispensed was 2,657,001, and the number of doses dispensed was 157,555,903. The number of dispensed prescriptions for a monitored prescription drug this quarter is approximately 6% less than the same quarter in 2015. Similarly, the number of dispensed doses for a monitored prescription drug this quarter is approximately 7% less than the same period in 2015.

While there was a reduction in the volume of monitored prescription drugs dispensed, there has been little change in the 15 most dispensed monitored prescription drugs. The tables below show the top 15 most dispensed monitored prescription drugs between July 1 and September 30, 2016 and the top 15 most dispensed monitored prescription drugs during the same period in 2015.

Top 15 Monitored Prescription Drugs Dispensed Between July and September 2016		
Drug Name	Prescriptions	Quantity Dispensed
HYDROCODONE/ACETAMINOPHEN	389,632	22,269,636
DEXTROAMPHETAMINE/AMPHETAMINE	208,954	10,100,647
TRAMADOL HCL	198,362	15,095,871
OXYCODONE HCL	190,063	16,472,754
ALPRAZOLAM	173,583	10,199,304
LORAZEPAM	172,093	8,348,298
CLONAZEPAM	141,305	8,434,444
OXYCODONE HCL/ACETAMINOPHEN	140,847	9,457,861
ZOLPIDEM TARTRATE	139,336	4,615,915
METHYLPHENIDATE HCL	94,914	4,862,880
LISDEXAMFETAMINE DIMESYLATE	73,736	2,337,536
MORPHINE SULFATE	72,890	4,389,732
DIAZEPAM	67,557	2,969,951
PREGABALIN	58,234	4,369,183
ACETAMINOPHEN WITH CODEINE	51,001	2,386,879

The top 15 dispensed monitored prescription drugs accounted for over 86% of all monitored prescription drug doses dispensed between July 1 and September 30, 2016.

¹ The data presented in this section are from the records of the PDMP as of October 28, 2016. Because the PDMP is an accumulation of records submitted to it by pharmacies and other dispensers, the data are subject to correction and revision as the PDMP receives new data.

Top 15 Monitored Prescription Drugs Dispensed Between July and September 2015		
Drug Name	Prescriptions	Quantity Dispensed
HYDROCODONE/ACETAMINOPHEN	451,804	25,678,901
DEXTROAMPHETAMINE/AMPHETAMINE	214,635	10,307,051
TRAMADOL HCL	204,911	15,746,469
OXYCODONE HCL	203,196	17,820,075
ALPRAZOLAM	181,426	10,851,074
LORAZEPAM	180,710	8,825,318
OXYCODONE HCL/ACETAMINOPHEN	163,026	10,770,720
ZOLPIDEM TARTRATE	151,835	4,982,872
CLONAZEPAM	148,402	8,779,629
METHYLPHENIDATE HCL	95,324	4,915,617
MORPHINE SULFATE	78,574	4,832,945
DIAZEPAM	73,420	3,302,828
LISDEXAMFETAMINE DIMESYLATE	60,295	1,931,833
ACETAMINOPHEN WITH CODEINE	56,616	2,705,064
PREGABALIN	56,500	4,226,453

The top 15 dispensed monitored prescription drugs accounted for over 86% of all monitored prescription drug doses dispensed between July 1 and September 30, 2015.

Additionally, there was a nearly 10% reduction in the number of opioid prescriptions issued and opioid doses dispensed when comparing the data of the third quarter 2015 and third quarter 2016.

Amount of Opioid Prescriptions and Opioid Doses Dispensed		
Period	Opioid Prescription Orders	Quantity Dispensed
2015 Q3	1,280,367	83,223,662
2016 Q3	1,157,102	74,993,240
Difference	(123,265)	(8,230,422)
Percent Decrease	9.63%	9.89%

The current PDMP system identified the classes of prescriptions using the following AHFS Pharmacologic-Therapeutic Classifications:

Opioids:

- 280808: Opiate Agonists
- 280812: Opiate Partial Agonist

Data Submissions

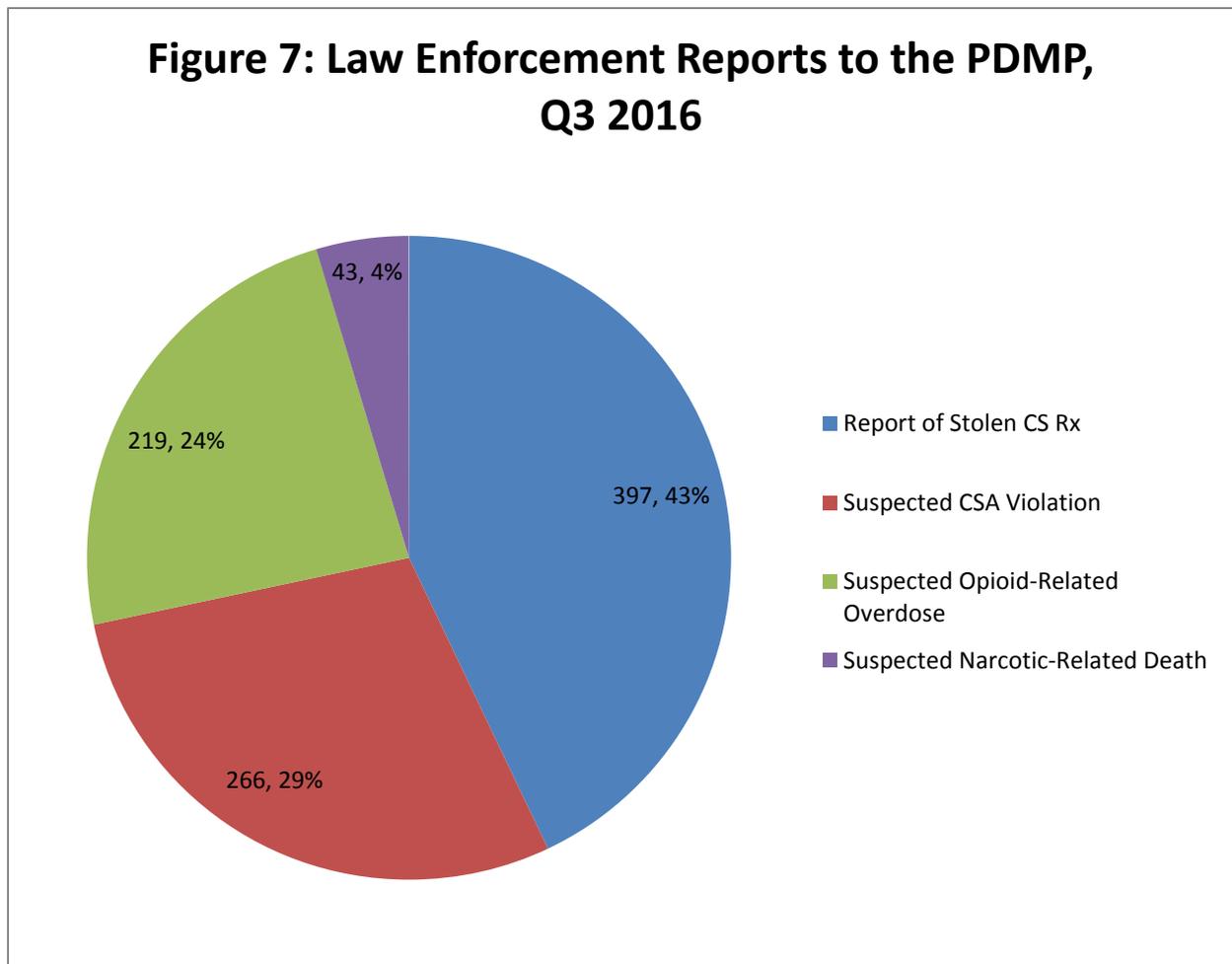
Between July 1 and September 30, 2016, 1,691 dispensers submitted 2,494,577 records to the PDMP. Of those dispensers, approximately 83% were located in Wisconsin, while 17% were located outside of Wisconsin. Approximately 89% of the dispensers were pharmacies, while the remaining 11% of the dispensers were dispensing practitioners. The profession of the dispensing practitioners is not currently reported in a consistent manner but will be available in future reports based on the enhancements being made to the PDMP application.

Law Enforcement Reports

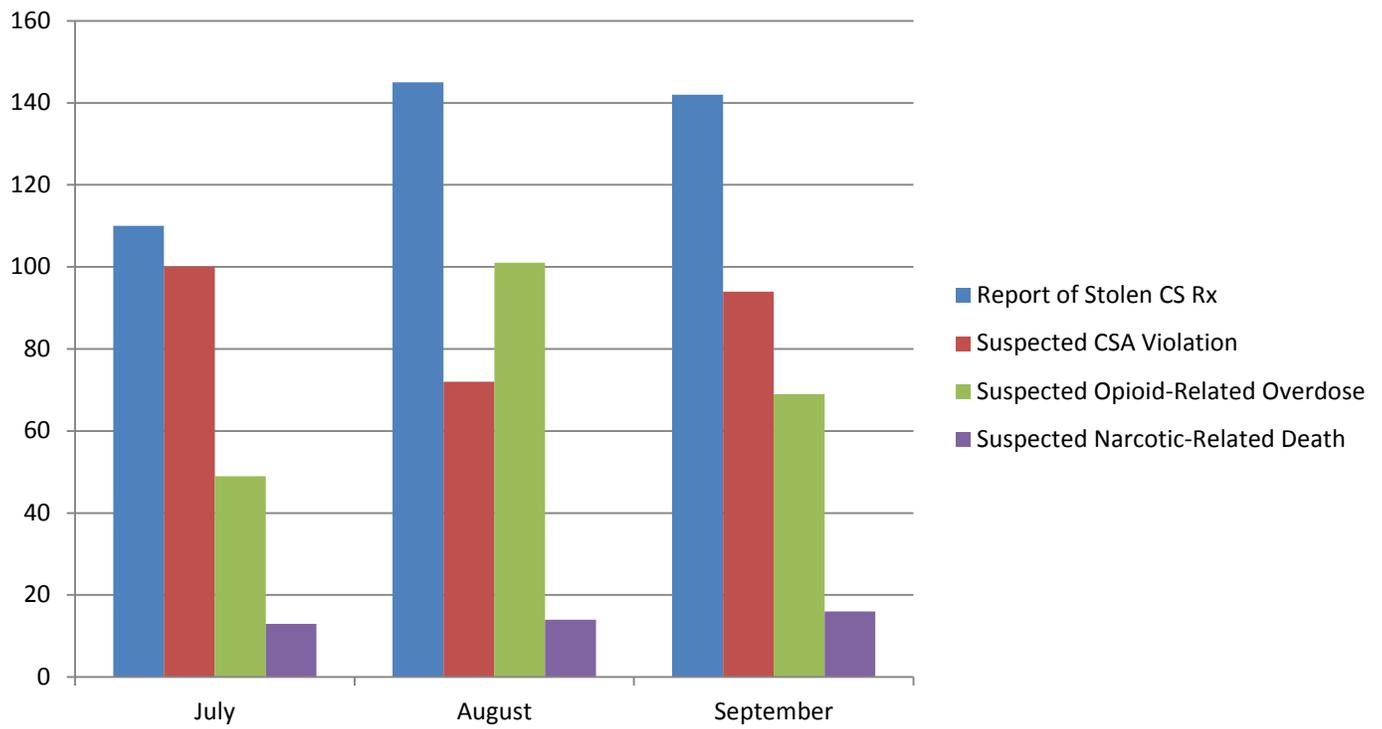
Between July 1, 2016, and September 30, 2016, 141 different Wisconsin law enforcement agencies submitted 925 reports to the PDMP as required by s. 961.37 (3) (a), Wis. Stat. The law requires the agencies to submit a report in each of the following situations:

1. When a law enforcement officer receives a report of a stolen controlled substance prescription.
2. When a law enforcement officer reasonably suspects that a violation of the Controlled Substances Act involving a prescribed drug is occurring or has occurred.
3. When a law enforcement officer believes someone is undergoing or has immediately prior experienced an opioid-related drug overdose.
4. When a law enforcement officer believes someone died as a result of using a narcotic drug.

Figures 7-8 show the breakdown of the reports submitted to the PDMP by type and by month.

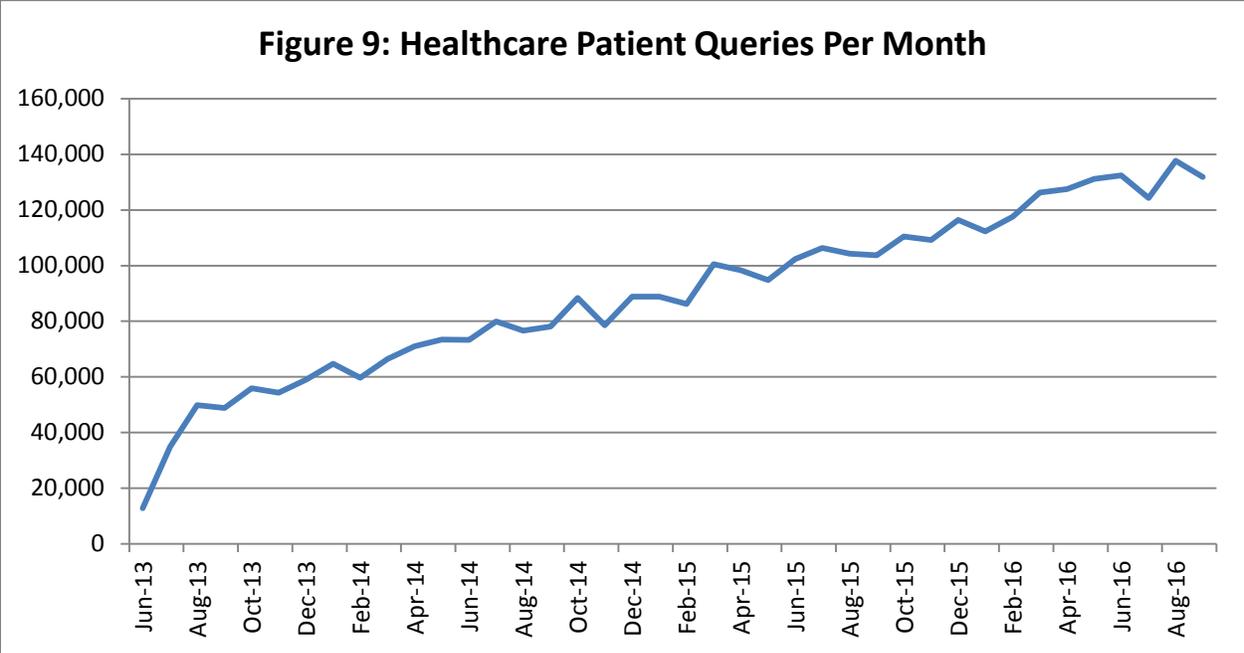


**Figure 8: Law Enforcement Reports to the PDMP,
Q3 2016**

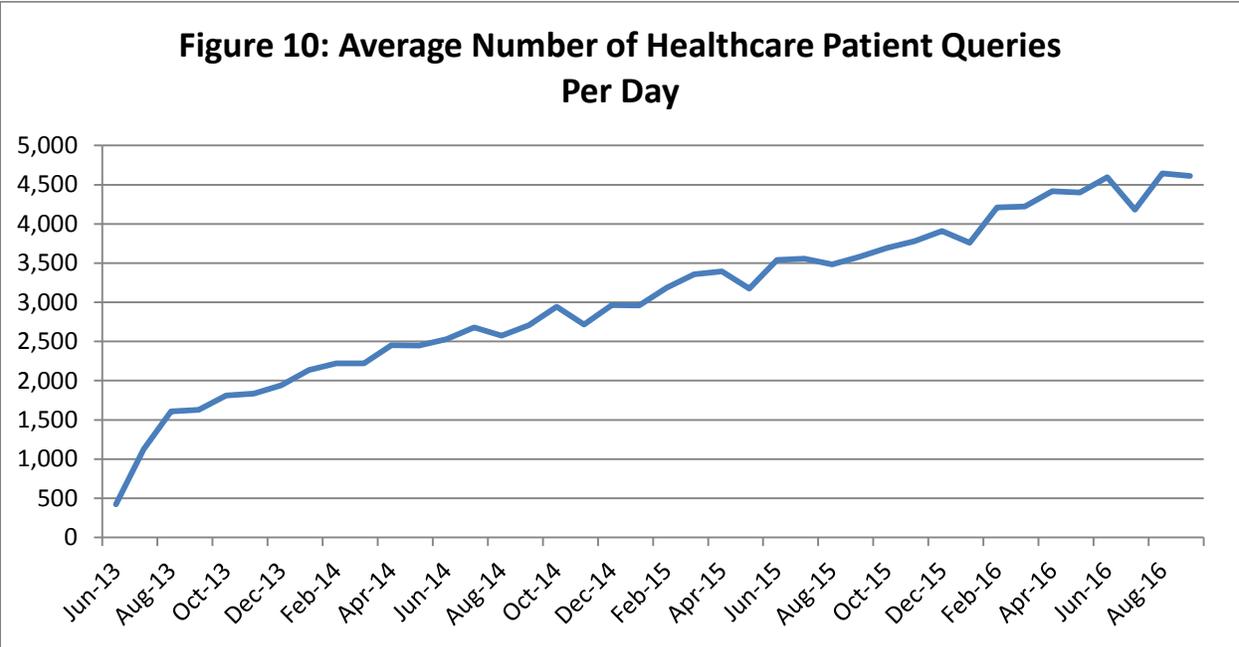


Disclosure of PDMP Data

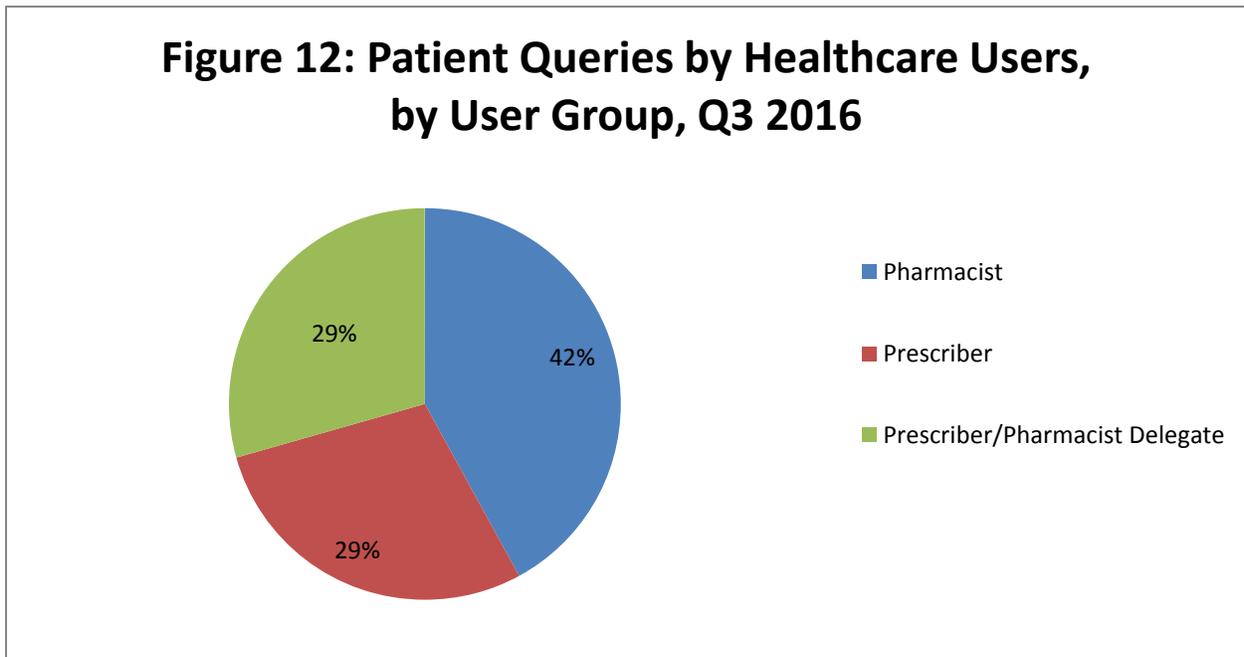
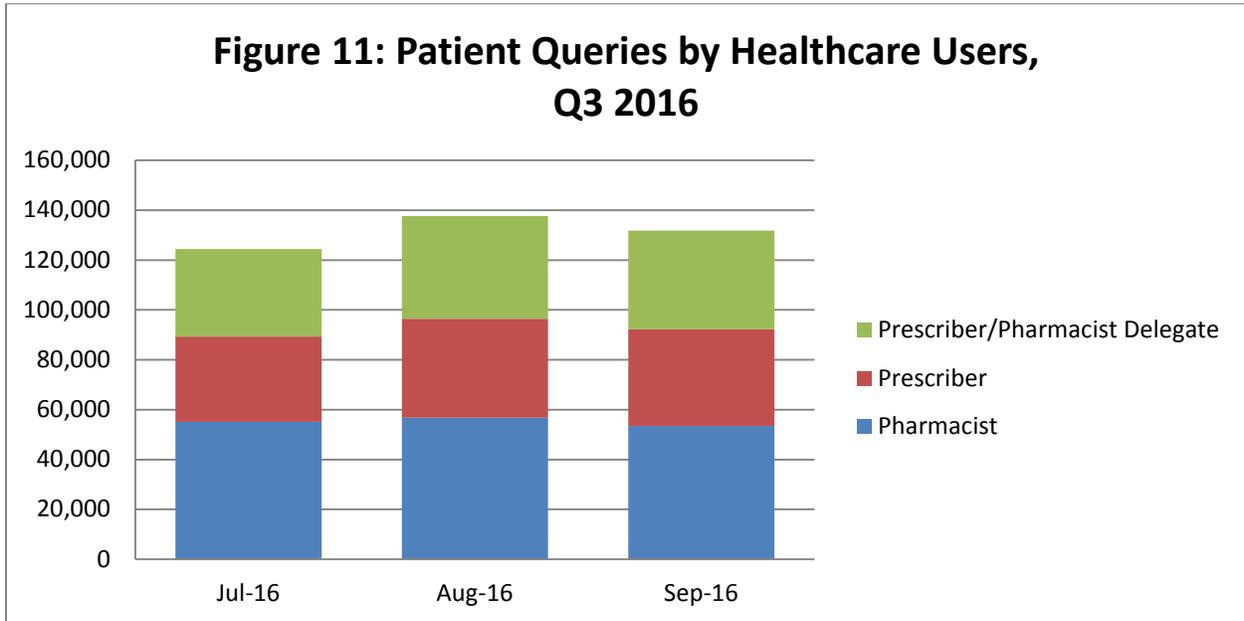
Between July 1, 2016, and September 30, 2016, healthcare users made 411,852 patient queries. The total number of patient queries by healthcare users has steadily increased since the program became operational in June of 2013, as seen in Figure 9.



The daily average of queries by healthcare users also reflects a steady increase, as seen in Figure 10.

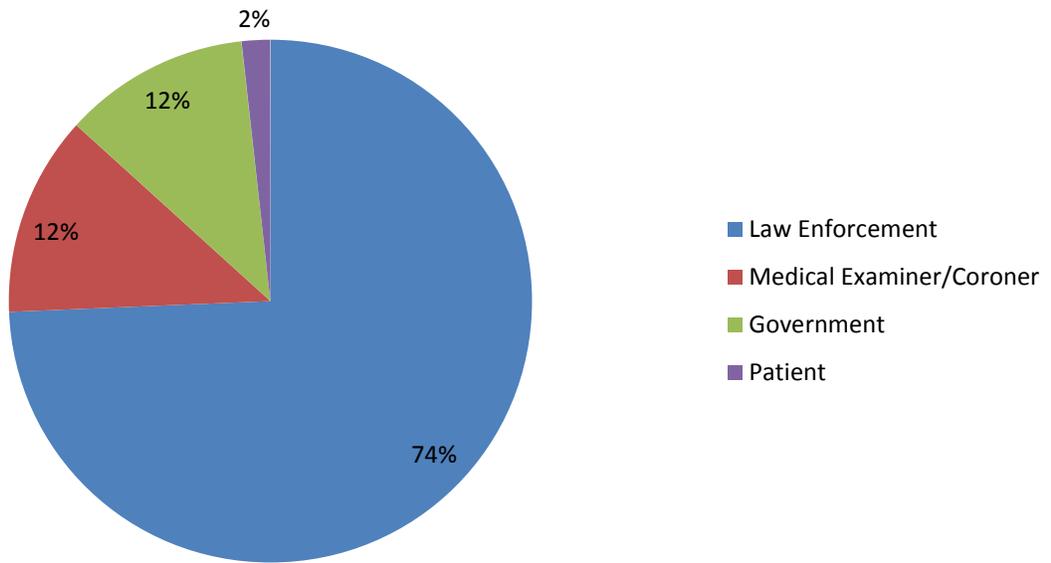


Figures 11 and 12 show the breakdown by profession of patient queries by prescribers, pharmacists, and prescriber/pharmacist delegates for this quarter.



Authorized individuals from non-healthcare groups made 113 requests for PDMP data this quarter. The breakdown among authorized non-healthcare groups can be seen in Figure 13.

Figure 13: Other Authorized Requests, Q3 2016



Doctor Shopping and Pharmacy Hopping

The current PDMP system is capable of calculating the number of individuals who received prescription orders from five or more prescribers and had those prescriptions dispensed by five or more pharmacies between July 1 and September 30, 2016.

According to the records submitted to the PDMP by pharmacies and other dispensers, 368 individuals obtained five or more prescription orders for a monitored prescription drug and had those drugs dispensed by five or more pharmacies this quarter.

Two individuals obtained prescription orders from 16 different prescribers between July 1 and September 30, 2016. One individual obtained monitored prescription drugs at 12 different pharmacies.

Based on its improved data-quality capabilities and analytics, the forthcoming ePDMP application will be able to alert providers about patients that meet doctor-shopping and pharmacy-hopping thresholds in real-time.

Morphine Milligram Equivalent (MME)

The current PDMP system is not capable of calculating morphine milligram equivalent doses of opioid drugs. However, pursuant to the authority provided in 2015 Act 267, DSPS included advanced data analytic functionalities in the scope and design of the new Enhanced Prescription Drug Monitoring Program (ePDMP) system. The ePDMP is currently under development. Once the ePDMP is deployed, DSPS will use it to fulfill the requirements of this section in retrospect and in all new reports.

Opioid-Benzodiazepine Overlap

The current PDMP system is capable of identifying the number of individuals to whom at least one opioid prescription and at least one benzodiazepine prescription were dispensed between July 1 and September 30, 2016. This does not necessarily mean that the prescriptions overlapped. It only means that at some point in the quarter the patient received an opioid prescription and that at some point in the quarter the same patient received a benzodiazepine prescription.

The current PDMP system identified the classes of prescriptions using the following AHFS Pharmacologic-Therapeutic Classifications:

Opioids:

- 280808: Opiate Agonists
- 280812: Opiate Partial Agonists

Benzodiazepines:

- 281208: Benzodiazepines (Anticonvulsants)
- 282408: Benzodiazepines (Anxiolytics, Sedatives, and Hypnotics)

According to the records submitted to the PDMP by pharmacies and other dispensers, 488,137 individuals received an opioid prescription and 283,439 individuals received a benzodiazepine prescription this quarter. Approximately 98,792 individuals received both an opioid prescription and a benzodiazepine prescription between July 1 and September 30, 2016.

Based on its improved data-quality capabilities and analytics, the forthcoming ePDMP application will be able to alert providers about patients that have overlapping benzodiazepine and opioid prescriptions as a standard function of the patient report.

Attachment

Wisconsin Prescription Drug Monitoring Program (PDMP) User Survey

1. What is your profession?

2. Are you registered to use the PDMP?

Yes

No

3. Overall, how satisfied are you with the PDMP?

Very Dissatisfied	Somewhat dissatisfied	I am not satisfied nor dissatisfied	Somewhat satisfied	Very satisfied	N/A
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4. How often do you or your delegate obtain data about a patient from the PDMP?

- I obtain data about virtually all of my patients.
- I obtain data about most of patients.
- I obtain data about approximately half of my patients.
- I obtain data about less than half of my patients.
- I obtain data about a few of my patients when I have a concern.
- I do not obtain data about my patients.

5. Which of the following barriers prevent you from using the PDMP more?

- Limitations with internet access/computer equipment
- Not enough time
- Lack of benefit for my practice
- Lack of training on how to use the PDMP
- The system is not easy to use
- Other (please specify)

6. How many seconds does it normally take you or your delegate to log into and access data in the PDMP?

- Less than 10 seconds
- Between 10 and 30 seconds
- Between 30 and 60 seconds
- More than 60 seconds
- N/A

7. Rate the following qualities of the PDMP

	Very frustrating	frustrating	Neutral	Intuitive	Very intuitive	N/A
Process to Register	<input type="radio"/>					
Process to Access Patient Data	<input type="radio"/>					
Process to Reset Your Password	<input type="radio"/>					
Process to Manage Delegate Accounts	<input type="radio"/>					
Layout of the Prescription History Data	<input type="radio"/>					
Usefulness of the Prescription History Data	<input type="radio"/>					

8. Which of the following actions have you taken as a result of using the PDMP? *check all that apply*

- spoken with a patient about controlled substance use
- contacted prescribers or other pharmacies
- confirmed patient not misusing prescriptions
- confirmed patient was doctor shopping
- denied prescription for a patient
- reduced or eliminated prescriptions for a patient
- dismissed patient from practice
- referred or recommended for substance abuse treatment
- referred or recommended for pain management
- referred or recommended for anxiety (or other psychiatric disorder) management
- Other (please specify)

9. How would you describe the PDMP in three or fewer words?

10. Do you have any other comments, questions, or concerns?

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Nifty Lynn Dio, Bureau Assistant On behalf of Tom Ryan, Executive Director		2) Date When Request Submitted: 11/07/2016 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: 11/16/2016	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? FSMB Matters 2016 Annual Report on the USMLE	
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: N/A	
10) Describe the issue and action that should be addressed: <p>Subject: 2016 Annual Report on the USMLE to Medical Licensing Authorities in the United States</p> <p>Dear Colleagues,</p> <p>On behalf of the FSMB and the NBME, I am pleased to provide you with the <i>2016 Annual Report on the USMLE to Medical Licensing Authorities in the United States</i>. This report is intended to provide state medical boards with an overview of the USMLE program and updates on recent changes that may be of interest to board staff and members. The report also includes USMLE performance data and a summary of state medical boards' interactions with the USMLE program over the past year.</p> <p>We encourage you to share this as part of your next report to your board members. I have attached a PDF version of a PowerPoint presentation entitled, "USMLE Primer" that provides additional information to assist you in these efforts. We also encourage you to share the report with any board staff that would benefit from information on the USMLE.</p> <p>Finally, we would like to thank the members of the State Board Advisory Panel to the USMLE for their review and approval of the report. We applaud and sincerely appreciate the following individuals for their time and expertise:</p> <p>Kimberly Kirchmeyer – California Medical Maria Laporta, MD – Illinois Kristin Spanjian, MD – Montana Lynnette Daniels – Nevada Medical Maegan Martin, JD – Tennessee Medical & Osteopathic David Cook, MD – Utah Medical Wayne Reynolds, DO – Virginia Bob Knittle, MS – West Virginia Medical Ken Simons, MD – Wisconsin Kevin Bohnenblust, JD – Wyoming</p>			

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

We hope you find this report useful. Please do not hesitate to contact me if you have any questions about either the report or the presentation.

Sincerely,

Frances

Frances Cain, MPA

Assistant Vice President, Assessment Services

11)

Authorization

Nifty Lynn Dio

11/07/2016

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:

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.

**Annual Report on the United States Medical Licensing Examination®
(USMLE®) to Medical Licensing Authorities in the United States**

October 2016

Prepared by the Federation of State Medical Boards of the United States, Inc.,
and the National Board of Medical Examiners®



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Executive Summary

The *Annual Report on the United States Medical Licensing Examination (USMLE) to Medical Licensing Authorities in the United States* provides state medical boards with an overview of the USMLE, a joint program of the Federation of State Medical Boards (FSMB) and the National Board of Medical Examiners (NBME). In addition to general information about the examination, the report provides updates on topics of specific interest to the boards, including recent changes to the USMLE, performance data, an overview of the standard setting process and schedule, and a summary of state medical boards' interactions with the USMLE program. Links to key USMLE resources and articles, and a summary of USMLE-related research and publications are also provided.

Over the next year, the USMLE program will continue efforts to enhance and update the USMLE, including increasing the focus on quality improvement principles and safety science in Step 1 and Step 2 CK. Other topics such as epidemiology; biostatistics and population health; professionalism; and interpersonal and communication skills, will also receive increased focus on Step 2 CK.

State medical boards' participation in the USMLE continues to be strong. In 2015, a total of 17 members and staff from 15 boards participated in the annual USMLE workshop and on the state board advisory panel to the USMLE. This is representative of the boards' long and storied participation in the USMLE program, from writing test items and serving on examination committees, to sitting on standard-setting panels and other workgroups. Since implementation of the USMLE in 1992, 202 members and staff from state medical boards have participated in the USMLE program in some capacity. These individuals represent 58 different medical and osteopathic licensing boards throughout the United States.

Introduction and Program Overview

The United States Medical Licensing Examination® (USMLE®) is a jointly owned program of the Federation of State Medical Boards of the United States, Inc., (FSMB) and the National Board of Medical Examiners® (NBME®). USMLE is a three-step examination sequence for medical licensure in the United States. The first administrations of the examination took place in 1992. Today, the program administers approximately 140,000 Step examinations or Step components annually with more than 2.7 million total test administrations since 1992. In fact, as of 2014 approximately 46% of this nation's 916,000 physicians with an active medical license have taken all or a part of the USMLE sequence.

Mission: The USMLE's stated mission is to support US medical licensing authorities through the development, delivery and continual improvement of high quality assessments across the continuum of physicians' preparation for practice. The program's goal is to provide medical licensing authorities with "meaningful information from assessments of physician characteristics—including medical knowledge, skills, values, and attitudes—that are important to the provision of safe and effective patient care."

The results of the USMLE are reported to medical licensing authorities for their use in the decision to grant a provisional license to practice in a post-graduate education program and the decision to grant an initial license for the independent practice of medicine. The USMLE is recognized and utilized by all state medical boards for licensing allopathic physicians and graduates of international medical schools. Some licensing authorities also recognize USMLE for licensing osteopathic graduates.

Governance: The FSMB and the NBME co-own the USMLE. However, much of the governance responsibility for the program resides with its Composite Committee. The committee comprises representatives from the FSMB, the NBME, the Educational Commission for Foreign Medical Graduates (ECFMG) and the American public. The Composite Committee is responsible for overseeing and directing USMLE policies. Specific functions of the committee include establishing policies for scoring and standard setting; approving Step examination blueprints and test formats; setting policies for test administration, test security and program research. The membership of the Composite Committee routinely includes current or former members of state medical boards. At this time, current and former members of the Iowa, Minnesota, North Carolina, and Vermont-Medical medical boards serve on the USMLE Composite Committee.

The three USMLE Step examinations are overseen by a Management Committee composed of physicians and scientists drawn from the licensing, practice and medical education communities and members of the public. At this time, current and former members of the Florida-Medical, Hawaii, Iowa, Minnesota, North Carolina and Wisconsin medical boards serve on the USMLE Management Committee.

Eligibility: USMLE is intended to be taken by graduates of U.S. and Canadian medical schools granting the M.D. degree and by graduates of international medical schools. The USMLE requirements are as follows:

To be eligible for Step 1, Step 2 CK, and Step 2 CS, the examinee must be in one of the following categories at the time of application and on test day:

- a medical student officially enrolled in, or a graduate of, a US or Canadian medical school program leading to the MD degree that is accredited by the Liaison Committee on Medical Education (LCME),
- a medical student officially enrolled in, or a graduate of, a US medical school leading to the DO degree that is accredited by the American Osteopathic Association (AOA), or
- a medical student officially enrolled in, or a graduate of, a medical school outside the United States and Canada who meets the eligibility criteria of the ECFMG.

To be eligible for Step 3, prior to submitting an application, the examinee must:

- obtain the MD degree (or its equivalent) or the DO degree,
- pass Step 1, Step 2 CK, and if required, Step 2 CS (additional information available at www.usmle.org),
- obtain certification by the ECFMG if the examinee is a graduate of a medical school outside the United States and Canada.

The USMLE program recommends that for Step 3 eligibility, examinees should have at least one postgraduate training (PGT) year in a program of an accredited graduate medical education (e.g., accredited by the ACGME or the AOA) that would qualify for medical licensure in the United States.

A physician who received his or her basic medical degree or qualification from a medical school outside the United States and Canada may be eligible for certification by the ECFMG if the medical school and graduation year are listed in the *World Directory of Medical Schools*. This applies to citizens of the United States who have completed their medical education in schools outside the United States and Canada but not to foreign nationals who have graduated from medical schools in the United States and Canada. Specific eligibility criteria for students and graduates of medical schools outside the United States and Canada to take Step 1 and Step 2 are described in the Information Booklet provided by the ECFMG.

Once an individual passes a USMLE Step, it may not be retaken. Rare exceptions to this policy can be found at <http://www.usmle.org/bulletin/eligibility/>.

Content: The USMLE is comprised of three Steps: Step 1, Step 2, and Step 3. Step 2 has two separately administered components, Clinical Knowledge (CK) and Clinical Skills (CS). Although the USMLE is generally completed over the course of several years in the career of a prospective physician, it constitutes a single examination system. Each of the three Steps complements the others; no Step can stand alone in the assessment of readiness for medical licensure.

Content for the USMLE is developed by committees of medical educators and clinicians. Committee members broadly represent the teaching, practice and licensing communities across the United States. At least two of these committees critically appraise each test item or case before it is used as live (i.e., scored) material on the USMLE. These committees may revise or discard materials for any of several reasons, e.g., inadequate clinical relevance, outdated content, failure to meet acceptable statistical performance criteria, etc. For a more detailed explanation of content development, contact FSMB for a copy of the 2009 *Journal of Medical Licensure and Discipline* article, “Developing Test Content for the USMLE”.

Step 1 assesses whether a candidate understands and can apply important concepts of the sciences basic to the practice of medicine, with special emphasis on principles and mechanisms underlying

health, disease and modes of therapy. Step 2 assesses whether the candidate can apply medical knowledge, skills and understanding of clinical science essential for providing patient care under supervision. This includes an emphasis on health promotion, disease prevention and basic patient-centered skills. Step 3 assesses whether the candidate can apply medical knowledge and understanding of biomedical and clinical science essential for the unsupervised practice of medicine with emphasis on patient management in ambulatory settings. More detail on content specifications for each USMLE Step is provided at www.usmle.org.

The Step 1 examination has 280 multiple-choice test items, divided into seven 60-minute blocks, administered in a one-day, eight-hour testing session. The Step 2 CK examination has 318 multiple-choice test questions, divided into eight 60-minute blocks, administered in a one-day, nine-hour testing session. The Step 2 CS examination has 12 standardized patient cases, administered in a one-day testing session of approximately eight hours. Examinees have 15 minutes for each patient encounter and 10 minutes to record each patient note. The Step 3 examination has 413 multiple-choice test items, divided into blocks of 30-40 questions, with 45 to 60 minutes to complete each block. In addition, Step 3 includes 13 computer-based case simulations (CCS). Each simulation is allotted either 10 or 20 minutes of testing time. Step 3 is administered over two testing days – seven hours for Day 1 and nine hours for Day 2.

Test Administration: Parts of the USMLE are administered by computer. Prometric provides scheduling and test centers for the computer-based components of the USMLE. Step 1 and Step 2 CK examinations are given around the world at Prometric Test Centers (PTCs). Step 3 is given at PTCs in the United States and its territories only. Step 2 CS is administered at five regional test centers managed by the Clinical Skills Evaluation Collaboration (CSEC). The CSEC centers are in Atlanta, Chicago, Houston, Los Angeles, and Philadelphia.

All USMLE examinations are proctored and videotaped. Strict guidelines are followed for proper identification of examinees. Efforts are made to reduce the overlap of test content from examinee to examinee and from test day to test day. Any significant breaches in security can result in the cancellation of results, suspension of an individual from USMLE, and/or annotation of results.

Test Accommodations: Various test accommodations are provided in accordance with the Americans with Disabilities Act (ADA) for qualified individuals. Requests for test accommodations are reviewed by two NBME staff trained in clinical and school psychology at the doctoral level. Further review of the request and supporting documentation is provided by professionals in the respective fields of disability with whom NBME consults in making determinations regarding the presence of a disability and the appropriate accommodation(s). NBME reviews all requests for accommodations for USMLE and makes decisions for all Step examinations (1, 2CK, 2CS and 3). Efforts are made to match accommodations to the individual's functional limitations.

Examinees protected under the ADA may be provided with a variety of accommodations. The NBME currently prepares audio recorded versions of the examinations for candidates with visual or visual processing disabilities. Special tactile versions of visual material for a Step examination may be provided for examinees with severely impaired vision. Items with an audio component may include a visual representation of the sound for hearing impaired examinees. A sign language interpreter may be provided for deaf examinees for Step 2 CS. Examinees are informed of the availability of test accommodations in the USMLE Bulletin of Information, which can be found at www.usmle.org. While presumably the use of accommodations in test activity will enable the individual to better

demonstrate his/her knowledge or mastery, accommodations are not a guarantee of improved performance, test completion, or a passing score.

Score Reporting: When examinees take Step 1, Step 2 CK, or Step 3, the computer records their responses. After the test ends, examinee responses are transmitted to the NBME for scoring. For Step 2 CS, examinees are assessed on their physical examination and communication skills (including spoken English) by the standardized patients, and on their ability to complete an appropriate patient note by physician raters. With the exception of Step 2 CS, which is reported as Pass/Fail, USMLE results are reported on a 3-digit scale. On the 3-digit scale, most Step 1 and Step 3 scores fall between 140 and 260 and most Step 2 CK scores fall between 190 and 270. The means and standard deviations for recent, first-time examinees from accredited medical school programs in the United States and Canada were: Step 1, 229 (20); Step 2 CK, 242 (17); and Step 3, 225 (16). Examinee score reports will include the mean and standard deviation for a recent administration of the examination.

USMLE score reports and transcripts show scores (for Step 1, Step 2 CK, and Step 3) and an indication of whether an examinee passed or failed (for all examinations). The same information is sent to medical licensing authorities upon examinee authorization for their use in making licensure decisions.

Under most circumstances, to receive a score on Step 1, Step 2 CK, and Step 3, an examinee must begin every block of the test. If an examinee does not begin every block and no results are reported, an "incomplete examination" attempt appears on the USMLE transcript. If an examinee registers for but does not begin an examination, no record of the test will appear on the examinee's transcript.

For Step 2 CS, if an examinee leaves the test early, or for some other reason fails to carry out one or more of the cases, performance may be assessed on those cases completed. If this assessment were to result in a passing outcome no matter how poorly an examinee may have performed on the missed case(s), then a "pass" will be reported. If this assessment were to result in a failing outcome no matter how good an examinee's performance may have been on the missed case(s), then a "fail" will be reported. Otherwise, the attempt may be recorded as an "incomplete."

Some unscored items and cases may also be included in the Step examinations for research purposes.

A Score Interpretation Guide (SIG) and annual performance data for all Step examinations are available in the "Data and Research" section of the USMLE website (<http://www.usmle.org/data-research/>).

Minimum Passing Scores: The USMLE program provides a recommended pass or fail outcome for all Step examinations. Recommended performance standards for the USMLE are based on a specified level of proficiency. As a result, no predetermined percentage of examinees will pass or fail the examination. The recommended minimum passing level is reviewed periodically and may be adjusted at any time. Notice of such review and any adjustments will be posted at the USMLE website.

A statistical procedure ensures that the performance required to pass each test form is equivalent to that needed to pass other forms; this process also places scores from different forms on a common scale.

For Step 3, performance on the case simulations affects the Step 3 score and could affect whether examinees pass or fail. The proportional contribution of the score on the case simulations is no greater than the amount of time examinees are allowed for the case simulations.

Current minimum passing scores for each Step are as follows (mean scores are provided in the SIG):
Step 1: 192
Step 2 CK: 209
Step 3: 196

Although 2-digit scores are no longer reported, test results reported as passing on the three-digit scale would represent an exam score of 75 or higher if a two-digit score had been reported.

Score Reliability: Reliability refers to a score's expected consistency. Candidates' test scores are reliable to the extent that an administration of a different random sample of items from the same content domain would result in little or no change in each candidate's rank order among a group of candidates. In general, long examinations of very similar items administered to a diverse group of examinees yield high reliabilities.

One of the ways that reliability is measured is through the standard error of measurement (SEM). The SEM provides a general indication of how much a score might vary across repeated testing using different sets of items covering similar content. As a general rule of thumb, chances are about two out of three that the reported score is within one SEM, plus or minus, of the score that truly reflects the examinee's ability (i.e., of the score that would be obtained if the examination were perfectly reliable). The current SEM is approximately 6 points on the three-digit reporting scale for Steps 1, 2CK, and 3. The Step 2 CS is only reported as a pass or fail, without a reported score.

Score Validity: Score validity refers to the extent to which existing evidence supports the appropriateness of the interpretation of test outcomes. For USMLE, the intended interpretation of passing all examinations is that the individual has the fundamental knowledge and skills required to begin patient care in a safe and effective manner. The best way to support a proposed score interpretation is through accumulation of developmental documentation and research on all components of the test design, delivery, and scoring processes, and through tracking the relationship of examination outcomes with later measures of the individual's ability. The USMLE program has a fairly extensive history of such activity. A list of research citations as well as descriptions of many of the USMLE processes is available on the USMLE website. (<http://www.usmle.org/data-research/>)

USMLE Program News, 2014-2016

Following are abbreviated versions of news items posted on the USMLE website from 2014-2016.

New Features in USMLE Step 1 and Step 2 CK Examinations (posted March & June 2016)

The NBME has developed new software to deliver Step 1 and Step 2 CK that incorporates user-adjustable display features, specifically text and image magnification and reverse color (color inversion). The new features began to be administered in Step 1 examinations during a transition period beginning the week of May 9, and in Step 2 CK examinations during a transition period beginning the week of July 10.

Step 2 CK – Delay in score reporting and change in number of test items (posted May 2016)

Most score reporting of Step 2 CK results occurs within four weeks of testing. However, because of necessary modifications to the test item pool, as well as a change to new test delivery software, there will be a delay in reporting for some examinees who test beginning the week of July 10, 2016. The target date for reporting Step 2 CK scores for most examinees testing the week of July 10 through late August will be September 14, 2016.

During this time period, a transition will occur in the number of items in current forms of the Step 2 CK examination. The total number of items will decrease from no more than 355 to no more than 318. Please note the following:

- Scores on new and old exam forms will be comparable; the decrease in the number of items per form will be accounted for in scoring the examination results.
- The length of the examination day will remain unchanged. The test day will continue to be divided into eight 60-minute item blocks, an optional 15-minute tutorial, and 45 minutes of break time, for a total of 9 hours.
- The number of items per block on a given examination form will vary but will not exceed 40 items.
- The number of items in a block is displayed on the screen at the beginning of the block. Please note this information and pace yourself accordingly.

2017 schedule for reporting Step 2 CS results is available (posted May 2016)

The 2017 schedule provides guidelines regarding when a result for a Step 2 CS exam date will be reported. The schedule is available at <http://www.usmle.org/step-2-cs/#reporting>.

USMLE takes action against individuals found to have engaged in irregular behavior (posted April 2016)

The USMLE Committee for Individualized Review (CIR) meets periodically throughout the year to review cases involving allegations of irregular behavior by applicants and/or examinees. At its recent meetings, the CIR considered multiple cases involving the following:

- falsifying information, including the creation of falsified score reports
- seeking to obtain unauthorized access to examination materials
- communicating about specific test items, cases, and/or answers with other examinees
- providing unauthorized access to examination content on the internet
- applying for and/or attempting to take an examination when ineligible
- making notes on test day on something other than materials provided

- failure to follow test center instructions, including typing past the ‘End Patient Note’ announcement in Step 2 CS

Actions taken by the CIR at its recent meetings included:

- annotating individual USMLE records with a finding of irregular behavior
- barring access to USMLE for periods up to 3 years
- reporting the finding of irregular behavior to FSMB’s Physician Data Center; state boards routinely query this data bank as part of their licensing processes
- cancelling the examinee’s score because the validity of a passing level score is in question

Images in Step 2 Clinical Skills examination (posted March 2016)

Beginning May 22, 2016, USMLE Step 2 CS examinees may see a case in which the standardized patient provides a digital image (for example, a photograph, x-ray, MRI, or CT) on a tablet computer. Examinees will be able to enlarge the image. During the pre-session orientation, examinees will have an opportunity to view a sample image on a tablet, and to practice enlarging the image. Not all examinations will include a case with an image. Examinees will see a maximum of one case with an image per examination.

Important announcement regarding Fifth Pathway certificates and USMLE Step 3 (posted March 2016)

As previously announced, the governing committee of the USMLE program and the USMLE parent organizations (FSMB & NBME) have determined that USMLE will cease acceptance of Fifth Pathway certificates for the purpose of meeting Step 3 eligibility requirements, effective January 1, 2017.

Currently, the USMLE program accepts either a valid Standard ECFMG Certificate or a valid Fifth Pathway certificate (issued through December 31, 2009) from international medical graduates for purposes of meeting Step 3 eligibility requirements. Individuals who hold valid Fifth Pathway certificates, and are otherwise eligible, may use their Fifth Pathway certificates to meet Step 3 eligibility requirements, and may apply for Step 3 through December 31, 2016. Individuals holding Fifth Pathway certificates that are not accepted by the USMLE program for purposes of meeting Step 3 eligibility will be required to obtain ECFMG certification in order to be eligible for Step 3.

Step 1 – Delay in score reporting and change in number of test items (posted March 2016)

Most score reporting of Step 1 results occurs within four weeks of testing. However, because of necessary modifications to the test item pool, as well as a change to new test delivery software, there will be a delay in reporting for some examinees who test beginning the week of May 9, 2016. The target date for reporting Step 1 scores for most examinees testing the week of May 9 through late June will be July 13, 2016. During this time period, a transition will occur in the number of items in current forms of the examination. The total number of items will decrease from 308 to no more than 280.

Please note the following:

- Scores on new and old exam forms will be comparable; the decrease in the number of items per form will be accounted for in scoring the examination results.
- The length of the examination day will remain unchanged. The test day will continue to be divided into seven 60-minute item blocks, an optional 15-minute tutorial, and 45 minutes of break time, for a total of 8 hours.

- The number of items per block on a given examination form may vary but will not exceed 40 items. The number of items in a block is displayed on the screen at the beginning of the block. Please note this information and pace yourself accordingly.

USMLE Security Video (posted January 2016)

Remember, the stakes on a medical licensing exam are high! Don't do something that might jeopardize your future as a licensed physician. Be sure you understand all the USMLE policies on security and irregular behavior by viewing our new security video, <http://www.usmle.org/security>.

Change in minimum passing requirements for Step 3 (posted December 2015)

The USMLE program recommends a minimum passing level for each Step examination. The USMLE Management Committee is responsible for establishing and monitoring these standards, and is asked to complete an in-depth review of standards for each examination every three to four years. At its December 2015 meeting, the USMLE Management Committee conducted a review of the Step 3 examination minimum passing score and considered information from multiple sources:

- Recommendations from independent groups of physicians who participated in content-based standard-setting activities in 2015;
- Results of surveys of various groups (e.g., state licensing representatives, medical school faculty, examinees) concerning the appropriateness of current passing requirements for the Step 3 examination;
- Data on trends in examinee performance; and
- Data on precision of pass/fail classifications.

As a result of its review, the Management Committee decided to raise the recommended Step 3 minimum passing score from 190 to 196. This change will affect examinees whose first day of testing is on or after January 1, 2016.

Step 3 – Change in number of items and score delay (posted November 2015)

Beginning the week of January 18, 2016, the number of items on the Step 3 examination will decrease. There will be a delay in reporting scores for exams administered between January 18 and April 30, 2016. The target date for reporting Step 3 scores for most examinees testing during this time period is May 25, 2016. Please note that:

- The length of the testing days will not change.
- Day 1 (Foundations of Independent Practice [FIP]) will continue to be an approximately 7-hour testing session, including time for breaks and tutorials.
- Day 2 (Advanced Clinical Medicine [ACM]) will continue to be a 9-hour testing session, including time for breaks and tutorials.
- Day 1 (FIP) will continue to be divided into six 60-minute blocks.
- Each FIP block will have 38 to 40 multiple-choice questions (MCQs).
- The total number of MCQs on the FIP portion of the examination will be 233.
- Day 2 (ACM) will continue to be divided into six 45-minute blocks of MCQs, and 13 computer-based case simulations (CCS).
- Each ACM MCQ block will have 30 items.
- The total number of MCQ items on the ACM portion of the examination will be 180.
- Scores on examination forms taken before and after the change – as well as scores on forms with different numbers of items – will be comparable; the possible variation in the number of items per form will be accounted for in scoring the examination.

Expanded Version of USMLE Content Outline (posted April 2015)

An expanded version of the USMLE Content Outline, which provides a common organization of content across all USMLE exams, is available at www.usmle.org/pdfs/usmlecontentoutline.pdf.

The expanded version provides additional detail about subcategories of the 18 sections of the content outline. It is important to note that the USMLE Content Outline is not intended as a curriculum development or study guide. It provides a flexible organization of content for test construction that can readily accommodate new topics, emerging content domains, and shifts in emphasis. While the USMLE Content Outline is common to all exams, each exam continues to have its own test specifications. Each exam emphasizes certain parts of the outline, and no single examination will include questions on all topics in the outline.

USMLE Score Interpretation Guidelines (posted October 2014)

USMLE Score Interpretation Guidelines have been posted to the USMLE website. Topics include:

- Description of Examinations
- Understanding Your Score
- Recent Means and Standard Deviations (SDs)
- Norm Table
- Passing Scores
- Precision of Scores
- Guidelines for Use of USMLE Step Scores for Selection Decisions

The means and SDs and the norm table will be updated annually. Because percentile ranks depend on the cohort of examinees, you should always use the most recent norm table available on the USMLE website to obtain percentile ranks.

Score Reporting of Administrations with Accommodations (posted September 2014)

The USMLE Program provides reasonable and appropriate accommodations in accordance with the Americans with Disabilities Act for individuals with documented disabilities who demonstrate a need for accommodation. The USMLE Composite Committee has directed that USMLE score reports and transcripts issued on or after September 10, 2014 will not include an annotation that a test accommodation was granted.

USMLE Physician Tasks/Competencies (posted July 2014)

USMLE Physician Tasks/Competencies, a publication that provides a common organization of competencies and tasks assessed in USMLE examinations, is now available. This publication is available at www.usmle.org/pdfs/tcom.pdf and is useful for understanding competencies assessed by multiple-choice question (MCQ) formats such as Step 1, Step 2 Clinical Knowledge, and the MCQ portion of Step 3.

The outline comprises seven major sections - Medical Knowledge/Scientific Concepts; Patient Care: Diagnosis; Patient Care: Management; Communication and Interpersonal Skills; Professionalism, including Legal and Ethical Issues; Systems-based Practice, including Patient Safety; and Practice-based Learning. While this outline is common to all USMLE examinations, each Step will continue to have test specifications specific to that Step and will emphasize certain parts of the outline. The outline will be updated as work to identify competencies covered by non-MCQ exam formats progresses.

Use caution in selecting review courses (posted April 2014)

Orientation, Practice, and Self-Assessment Materials Available through USMLE, NBME, and Third Parties

The USMLE program recognizes the importance of providing all examinees the opportunity to learn about the design and content of its examinations and to have some exposure, before examination day, to samples of testing formats and materials. USMLE provides orientation and practice materials for all USMLE Steps and Step Components. In addition, the NBME provides, for a fee, self-assessment services to help the examinee evaluate his or her readiness to take USMLE. These services help individuals become familiar with questions like those that have appeared on USMLE and provide performance feedback on the individual's areas of relative strength and weakness.

Beyond these USMLE and NBME services, there are a variety of commercial test preparation materials and courses that claim to prepare examinees for USMLE examinations. Examinees who are considering using such services should fully understand the nature of these services, the sources of any content being used, and the basis for any claims being made. None of these third-party materials or courses are affiliated with or sanctioned by the USMLE program and information on such materials and courses is not available from the ECFMG, the FSMB, NBME, USMLE Secretariat, or medical licensing authorities.

Please note that it is unlawful for any test preparation program or any individual to use, disclose, distribute, or provide access to questions or answers from actual USMLE exams. An examinee who is involved with any enterprise that disseminates USMLE content should be aware of the consequences, which include the possible cancellation of USMLE registration and/or testing, the withholding or cancellation of scores, and the imposition of additional sanctions.

USMLE Step 2 CS

Background

In late February 2016, a group of fourth-year medical students at Harvard initiated a national petition to end the Step 2 CS requirement for students from LCME-accredited medical schools (the petition does not recommend discontinuation of the requirement for international medical students/graduates). The students' objections can be summarized as follows:

- The exam is expensive and inconvenient.
- Students do not get useful feedback on performance.
- The medical schools have OSCEs or similar examinations that assess the same skills.
- There is no evidence that we have improved patient safety with inclusion of this exam component in 2004.

In addition to an End Step 2 CS website (<http://endstep2cs.com/>), various other means (e.g., Facebook, Twitter, YouTube, listservs) are also being used to obtain support.

Medical societies vote to oppose Step 2 CS

In May 2016, both the Michigan Medical Society and the Massachusetts Medical Society voted in favor of resolutions urging their states to abandon the Step 2 CS exam as a licensure requirement for graduates of U.S. medical schools. A resolution template, online at www.endstep2CS.com, reads: "RESOLVED, That the [State Medical Society] advocates for the [State Medical Board] to eliminate the Step 2 CS Exam [and the COMLEX Level 2 PE if applicable] requirement for U.S. Medical Graduates who have passed a school-administrated clinical skills examination."

AMA House of Delegates action

In June 2016 meeting, the AMA House of Delegates adopted the following resolution regarding the USMLE Step 2 CS. Testimony in opposition to the resolution was provided by students, licensing board executive directors, academic deans, and other practicing physicians, as well as representatives from the USMLE program and the FSMB and the NBME.

Resolved, that our AMA work with the FSMB, NBME and other key stakeholders to pursue transition from and replacement for the current USMLE Step 2 CS and COMLEX Level 2 PE as a requirement for LCME-accredited and COCA-accredited medical school graduates who have passed a school-administered clinical skills examination (*Directive to Take Action*); and be it further

Resolved, that our AMA work to:

- 1) ensure rapid yet carefully considered changes to the current examination process to reduce costs, including travel expenses, as well as time away from educational pursuits, through immediate steps by FSMB and NBME;
- 2) encourage a significant and expeditious increase in the number of available testing sites;
- 3) engage in a transparent evaluation of basing this examination within our nation's medical schools, rather than administered by an external organization; and
- 4) include active participation by faculty leaders and assessment experts from US medical schools, as they work to develop new and improved methods of assessing medical student competence for advancement into residency (*New HOD Policy*).

USMLE program efforts

As part of an overall response to this issue, USMLE program staff have also taken this opportunity to explore possible approaches to providing additional feedback on Step 2 CS performance – to examinees, to schools, and to other stakeholders. We have also:

- Surveyed state medical boards executive directors about the Step 2 CS. A summary of their responses is provided below.
- Conducted informational sessions for state boards on this issue using the FSMB Roundtable and the FSMB annual meeting
- Distributed discussion points regarding the value of USMLE in general, and Step 2 CS specifically (see below).
- Commented when possible on the various published articles to provide our side of the story.
- Spoken directly with leaders of national medical student organizations to gain their input into this issue. Groups include the AMA medical student and resident sections; the Organization of Student Representatives; the American Medical Student Association; and the Student National Medical Association
- Testified at the AMA in opposition to the resolution that was submitted (see above).
- Contacted the End Step 2 CS website owners regarding misinformation originally published on the site (i.e., the original postings stated that NBME is solely responsible for USMLE, with no mention of the role of FSMB and the state medical boards). They have since corrected the misstatements but the focus of the students' concern remains on NBME.

Discussion Points

What are we doing? First, listening - and hope students will, too.

At our request, we met by phone with the Harvard students who began the End Step 2 CS petition to hear directly about their concerns. We have also convened a staff task force to look specifically at ways we might address one of the student concerns by providing more feedback on exam performance without compromising the reliability or fairness of the exam. We also hope the students will listen with open minds to why we see Step 2 CS as a critical part of our collective social compact with the public. Patients grant us the privilege of taking part in some of the most important and intimate decisions in their lives. In return, we promise that as a profession, we will do all we can to monitor ourselves and assure the competence of their physicians.

Variability is a serious issue.

Step 2 CS represents a great advance in our ability to fulfill that social contract. All of the resolutions ask the states to delegate the evaluation of clinical and communication skills to 170 osteopathic and allopathic medical schools. That is 170 different curricula, means of testing students, and standards for doing so. Until we could assure the reliability and fairness of a clinical skills exam in 2004, we collectively needed to accept that variation. Now we can do better. Currently, pass rates of first-time test-takers from US and Canadian schools vary by school from below 90% to 100%. Step 2 CS also means that graduates of American and international medical schools must meet the same standard for communications and clinical skills, which addresses our value of fairness for all medical graduates.

The raw numbers matter.

In 2013-14, 839 first-time test takers from US and Canadian schools failed Step 2 CS. While they represented only 4% of the total number of test-takers, if it were not for the Step 2 CS, 839 physicians would have hundreds of thousands of patient encounters without ever having to remediate

deficiencies in their clinical skills. That is hundreds of thousands of patients that Step 2 CS has protected. No price can be put on that.

State boards strongly affirm their support.

Recently 98% of the 47 state medical boards that responded to an FSMB survey resoundingly voiced their support for continuing the Step 2 CS. This level of approval is not surprising. A 2014 study in the Journal of Medical Regulation showed just how important these skills are to medical boards. A review of complaints made to the North Carolina medical board between 2002--2012 showed that complaints involving communications were the single largest complaints category at 20% of all complaints. State medical boards see daily the importance of clinical and communications skills in the actual practice of medicine, and they know medical schools do not have the resources to ensure that all the applicants for licensure have demonstrated the same basic competencies.

Published articles and op-eds (both in support of and in opposition to the Step 2 CS)

- Harvard Crimson: <http://www.thecrimson.com/article/2016/3/25/medical-school-students-petition/>
- College USA Today: <http://college.usatoday.com/2016/03/25/harvard-medical-students-call-for-elimination-of-unnecessary-exam/>
- LA Times: <http://www.latimes.com/opinion/op-ed/la-oe-0329-henderson-morris-step2cs-exam-20160329-story.html>
- KevinMD:
 - <http://www.kevinmd.com/blog/2016/04/objective-national-standard-clinical-skills-critical-heres.html>
 - <http://www.kevinmd.com/blog/2016/07/cost-taking-usmle-exams-staggering.html>
- JAMA: <http://archinte.jamanetwork.com/article.aspx?articleid=2532794>
- NEJM Open Forum: <https://medstro.com/groups/nejm-group-open-forum/discussions/265>

USMLE Enhancements

Design Review of Step 1 and Step 2 Clinical Knowledge Examinations

Similar to the review of the USMLE Step 3 examination that prompted recent changes to the examination, USMLE governance is conducting a review of the Step 1 and Step 2 Clinical Knowledge examinations to determine if these examinations should be redesigned. The USMLE Management Committee is investigating a potential expansion of the competencies important to supervised practice, including but not limited to further development of content related to communication, patient safety, and professionalism. Planned changes will be announced on the USMLE website well in advance of implementation.

Investigating Improvements to Reporting of USMLE Results to Examinees and Medical Schools

The USMLE program continues to investigate ways to improve the reporting of USMLE results to examinees and medical schools. The investigation includes a review of the current reports; surveys to both examinees and schools to determine how examinees and medical schools use and interpret score reports; a review of the informational materials provided to examinees and medical schools; and input from USMLE governance.

Medical Licensing Authorities and the USMLE

USMLE Services to State Medical Boards

In 2015, the FSMB registered approximately 34,000 applicants for the USMLE Step 3. Step 1 and Step 2 registration services are provided by NBME for students and graduates in US medical and osteopathic schools and by ECFMG for students and graduates of international medical schools under eligibility requirements established by the USMLE Composite Committee.

The FSMB also produced and delivered approximately 70,000 USMLE transcripts, including approximately 20,000 transcripts produced as part of the Federation Credentials Verification System profile sent to state medical boards for physicians seeking licensure.

The USMLE makes a wide range of informational materials available to medical licensing authorities on the program. A series of informational articles on USMLE have appeared in the FSMB's *Journal of Medical Regulation* (See Section 7). Since 2009, the FSMB has hosted multiple web seminars on USMLE-related topics. Subjects covered in these webinars include USMLE attempt, time limit, and retake policies; update on content changes to Step 3, including the discontinuance of state board sponsorship for Step 3; challenges to the Step 2 CS; and annotations on the USMLE transcript. Copies of these presentations are available upon request from the FSMB.

State Medical Boards' Participation in USMLE

The FSMB and NBME also hosts an annual USMLE Orientation workshop for members of state medical boards. This free workshop is open to current and former members of state medical boards with an interest in participating in the program. The tenth workshop took place in late September 2016 in Philadelphia. Ten members and staff from the following medical boards participated: Arizona-Medical, Florida-Medical, Georgia, Kansas, North Carolina and Texas. To date, 96 individuals from 39 medical and osteopathic boards have participated. Thirty-six (36) past workshop participants have served subsequently with the USMLE program. This includes participation on standard-setting and advisory panels, as well as serving on the USMLE Management Committee and item-writing committees for the program. The next workshop is set for fall 2017. Physician and public members of state medical and osteopathic boards interested in attending this workshop should contact the FSMB for more information.

In 2011, the USMLE established an advisory panel composed of members and senior staff from state medical boards. The State Board Advisory Panel to the USMLE convened again in September 2016. The panel provides the USMLE with firsthand feedback on timely issues and major initiatives from the primary intended user of USMLE scores – state medical boards. Topics addressed by the panel in September 2016 included forthcoming updates to USMLE exams, USMLE research agenda, reporting of irregular behavior to state medical boards, the Step 2 CS exam (including a tour of the Step 2 CS site in Philadelphia), requests for exceptions to USMLE policies and issues of interest to public stakeholders. The current members of the panel include staff and board members from the California-Medical, Illinois, Montana, Nevada-Medical, Tennessee-Medical & Tennessee-Osteopathic, Utah-Medical, Virginia, West Virginia-Medical, Wisconsin and Wyoming boards.

Groups such as the State Board Advisory Panel to USMLE and outreach efforts such as the annual orientation workshop for medical board members continue the long history of the USMLE program involving the state medical board community directly in the operations of the program. Since its implementation in 1992, 202 members and staff from state medical boards have participated in the

USMLE program in some capacity. These individuals represent 58 different medical and osteopathic licensing boards throughout the United States.

USMLE Policies

The USMLE recommends that state medical boards require the dates of passing Step 1, Step 2, and Step 3 to occur within a seven-year period. The program, however, recommends that state medical boards consider additional time for individuals completing a dual degree program (MD/PhD; DO/PhD). Additionally, the USMLE program imposes a limit of no more than six attempts to pass each of the Step or Step Components. Additional attempts are allowed only at the written request of a state medical board.

Most state medical boards utilizing the USMLE impose both time and attempt limits on the USMLE as part of their requirements for obtaining an initial medical license. Currently, 41 out of 51 medical boards impose some limit on the number of attempts at the USMLE; 46 out of 51 medical boards impose a time limitation for the completion of the USMLE sequence. For a complete listing, please visit: www.fsmb.org/licensure/usmle-step-3/state_specific.

Specific requirements for taking and retaking USMLE are provided in the FAQs on the USMLE website at: www.usmle.org/frequently-asked-questions/.

For information on exceptions to USMLE policy, contact the FSMB or visit the USMLE website at www.usmle.org/bulletin/eligibility/.

USMLE Data and Research

Aggregate Performance Data

The USMLE program publishes aggregate performance data for all Steps since the program's inception. These data include examinee volume and passing percentages categorized by first-taker and repeater examinees; US/Canadian and international students/graduates; allopathic and osteopathic examinees. These performance data are available at the USMLE website at www.usmle.org/performance-data/.

Passing rates and examinee counts for 2013-2015 are provided for each Step in this report's Appendix.

Research Agenda

Each year, the USMLE Composite Committee reviews and endorses a research agenda for the program. The committee endorsed the following research themes and/or topics for the program for 2016-2017: enhancements to the USMLE; relating scores and pass/fail outcomes to external measures; determining strategies for providing meaningful performance feedback to examinees and stakeholders; and USMLE security procedures.

2015 Publications

Below is a list of program-related publications by USMLE staff in 2015. A more extensive listing (2009-2015) is available on the USMLE website at <http://usmle.org/data-research/>.

Cuddy MM, Winward ML, Johnston MM, Lipner RS, Clauser BE. Evaluating validity evidence for USMLE Step 2 Clinical Skills data gathering and data interpretation scores: does performance predict history-taking and physical examination ratings for first-year internal medicine residents? *Academic Medicine*. 2015. Sept 21 [Epub ahead of print]

Dong T, LaRochelle JS, Durning SJ, Saguil A, Swygert KA, Artino AR. Longitudinal effects of medical students' communication skills on future performance. *Military Medicine*. 2015;180(4 Suppl):24-30.

Feinberg RA, Raymond MR, Haist SA. Repeat testing effects on credentialing exams: are repeaters misinformed or uninformed? *Educational Measurement: Issues and Practice*. 2015;34(1):34-39.

Furman G. Proving our worth: foundational literature supporting the standardized patient educational methodology. *ASPE eNews*. 2015; December
8. <http://multibriefs.com/briefs/aspeorg/ASPEORG120815.php>. Accessed 01/13/2016

Kahraman N, Brown CB. Using multigroup confirmatory factor analysis to test measurement invariance in raters: a clinical skills examination application. *Applied Measurement in Education*. 2015;28:350-366.

Lane S, Raymond MR, Haladyna TM, Downing SM. Test development process. In: Lane S, Raymond MR, Haladyna TM, eds. *Handbook of test development*. 2nd ed. New York: Routledge; 2015:3-18.

Ouyang W, Cuddy MM, Swanson DB. US medical student performance on the NBME Subject Examination in Internal Medicine: do clerkship sequence and clerkship length matter? *Journal of General Internal Medicine*. 2015;30:1307-1312.

Peitzman SJ, Cuddy MM. Performance in physical examination on the USMLE Step 2 Clinical Skills examination. *Academic Medicine*. 2015;90:209-213.

Prober CG, Kolars JC, First LR, Melnick DE. A plea to reassess the role of United States Medical Licensing Examination Step 1 scores in residency selection. *Academic Medicine*. 2015. Aug 3. [Epub ahead of print]

Standard Setting

USMLE General Procedures for Standard Setting

The USMLE system for setting standards is established by the USMLE Composite Committee, which includes representatives of the ECFMG, FSMB, NBME and the public. The system specifies the kinds of data to be gathered and how the data are to be gathered, the frequency of reviewing the standards and adjusting them, and assigns the judgment task to the Management Committee. The Management Committee, jointly appointed by the FSMB and NBME, must use the procedures defined by the Composite Committee, but is free to set the standard and revise the standard as it deems necessary. The decision of the Management Committee is final; no superior governing committee is authorized to alter its decision. The Management Committee includes those with educational, licensing, and clinical practice perspectives, as well as a representative from the public.

Current policy requires that the Management Committee review the effectiveness of Step standards at least annually. A comprehensive review and possible adjustment of the standard must be undertaken approximately every four years. In addition, when there are any major changes to the design or format of the Step examination, the Management Committee is asked to establish new passing requirements for the redesigned components. USMLE believes that there must be an opportunity for review and adjustment of standards in order to reflect the realities of change in the content of medicine, the nature of the test, the characteristics of examinees, and the expectations of stakeholders. Such review of the standard is essential to assure that the judgment inherent in defining the standard reflects current conditions, not those that were pertinent in the past.

Mandated Data Sources Informing the Judgment Process

USMLE policy mandates the use of four categories of data in making judgments about standards. These are:

- Content-referenced judgments of experts. Content experts provide their opinions, based upon review of content and examinee performance, on the appropriate requirements for passing the examination.
- Survey of stakeholders. Expectations of stakeholders for the percent of examinees, to whom the stakeholder is exposed, that should pass the examination.
- Cohort performance trends. Trends in examinee performance over a long period of time and the effect of repeated attempts at the examinations on the failure rate in a defined cohort of examinees.
- Confidence intervals in the region of the cut-score. Estimates of numbers of misclassified examinees based on historical distributions of examinee performance and the measurement error in the scale area under consideration for the cut-score.

Setting the Standard

The Management Committee meets to consider the collected data. As part of this process the committee reviews all of the data collection processes and considers the combined data as part of the decision-making process. Typically, the question posed of the committee is whether the externally collected data, performance trends, and score reliability data suggest that the current standards need to be changed. The committee can allow the standards to remain the same or can vote to make a change. If the latter occurs then the committee identifies the new performance requirements.

USMLE policy requires that standards be implemented on the first day of the month following the decision of the Management Committee. Information regarding the timing of the standard setting process and its outcomes is posted on the USMLE web site.

Resources

Websites: Multiple avenues for obtaining additional information on the USMLE exist. The most current information on the program can be obtained from the USMLE website at www.usmle.org. In addition, the websites of the FSMB (www.fsmb.org) and the NBME (www.nbme.org) contain much information specific to registering for the USMLE. Students and graduates of international medical schools seeking information on the USMLE should contact the ECFMG website at www.ecfmg.org

Written materials: USMLE policies and procedures are reflected in the program's *Bulletin of Information*. The current *Bulletin of Information* can be accessed from the main page of the USMLE website. Additional USMLE information can also be found in the NBME *Examiner*, the official newsletter of the NBME. The current issue of the NBME *Examiner* and archived issues can be found under the Publications tab at www.nbme.org. Informational articles summarizing major aspects of the USMLE program have appeared in the *Journal of Medical Regulation* (previously titled the *Journal of Medical Licensure and Discipline*). Topics covered in the series of USMLE articles include Step 2 Clinical Skills, the development of multiple-choice questions for test content, research and processes for maintaining program security, etc. The following articles are available upon request from the FSMB:

- “Implementing Strategic Changes to the USMLE.” *Journal of Medical Regulation*. Vol. 100, No. 3, 2014
- “An Assessment of USMLE Examinees Found to Have Engaged in Irregular Behavior, 1992-2006.” *Journal of Medical Regulation*. Vol. 95, No. 4, 2010
- “Developing Content for the United States Medical Licensing Examination.” *Journal of Medical Licensure and Discipline*. Vol. 95, No. 2, 2009
- “Maintaining the Integrity of the United States Medical Licensing Examination.” *Journal of Medical Licensure and Discipline*. Vol. 92, No. 3, 2006
- “The Introduction of Clinical Skills Assessment into the United States Medical Licensing Examination (USMLE): A Description of the USMLE Step 2 Clinical Skills (CS).” *Journal of Medical Licensure and Discipline*. Vol. 91, No. 3, 2005.
- “The United States Licensing Examination.” *The Journal of Medical Licensure and Discipline*. Vol. 91, No. 1, 2005.

Key contacts: The following individuals are key contacts for state medical boards on matters involving the USMLE.

David Johnson, MA
Federation of State Medical Boards
Sr. Vice President for Assessment Services
400 Fuller Wiser Road, Suite 300
Euless, Texas 76039
817-868-4081; djohnson@fsmb.org

Gerry Dillon, PhD
National Board of Medical Examiners
Vice President, Licensure Programs
3750 Market Street
Philadelphia, PA 19104-3190
215-590-9739; gdillon@nbme.org

Amy Buono
Office of the USMLE Secretariat
3750 Market Street
Philadelphia, PA 19104-3190
215-590-9877; abuono@nbme.org

APPENDIX

The data tables below are extracted from the performance data provided on the USMLE website at <http://www.usmle.org/performance-data/>. Similar data are available for all years of the USMLE program.

Table 1

2015 STEP 1 ADMINISTRATIONS * Number Tested and Percent Passing		
	# Tested	# Passing
Examinees from US/Canadian Schools that Grant:		
MD Degree	21,111	94%
1st Takers	20,213	96%
Repeaters**	898	68%
DO Degree	3,222	93%
1st Takers	3,185	93%
Repeaters**	37	65%
Total US/Canadian	24,333	94%
Examinees from Non-US/Canadian Schools		
1st Takers	15,030	78%
Repeaters**	2,719	38%
Total non-US/Canadian	17,749	72%

Notes for Table 1

* Represents data for examinees tested in 2015 and reported through February 3, 2016.

** The # tested listed for repeaters represent examinations given, not the number of examinees for the specified time period.

Table 2

2014- 2015 STEP 2 CLINICAL KNOWLEDGE (CK) ADMINISTRATIONS *		
Number Tested and Percent Passing		
	# Tested	# Passing
Examinees from US/Canadian Schools that Grant:		
MD Degree	21,174	94%
1st Takers	20,120	96%
Repeaters**	1,054	65%
DO Degree	2,143	92%
1st Takers	2,104	92%
Repeaters**	39	67%
Total US/Canadian	23,317	94%
Examinees from Non-US/Canadian Schools		
1st Takers	12,247	75%
Repeaters**	2,409	46%
Total non-US/Canadian	14,656	71%

Notes for Table 2

* Data for Step 2 CK are provided for examinees tested during the period of July 1, 2014 to June 30, 2015.

** The # tested listed for repeaters represent examinations given, not the number of examinees for the specified time period.

Table 3

2014- 2015 STEP 2 CLINICAL SKILLS (CS) ADMINISTRATIONS *		
Number Tested and Percent Passing		
	# Tested	# Passing
Examinees from US/Canadian Schools that Grant:		
MD Degree	20,190	96%
1st Takers	19,373	96%
Repeaters**	817	86%
DO Degree	62	90%
1st Takers	61	90%
Repeaters**	1	§
Total US/Canadian	20,252	96%
Examinees from Non-US/Canadian Schools		
1st Takers	11,782	80%
Repeaters**	2,760	71%
Total non-US/Canadian	14,542	78%

Notes for Table 3

** Data for Step 2 CS are provided for examinees tested during the period of July 1, 2014 to June 30, 2015.

** The # tested listed for repeaters represent examinations given, not the number of examinees for the specified time period.

§ USMLE does not report percent for cohort populations of five or fewer examinations

Table 4

2015 STEP 3 ADMINISTRATIONS * Number Tested and Percent Passing		
	# Tested	# Passing
Examinees from US/Canadian Schools that Grant:		
MD Degree	17,864	98%
1st Takers	17,296	98%
Repeaters**	568	74%
DO Degree	23	83%
1st Takers	21	91%
Repeaters**	2	§
Total US/Canadian	17,887	98%
Examinees from Non-US/Canadian Schools		
1st Takers	7,637	89%
Repeaters**	1,344	57%
Total non-US/Canadian	8,981	85%

Notes for Table 4

* The table represents data for examinees tested in 2015 with scores reported by February 3, 2016.

** The # tested listed for repeaters represent examinations given, not the number of examinees for the specified time period.

§ USMLE does not report percent for cohort populations of five or fewer examinations

USMLE

United States

Medical

Licensing

Examination

®

USMLE:

An Informational Overview from the Federation of State Medical Boards & the National Board of Medical Examiners

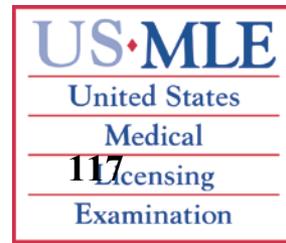
October 2016

Topics

- What is USMLE?
- Why is USMLE important?
- How is USMLE governed?
- How is the exam developed?
- How is the pass/fail standard determined?
- What is the future direction of USMLE?
- How can I get more information or data?

What is the USMLE?

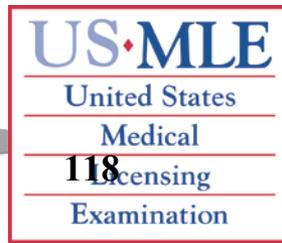
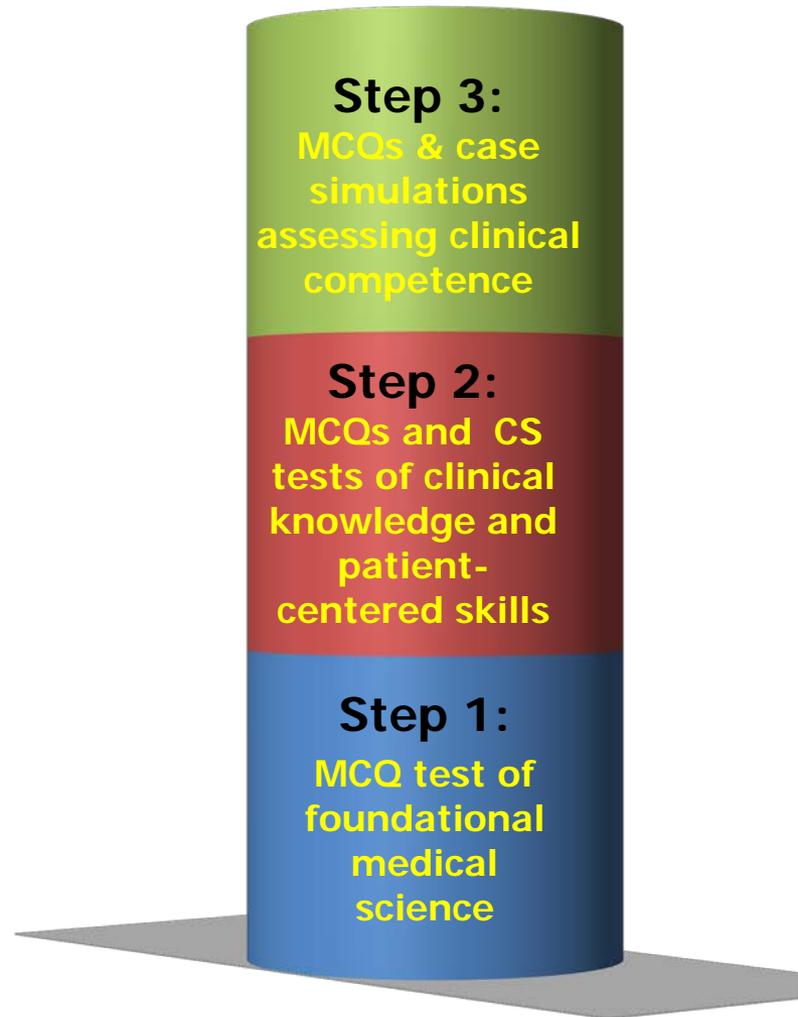
- The USMLE is a jointly sponsored program of
 - Federation of State Medical Boards (FSMB)
 - National Board of Medical Examiners (NBME)
- A required examination for graduates of accredited US medical schools granting MD degree, and all graduates of international medical schools



USMLE

A single three Step examination for initial medical licensure

- Assesses physician cognitive, clinical and communication skills
- Provides a national standard
- Assists medical boards in their public protection mission
- Facilitates license portability



Comparison of USMLE Components

October 2016

		Step 1	Step 2		Step 3
			CK	CS	
Eligibility requirements		Medical student/graduate			MD or DO; Pass 1&2
Test administration		Offered year-round; 6 attempt limit; 3 attempts/12 months; then 6 month wait			
Test length (days)		1	1	1	2
Format	MCQ items*	280	320		415
	SP stations			12	
	CCS cases				13

*Approximate

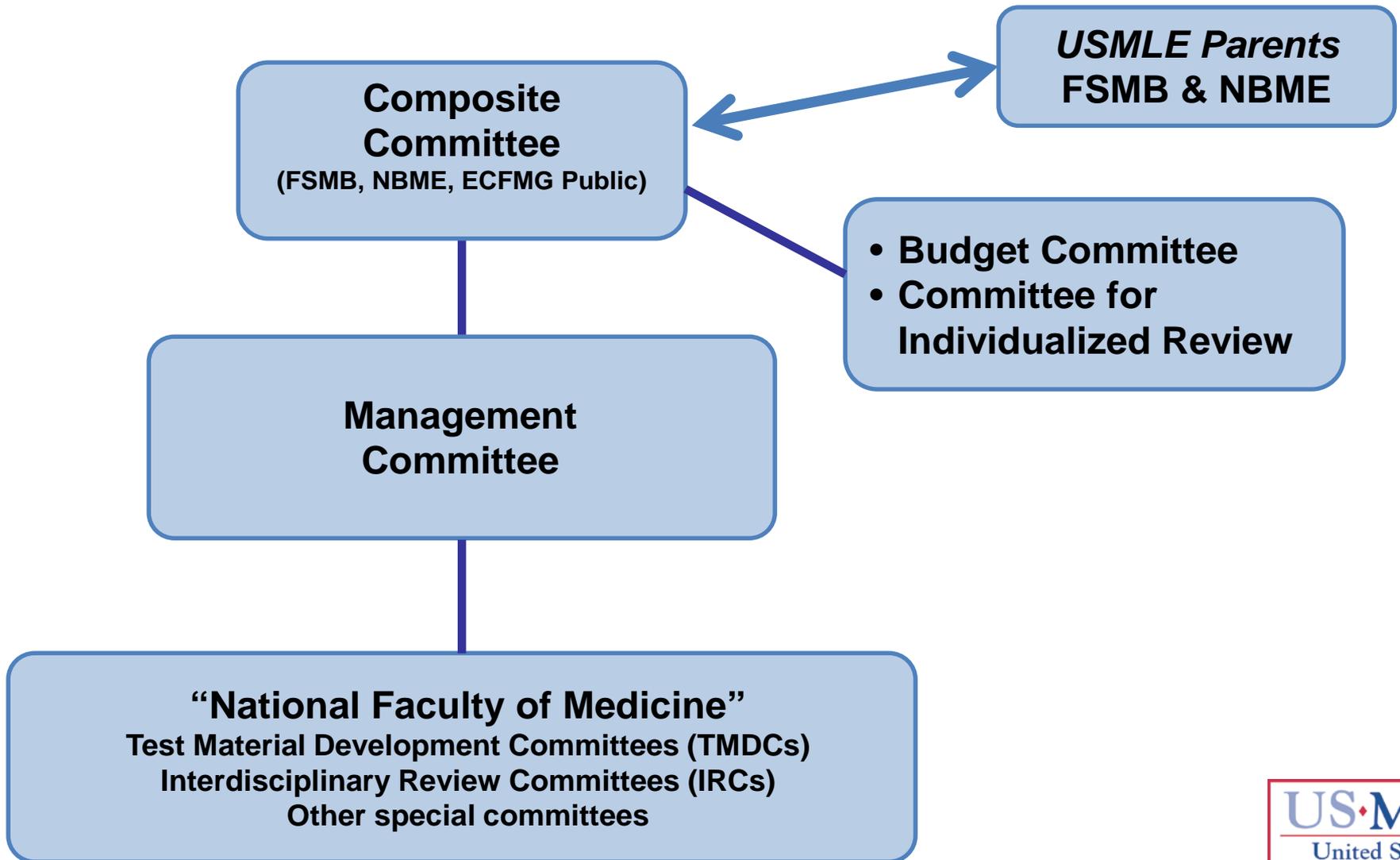
Why is USMLE important?

Users and Uses of USMLE Results

User	Step 1	Step 2	Step 3
Licensing Jurisdictions	Protecting the health of the public Training and unrestricted licenses		
ECFMG (IMGs only)	ECFMG Certification Entry into GME		
Medical Schools	Promotion & graduation decisions Curriculum evaluation		
Residency Programs	Screening for interviews Ranking of applicants		
LCME	Accreditation (aggregated results)		
Examinees	(all of the above)		

How is USMLE governed?

USMLE Committee Structure

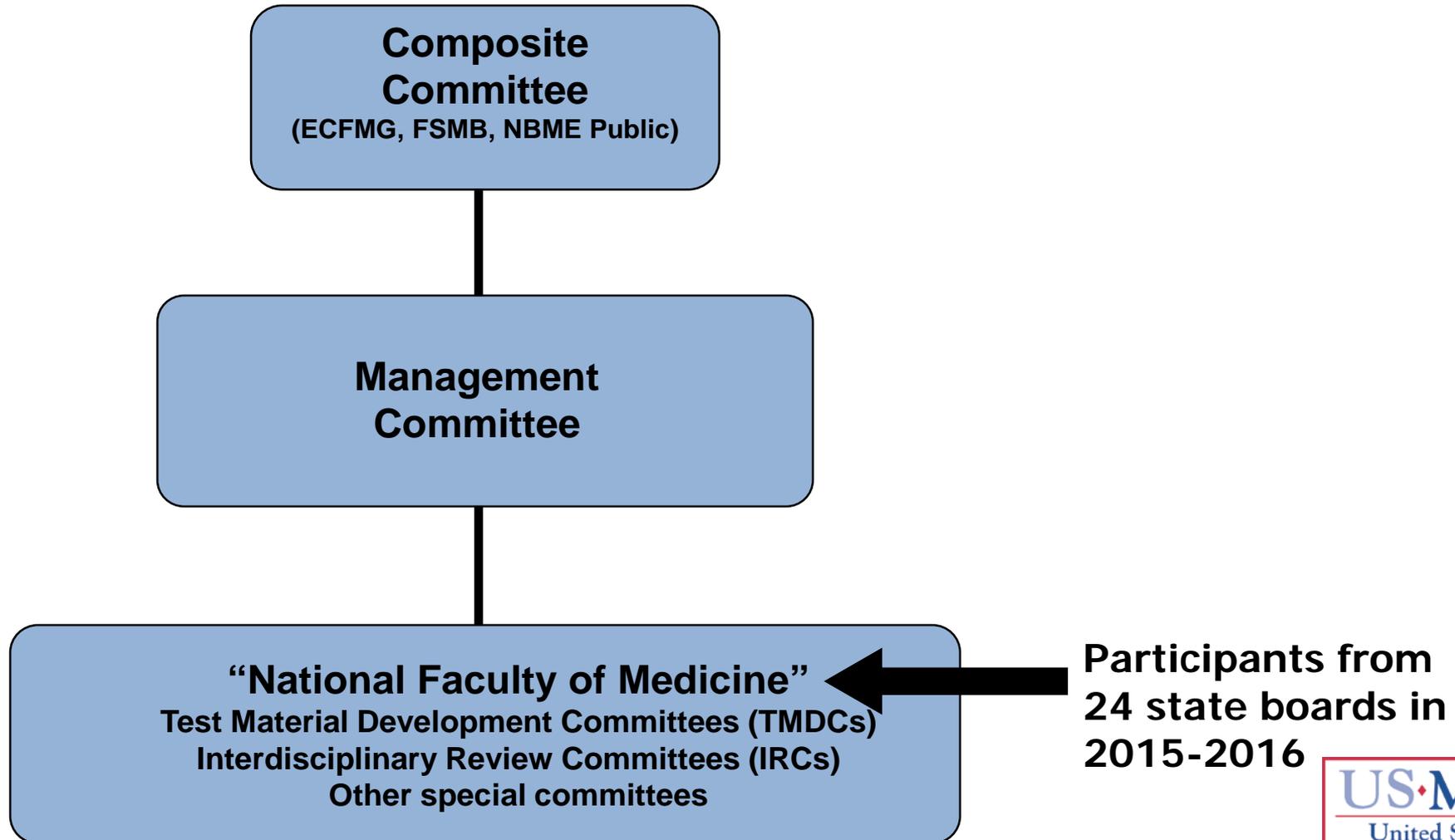


How is the exam developed?

Developing Content for USMLE

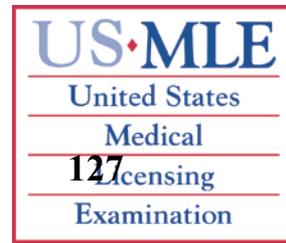
- Content is developed by a “national faculty” of physicians and scientists...
 - All volunteers
 - Drawn from the academic, licensing and practice communities
 - 300+ physicians representing specialties and expertise from across the country

USMLE Committee Structure



USMLE Test Development

- All items and cases...
 - Are developed and reviewed by content experts
 - Pass through multiple levels of review
 - Are pre-tested prior to use as live (scored) material
- Each Step (or its Component)...
 - Uses multiple test forms
 - Has thousands of items (or hundreds of cases) in the test pool



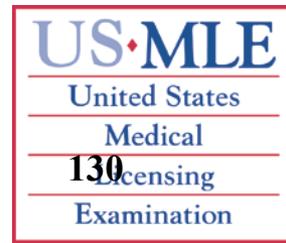
How is the pass/fail standard determined?

Standard setting (minimum pass score)

- USMLE uses an “absolute” standard
 - A minimum level of demonstrated proficiency for examinees is established in advance; there is no ‘curve’ applied
- Set by the Management Committee
- Reviewed approximately every 4 years

Standard setting (cont'd)

- Management Committee reviews information & data from variety of sources
 - Results from standard setting exercises involving panels of physician experts unaffiliated with USMLE
 - Survey input from state boards, deans, faculty, students
 - Trends in examinee performance
 - Data on reliability of scores



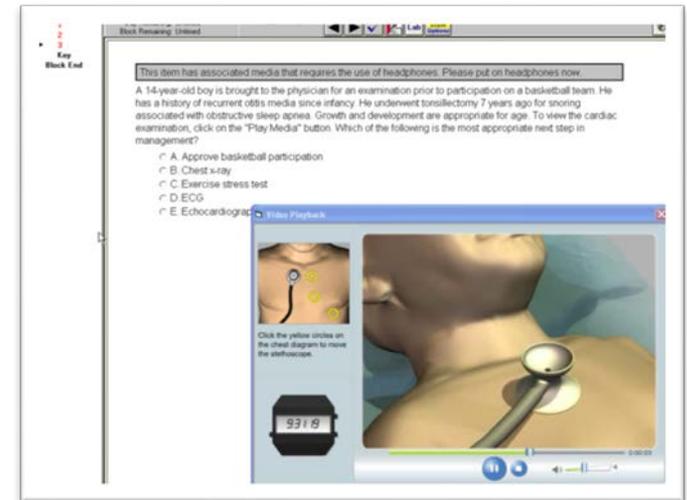
*What is the future direction
of the program?*

What has changed

- Behind the scenes
 - Attention to differences in decisions about readiness for supervised and unsupervised practice
 - Recoding of all test content to reflect competencies
 - Setting priorities for physical-exam related competencies that should be assessed for licensing decisions

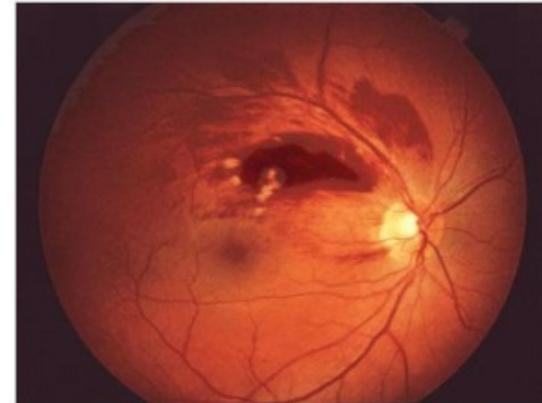
What has changed

- Changes stakeholders can see
 - Revisions to content outlines
 - Enhancements to Step 2 CS
 - New focus/design for Step 3
 - New item formats
 - Simulations, drug ads, journal abstracts



Changes in 2016

- Adjustments to examination pacing
 - All MCQ exams 40 items/hour
- Digital images in Step 2 CS
- New test delivery software
 - Image and font magnification
 - Reverse color



63. A 35-year-old man is brought to the emergency department because of altered mental status. He is disoriented and complains about his vision. You have been his physician for the past 3 years. He has type 1 diabetes mellitus and a known history of intravenous drug abuse. You last saw him 2 weeks ago, at that visit his serum glucose concentration was 150 mg/dL, 3 hours after eating. Today, vital signs are temperature 38.1°C (100.5°F), pulse 110/min, and blood pressure 190/70 mm Hg. On physical examination pupils are constricted; fundoscopic examination of the left eye following dilation is shown. Which of the following is the most appropriate test at this time?
- (A) Blood cultures
 - (B) Chest x-ray
 - (C) Hemoglobin A_{1c} level
 - (D) HIV antibody titer
 - (E) Plasma renin activity

Planned Changes

- Develop additional content that assesses communication skills, patient safety, and legal/ethical issues across all examinations
- Continue efforts to better assess physical examination related competencies
- 'Make room' for this new content by reducing overlap in Foundational Science, Diagnosis, and Management
- New content development will be gradual

*How can I get more
information or data?*

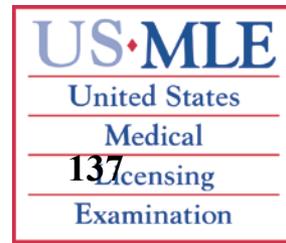
USMLE Website

<http://www.usmle.org/data-research/>

- Score Interpretation Guidelines
- Performance Data
- USMLE-related publications (2009+)

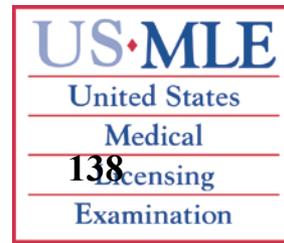
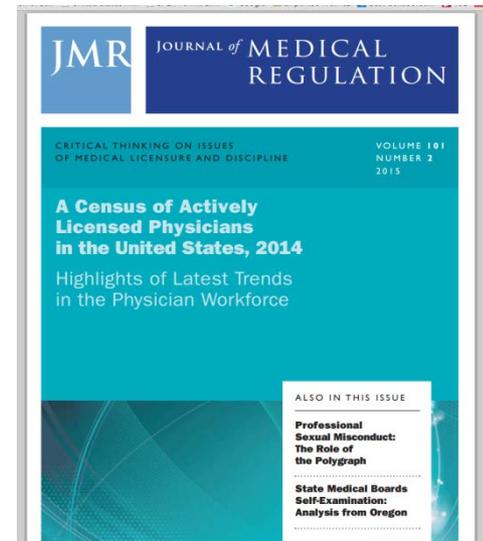
<http://www.usmle.org/practice-materials/index.html>

- Practice materials



Other informational resources

- FSMB presents webinars throughout the year on topics such as...
 - Attempt limit policy
 - Annotating for test accommodations
 - Changes to Step 3
- FSMB publications
 - *Journal, eNews, NewsLine*
- Extensive research on USMLE has been published in professional, peer-review journals such as *Academic Medicine*



Key Contacts

Office of the USMLE Secretariat
3750 Market Street
Philadelphia, PA 19104-3190
(215) 590-9877

David Johnson, M.A.
FSMB Senior Vice President for Assessment Services
djohnson@fsmb.org

Gerry Dillon, Ph.D.
NBME Vice President for Licensing Programs
gdillon@nbme.org

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Nifty Lynn Dio, Bureau Assistant On behalf of Tom Ryan, Executive Director		2) Date When Request Submitted: 11/07/2016 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: 11/16/2016	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? FSMB Matters FSMB Workgroup on Team-Based Regulation – Request for Review and Comment	
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: N/A	
10) Describe the issue and action that should be addressed: Subject: Draft Report on Team-Based Regulation - for Comment Dear Board Chairs/Presidents and Executive Directors, The FSMB Workgroup on Team-Based Regulation was established last year by Past FSMB Chair, J. Daniel Gifford, MD, FACP, and charged to identify best state-based practices and recommend regulatory strategies for achieving greater cooperation and collaboration among health professional boards in carrying out their shared responsibility to protect the public. This Workgroup is chaired by Ralph C. Loomis, MD (North Carolina), and members are Claudette E. Dalton, MD (Virginia), Kathleen Haley, JD (Oregon), Lyle R. Kelsey, MBA (Oklahoma), Susan Ksiazek, RPh (NABP), Louis J. Prues, DMin, MBA (Michigan), Jean L. Rexford (Connecticut), Cheryl L. Walker-McGill, MD (North Carolina), and Katherine A. Thomas, MN, RN, FAAN (NCSBN). Under the direction of FSMB Chair, Arthur S. Hengerer, MD, the Workgroup has completed its draft policy document for which it is seeking stakeholder review and comment. The draft report, <i>Regulatory Strategies for Achieving Greater Cooperation and Collaboration Among Health Professional Boards</i> , may be accessed at: https://www.fsmb.org/Media/Default/PDF/FSMB/Advocacy/FSMB_workgroup_on_team_based_regulation_report_for_comment102516.pdf . Please e-mail comments to me by December 15, 2016. The Workgroup will consider all comments received in drafting its final recommendations for submission to the FSMB Board of Directors in February 2017 and thereafter to the House of Delegates for consideration in April 2017. Thank you, Shiri Shiri Ahronovich Hickman, JD Director, State Policy and Legal Services			

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

11)	Authorization
Nifty Lynn Dio	11/07/2016
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: 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
Department of Safety & Professional Services**

AGENDA REQUEST FORM

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3) Name of Board, Committee, Council, Sections: Medical Examining Board			
4) Meeting Date: 11/17/2016	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? FSMB Matters Nominations for Elected Officers	
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: N/A	
10) Describe the issue and action that should be addressed: Dear Colleagues: FSMB Needs YOUR Leadership Skills. One of the most rewarding experiences for members of state medical and osteopathic boards is the opportunity to serve on FSMB's Board of Directors or its Nominating Committee, helping guide our organization's vision and mission. Each year, FSMB's Nominating Committee seeks capable and committed individuals for consideration as candidates, and we would like to hear from you. Service in a leadership position brings many benefits, notably the opportunity to make a real impact in the direction and policy of a national organization with a vital role in health care. Nominations by FSMB Member Medical Boards are open starting today and will close on December 30, 2016 . Elections will be held at the FSMB's April 22, 2017 House of Delegates annual business meeting. Details regarding the nomination process and eligibility requirements are attached. We encourage you to make national service a part of your experience as an FSMB Fellow. Sincerely yours, Humayun J. Chaudhry, D.O., M.S., MACP, MACOI President and Chief Executive Officer Federation of State Medical Boards 1300 Connecticut Avenue NW Suite 500 Washington, DC 20036 202-463-4007 direct 817-868-8888 fax			

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

11)	Authorization
Nifty Lynn Dio	11/07/2016
Signature of person making this request	Date
Supervisor (if required)	Date
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ELIGIBILITY REQUIREMENTS

Eligibility

Any person who is or will be a Fellow of the FSMB **at the time of the election on April 22, 2017** is eligible for nomination. The Bylaws of the FSMB define Fellows as: *An individual member who as a result of appointment holds full time membership on a Member Medical Board shall be a Fellow of the FSMB during the member's period of service on a Member Medical Board, and for a period of 36 months thereafter.*

Core Competencies of Candidates

A candidate for elected office must:

- Support the vision, mission and strategic goals of the FSMB;
- Possess a positive outlook on the role and function of state medical boards in the medical regulatory field;
- Bring a broad, national perspective to specific issues;
- Have adequate time and commitment necessary to fulfill the responsibilities of the office (*please see attached "Responsibilities of Elected Positions"*); and,
- Demonstrate professionalism, personal integrity, and the ability to work effectively with others.

Additional Qualifications for Chair-elect of the Board of Directors: Suggested but not mandatory: One or more years experience on the FSMB Board of Directors and, if applicable, a commitment of time that may require reduction by one-third or more of patient care duties in medical practice.

Additional Qualifications for Board of Directors: These are strongly suggested but not mandatory: One-and-a-half or more years on a State Medical Board; Committee or Task Force participation with the FSMB; and prior attendance of **at least one** FSMB Annual Meeting. Significant experience on a non-profit Board of Directors or Foundation may be considered an equivalent for one of the above.

DOCUMENTATION REQUIREMENTS (Electronic submission preferred method)

Letter of Nomination

The letter of nomination **must** come from the candidate's state medical or osteopathic board to the Nominating Committee and should specify: (1) the name of the candidate to be considered; (2) the office for which the candidate is being recommended; (3) a description of the candidate's ability to demonstrate the core competencies and/or additional position-specific qualifications stated above; (4) the candidate's agreement to the submission of his/her name for potential nomination; (5) the candidate's affirmation that he/she is aware of the time commitment required for the position to which he/she may be elected; and (6) the candidate's daytime telephone number and email address. **[Note: This letter will be posted on the Candidate's Website for public viewing.]**

Additional Materials

The following materials should accompany the letter of nomination:

1. **Candidate's Personal Statement (in WORD, if provided electronically) (sample attached) – (500 word limit).** The candidate should state why he/she wants to serve in the particular position for which he/she will be

- campaigning for election; how he/she fulfills the core competencies and/or additional position-specific qualifications of candidates, and what he/she will contribute to FSMB. The personal statement will be included in the Election Manual and placed on the Candidates Website.
2. **Candidate's General Information Questionnaire (separate attachment in WORD for typing).** In the interest of uniformity and fairness to all candidates, the Nominating Committee requests that the information contained on the Candidate's General Information Questionnaire be limited to the space provided, *except where otherwise stated*.
 3. **Candidate's Signatory Form (separate attachment in WORD for typing).** The candidate **must submit a signed** confirmation that the candidate: 1) will be a Fellow as defined by the FSMB Bylaws at the time of the election on Saturday, April 22, 2017; 2) is aware of the time commitment required for the position to which he/she may be elected; and 3) is disclosing any potential conflict(s) of interest.
 4. **Copy of the candidate's summary CV (maximum five (5) pages) and/or bio.** Please provide relevant information including important appointments, honors and awards received, etc. Please note that **these documents will be PUBLISHED** on the Candidates Website; therefore, social security numbers and all other private information **must be removed** prior to submitting with letter of nomination.
 5. **Candidate's photograph – color (jpg).** Copies of the photo will be included in the Nominating Committee meeting agenda book. If the candidate is selected, the photo will also be used in the Election Manual that is distributed at the Annual Meeting and placed on the Candidates Website. **Questions regarding photos should be directed to David Hooper, Sr. Director of Marketing, at 817-868-4070 or dhooper@fsmb.org.**

Deadline for Submission of Letters and Materials

The members of the Nominating Committee request that all nominations be submitted in writing by mail, fax or email (preferred method) to:

J. Daniel Gifford, MD, FACP, Chair
Nominating Committee
c/o Pat McCarty, Director of Leadership Services
Federation of State Medical Boards
400 Fuller Wisser Road, Suite 300
Euless, TX 76039-3855
Fax: (817) 868-4167
Email: pmccarty@fsmb.org

All letters of nomination and accompanying materials should be received at the Euless, TX office by end of business on **Friday, December 30, 2016. No nominations will be accepted after end of business December 30.**

A confirmation acknowledging receipt of nominations will be sent within two business days. If you do not receive confirmation, please contact Pat McCarty at (817) 868-4067 or at the email above.

RESPONSIBILITIES OF ELECTED POSITIONS

BOARD OF DIRECTORS

The FSMB Board of Directors is responsible for the control and administration of the FSMB and reports to the House of Delegates; the Board provides leadership in the development and implementation of the FSMB's Strategic Goals and the Board's Annual Action Plan; the Board is responsible for governing and conducting the business of the corporation, including supervising the President/CEO; and, under the leadership of the Chair and President/CEO, represents the FSMB to other organizations and promotes recognition of the FSMB as the premier organization concerned with medical licensure and discipline. The Board of Directors is the fiscal agent of the corporation.

GENERAL RESPONSIBILITIES

The Board of Directors is responsible for the following:

1. Setting goals, objectives and priorities necessary to achieve the FSMB Strategic Goals.
2. Setting goals, objectives and critical success factors for the President/CEO.
3. Ensuring effective management of the FSMB's financial resources.
4. Approving systems for assessing and addressing needs of Member Boards.
5. Implementing adopted Board of Directors professional development and self-assessment plans.
6. Promoting use of FSMB services among targeted customer groups.
7. Enhancing communication with and among Member Boards.
8. Enhancing support and education for Member Board executives and their staff.

TIME COMMITMENT

Board Meetings

The Board of Directors will meet five times during the FY 2018 fiscal year:

April 23, 2017 – Fort Worth, TX (immediately following the Annual Meeting)

July 12-16, 2017 – Site TBD

October 25-29, 2017 – Dallas, Texas

February 6-10 or 13-17, 2018 (TO BE CONFIRMED) – Washington, DC

April 24-29, 2018 – Charlotte, NC (in conjunction with the Annual Meeting)

New Directors Orientation

Newly-elected directors will be asked to participate in the **New Directors Orientation** scheduled **June 25-26, 2017** at the FSMB Euless, TX Office.

Board of Directors State Medical Board Liaison Program

A director's participation in the Board of Directors State Medical Board Liaison Program may involve telephone communications with Member Board leadership (dependent upon the leadership's availability) and/or travel to a Member Board location (i.e., "site visit") in partnership with FSMB staff to meet with the Member Board representatives. New Directors may be asked to participate in one or two site visits during their first year on the Board of Directors, schedule permitting.

Subcommittees of the Board of Directors

All directors will be appointed to one subcommittee of the Board of Directors, which include the Awards, Governance and Planning Committees. Additionally, two directors will be elected by the Board to participate on the Executive, Compensation and Investment Committees with the officers of the Board.

NOMINATING COMMITTEE

COMMITTEE CHARGE

The charge of the Nominating Committee as currently set forth in the FSMB Bylaws is to submit a slate of one or more nominees for each of the offices and positions to be filled by election at the Annual Meeting of the House of Delegates. The Committee will mail its slate of candidates to Member Boards not fewer than 60 days prior to the meeting of the House of Delegates.

Tasks of the Committee include:

1. Soliciting recommendations for candidates for elected positions from Member Board Executive Directors/Secretaries and Active Fellows of the FSMB.
2. Assertively recruiting individuals who have the core competencies set forth on page 2 and who represent diversified backgrounds, experiences and cultures.
3. Educating potential candidates on core competencies for FSMB leadership roles and the responsibilities associated with respective leadership positions.
4. Reviewing letters of recommendation and supporting material of each individual nominated or recruited as a candidate for election.
5. Verifying that candidates have the core competencies for FSMB leadership positions.
6. Verifying that queries of FSMB Board Action Data Bank have been completed on physician candidates and that no actions have been reported which could call into question an individual's fitness for FSMB leadership.
7. Affirming that all candidates for elected leadership have disclosed any potential conflicts of interest.
8. Considering the importance of public representation on the FSMB Board of Directors and assuring the slate of candidates provides for election of adequate/qualified public representation.
9. Selecting and narrowing the slate of candidates to those who best demonstrate the core competencies, have the necessary qualifications and eligibility for a position, and bring valuable talents and perspectives to the FSMB.
10. Preparing a report to the House of Delegates that includes a slate of nominees for positions to be filled by election at the annual business meeting of the House of Delegates.
11. Determining process for notifying candidates of the Nominating Committee's decisions as soon as possible following the Committee's winter meeting and providing the Nominating Committee report to the FSMB Board of Directors.

TIME COMMITMENT

Members of the Nominating Committee serve a single two-year term. The Committee will have a kick-off breakfast in Fort Worth, TX on the morning of Sunday, April 23, 2017 immediately following the FSMB's Annual Meeting. The Committee will meet again via teleconference in July 2017 and March 2018 (dates TBD) and one face-to-face meeting at the FSMB Euless, TX Office in January 2018. In preparation for the January meeting, the Committee members will each interview three to five nominees. Members of the Committee will also receive scholarships to attend the FSMB's 2018 Annual Meeting in Charlotte, NC so they can be onsite to solicit membership interest in elected and appointed positions.

SAMPLE PERSONAL STATEMENT [500 words or less]

Please provide this document in WORD format

NAME: _____

CANDIDATE FOR: [Chair-elect, Board of Directors or Nominating Committee]

[SAMPLE TEXT BELOW – please describe your own experiences using your own words]

I am a candidate for [elected office]. Since beginning my medical career in a small rural town over 20 years ago, I have been involved in professionalism and upholding the higher standards of being a physician. Currently, I am the Chairman of the Department of [specialty] at the School of Medicine in [city].

My experiences with medical licensure began in 2000 when I was appointed to the advisory committee for athletic trainers of the [state medical board]. Subsequently, I was appointed as a member of the [state medical board] in 2013. I was elected Vice President in 2014 and have been serving as President since 2015.

Since being appointed to the [state medical board], I have been serving the [state medical board] in a number of capacities, which have included [committee/workgroups, etc.].

Additionally, I have worked as [other professional experiences and associations].

It is with great anticipation that I am running for [elected office]. I have the energy, enthusiasm and experience to represent the FSMB. My qualifications are broad and strong, which will allow me to function well within a system that is focused on licensure, discipline and protection of the public.

CANDIDATE'S GENERAL INFORMATION QUESTIONNAIRE

***PLEASE TYPE OR PRINT AND LIMIT YOUR INFORMATION TO THE SPACE PROVIDED
(except where otherwise stated)***

GENERAL

NAME: _____

CANDIDATE FOR: _____

DAYTIME TELEPHONE: _____

EMAIL : _____

EDUCATION

UNDERGRADUATE: _____

MEDICAL SCHOOL/GRADUATE SCHOOL: _____

POSTGRADUATE EDUCATION: _____

CURRENT PROFESSION: _____

AREA OF SPECIALIZATION: _____

FEDERATION ACTIVITIES

BOARD and/or COMMITTEES: _____

OTHER FSMB ACTIVITIES: _____

CANDIDATE SIGNATORY PAGE

STATE MEDICAL BOARD ACTIVITIES

On which state medical board are you currently serving?

If not serving, when did you leave the board? Month _____ Day _____ Year _____

How long have you served (did you serve) on your state medical board?

- I will be a Fellow as defined by the FSMB Bylaws at the time of the election on Saturday, April 22, 2017 and understand that only an individual who is a Fellow at the time of the individual’s election shall be eligible for election. The Bylaws of the FSMB defines Fellow as:
An individual member who as a result of appointment holds full time membership on a Member Medical Board shall be a Fellow of the FSMB during the member’s period of service on a Member Medical Board, and for a period of 36 months thereafter.
- I am aware of the time commitment for the position I wish to be elected.
- I am disclosing any potential conflict(s) of interest.



SIGNATURE: _____

Potential Conflict(s) of Interest

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Nifty Lynn Dio, Bureau Assistant On behalf of Tom Ryan, Executive Director		2) Date When Request Submitted: 11/07/2016 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: 11/17/2016	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? FSMB Matters Responsibilities of the FSMB BOD	
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: N/A	
10) Describe the issue and action that should be addressed: Dear Member Board Presidents/Chairs and Executive Directors, FSMB Board of Directors, and Administrators in Medicine: Nominations for an Associate Member to the FSMB Board of Directors are now being accepted from Member Medical Boards, the FSMB Board of Directors and Administrators in Medicine (AIM). FSMB Bylaws Article II. Classes of Membership, Election and Membership Rights. Section D. Associate Members states: <i>A Member Medical Board may designate one or more employees or staff members to be an Associate Member of the FSMB. No Associate Member shall continue in that capacity upon termination of employment by or service to the Member Medical Board.</i> The Board of Directors will elect one Associate Member at its February 2017 meeting. The Associate Member will serve a two-year term and will join the Board at its meeting on Sunday, April 23, 2017 , immediately following the 2017 Annual Meeting. Attached is a document outlining the responsibilities of the Board of Directors and time commitment for the 2017-2018 fiscal year. All letters of nomination should provide background information on the nominee and a description of the individual's ability and commitment necessary to fulfill the responsibilities of the Board. A summary CV (no more than 5 pages) or bio of the nominee should be included with the nomination letter. Should you wish to nominate an Associate Member to the FSMB Board of Directors, please submit your letter of nomination by December 30, 2016 via mail, fax or email to: Arthur S. Hengerer, MD, FACS, FSMB Chair Federation of State Medical Boards c/o Pat McCarty, Director of Leadership Services 400 Fuller Wisser Road, Suite 300 Euless, Texas 76039-3855			

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

Fax: (817) 868-4167
Email: pmccarty@fsmb.org

A confirmation acknowledging receipt of your nomination will be sent within 2 business days. If you do not receive confirmation, please contact Pat McCarty at (817) 868-4067 or by email.

Sincerely yours,

Humayun J. Chaudhry, D.O., M.S., MACP, MACOI
President and Chief Executive Officer

Federation of State Medical Boards
1300 Connecticut Avenue NW | Suite 500 | Washington, DC 20036
202-463-4007 direct | 817-868-8888 fax

11)	Authorization
Nifty Lynn Dio	11/07/2016
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:

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.

RESPONSIBILITIES OF FSMB BOARD OF DIRECTORS

The FSMB Board of Directors is responsible for the control and administration of the FSMB and reports to the House of Delegates; the Board provides leadership in the development and implementation of the FSMB's Strategic Goals and the Board's Annual Action Plan; the Board is responsible for governing and conducting the business of the corporation, including supervising the President/CEO; and, under the leadership of the Chair and President/CEO, represents the FSMB to other organizations and promotes recognition of the FSMB as the premier organization concerned with medical licensure and discipline. The Board of Directors is the fiscal agent of the corporation.

GENERAL RESPONSIBILITIES

The Board of Directors is responsible for the following:

1. Setting goals, objectives and priorities necessary to achieve the FSMB Strategic Goals.
2. Setting goals, objectives and critical success factors for the President/CEO.
3. Ensuring effective management of the FSMB's financial resources.
4. Approving systems for assessing and addressing needs of Member Boards.
5. Implementing adopted Board of Directors professional development and self-assessment plans.
6. Promoting use of FSMB services among targeted customer groups.
7. Enhancing communication with and among Member Boards.
8. Enhancing support and education for Member Board executives and their staff.

TIME COMMITMENT

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Subcommittees of the Board of Directors

All directors will be appointed to one subcommittee of the Board of Directors, which include the Awards, Governance and Planning Committees. Additionally, two directors will be elected by the Board to participate on the Executive, Compensation and Investment Committees with the officers of the Board.

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

AGENDA REQUEST FORM

1) Name and Title of Person Submitting the Request: Nifty Lynn Dio, Bureau Assistant On behalf of Tom Ryan, Executive Director		2) Date When Request Submitted: 11/07/2016 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: 11/17/2016	5) Attachments: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	6) How should the item be titled on the agenda page? FSMB Matters Committee Responsibilities 2017-2018	
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: N/A	
10) Describe the issue and action that should be addressed: Dear Colleagues: Following the 2017 Annual Meeting, incoming Chair, Gregory B. Snyder, MD, will finalize appointments for FSMB standing committees, including Audit, Bylaws, Editorial, Education, Ethics and Professionalism, and Finance, and potentially for an FSMB special committee(s) and/or workgroup(s). The charges and potential time commitments of these committees are attached. In accordance with the FSMB Bylaws, standing committees are composed <i>primarily</i> of Fellows of the FSMB defined as: <i>An individual member who as a result of appointment holds full time membership on a Member Medical Board shall be a Fellow of the FSMB during the member's period of service on a Member Medical Board, and for a period of 36 months thereafter.</i> A limited number of Honorary Fellows, Associate Members, Courtesy Members and non-member subject matter experts may also be appointed to committees and workgroups. Individuals interested in serving on a committee or workgroup should complete the following steps: 1) Fill out a brief questionnaire (6 questions) that can be accessed through this link: https://www.surveymonkey.com/r/Q29N69V 2) Submit letter of interest and/or recommendation with summary CV (no more than 5 pages) or bio by December 30, 2016 via mail, fax or email to: Gregory B. Snyder, MD, Chair-elect Federation of State Medical Boards c/o Pat McCarty, Director of Leadership Services 400 Fuller Wisser Road, Suite 300 Euless, Texas 76039-3855			

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

Fax: (817) 868-4167
Email: pmccarty@fsmb.org

A confirmation acknowledging receipt of completed questionnaire, letter and CV/bio will be sent within 5 business days. If you do not receive confirmation, please contact Pat McCarty at (817) 868-4067 or by email.

Sincerely yours,

Humayun J. Chaudhry, D.O., M.S., MACP, MACOI
President and Chief Executive Officer

Federation of State Medical Boards
1300 Connecticut Avenue NW | Suite 500 | Washington, DC 20036
202-463-4007 direct | 817-868-8888 fax

11)	Authorization
Nifty Lynn Dio	11/07/2016
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	

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FEDERATION OF STATE MEDICAL BOARDS
Responsibilities of Appointed Positions

Audit Committee

COMMITTEE CHARGE

The primary charge of the Audit Committee, as currently set forth in the FSMB Bylaws, Article VIII, Section B, is to review the audit of the FSMB.

Tasks of the Committee include:

1. Reviewing the auditor's report with particular attention to material deficiencies and recommendations.
2. Reporting any suggestions to the Board of directors on fiscal policy to ensure the continuing financial strength of the FSMB.

TIME COMMITMENT

Members of the Audit Committee serve one-year terms. Consistent with common practice of audit committees within the U.S., the Audit Committee expects to meet via teleconference one to two times during the year for 30-90 minutes for each conference call.

Bylaws Committee

COMMITTEE CHARGE

The charge of the Bylaws Committee, as currently set forth in the FSMB Bylaws, Article VIII, Section C, is to continually assess the Articles of Incorporation and the Bylaws and receive all proposals for amendments thereto. The Committee will, from time to time, make recommendations to the House of Delegates for changes, deletions, modifications and interpretations to the Bylaws.

Tasks of the Committee include:

1. Receiving requests for amendments or revisions from the Board of Directors or from Member Boards. Upon receiving requests, the Committee drafts Bylaws language that is appropriate in style and placement. The Bylaws Committee members may also propose amendments or revisions to the Bylaws, and draft language that is appropriate for inclusion.
2. Advising the House of Delegates with regard to each modification they have drafted, citing in their report to the House their choice to support, oppose or remain neutral regarding the language they have drafted. Members of the Committee may give testimony in support of their position before a Reference Committee.
3. Interpreting the Bylaws upon request of the Board of Directors, Member Boards or others.
4. Reviewing the Bylaws and Articles of Incorporation on a continual basis.

TIME COMMITMENT

Members of the Bylaws Committee serve one-year terms. The Committee will meet once by teleconference or as needed.

Editorial Committee

COMMITTEE CHARGE

The charge of the Editorial Committee, as currently set forth in the FSMB Bylaws, Article VIII, Section D, is to advise the Editor-in-Chief on editorial policy for the FSMB's official publication (*Journal of Medical Regulation*) and otherwise assist the Editor-in-Chief in the performance of duties as appropriate and necessary.

Tasks of the Committee include:

1. Reviewing articles submitted for publication in a timely manner.
2. Generating potential article topics and/or authors to write for the *Journal*.
3. Writing or working with the *Journal* Editor-in-Chief to create an editorial for the *Journal*.
4. Serve as ongoing ambassadors for the *Journal* during any appropriate business meetings or discussions with colleagues

TIME COMMITMENT

Members of the Editorial Committee serve three-year terms. The Committee will meet once each year at FSMB headquarters or other location and may meet via teleconference periodically during the year. Committee members will receive manuscript submissions throughout the year.

Education Committee

COMMITTEE CHARGE

The charge of the Education Committee as currently set forth in the FSMB Bylaws, Article VIII, Section E is to assist in the development of educational programs for the FSMB. This includes the Annual Meeting program as well as webinars, teleconferences and other educational offerings.

Tasks of the Committee include:

1. Providing consultation and recommendations in the development and review of the FSMB's annual education agenda.
2. Identifying and prioritizing educational topics in accordance with the mission, vision, core values and goals of the FSMB.
3. Evaluating education trends and opportunities to provide quality educational programming to FSMB membership.
4. Reviewing needs assessment data and stated knowledge gaps in order to identify appropriate speakers for chosen topics.
5. Ensuring balance, independence, objectivity and scientific rigor in the educational activity.
6. Responsible for compliance with ACCME guidelines for accreditation.

TIME COMMITMENT

Members of the Education Committee serve one-year terms. The Committee will meet several times per year either in person or via teleconference. The frequency of regular meetings will be determined by need, but will occur at least quarterly.

Ethics and Professionalism Committee

COMMITTEE CHARGE

The charge of the Ethics and Professionalism Committee as currently set forth in the FSMB Bylaws, Article VIII, Section F is to address ethical and professional issues pertinent to medical regulation.

Tasks of the Committee include:

1. Addressing ethical and/or professional concerns expressed by state medical boards.
2. Researching data pertinent to the issues and/or obtaining input from experts in the particular subject areas being considered.
3. Developing model policies for use by state medical boards to be submitted for approval by the FSMB House of Delegates.

TIME COMMITMENT

Members of the Ethics and Professionalism Committee serve one-year terms. The Committee will meet several times per year either in person or via teleconference. The frequency of regular meetings will be determined by need.

Finance Committee

COMMITTEE CHARGE

The charge of the Finance Committee as currently set forth in the FSMB Bylaws, Article VIII, Section G is to review the financial condition of the FSMB, review and evaluate the costs of the activities and/or programs to be undertaken in the forthcoming year, and recommend a budget to the Board of Directors for its recommendation to the House of Delegates at the Annual Meeting, and perform such other duties as are assigned to it by the Board of Directors.

Tasks of the Committee include:

1. Assessing prior financial performance in comparison to budget.
2. Reviewing the draft budget for alignment with organizational goals, programs and services.
3. Approving the budget for recommendation to the Board of Directors.

TIME COMMITMENT

Members of the Finance Committee serve one-year terms. The Committee will have one 60-90 minute teleconference in December and one in-person meeting at the Texas office in January. Other teleconference meetings will be determined by need, but no additional meetings have been required in the past 5 years.

Special Committees/Workgroups

Special Committees and workgroups are appointed by the Chair as necessary and are established for a specific purpose. Special Committees and workgroups usually meet approximately three times per year, in person and via teleconference, and continue their work for one or two years. Special Committees and/or workgroups for 2017-2018 are to be determined.

