



**Scott Walker, Governor**  
**Laura Gutiérrez, Secretary**

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**MEDICAL EXAMINING BOARD**  
**Room 121A, 1400 East Washington Avenue, Madison**  
**Contact: Tom Ryan (608) 266-2112**  
**July 11, 2018**

*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. Approval of Minutes of June 20, 2018 (5-9)**
- C. Introductions, Announcements and Recognition
- D. Conflicts of Interest**
- E. Administrative Matters**
  - 1. Department and Staff Updates
  - 2. Board Members – Term Expiration Dates
    - a. Alaa Abd-Elsayed – 07/01/2020
    - b. David Bryce – 07/01/2021
    - c. Mary Jo Capodice – 07/01/2018
    - d. Michael Carton – 07/01/2020
    - e. Padmaja Doniparthi – 07/01/2021
    - f. Rodney Erickson – 07/01/2019
    - g. Bradley Kudick – 07/01/2020
    - h. Lee Ann Lau – 07/01/2020
    - i. David Roelke – 07/01/2021
    - j. Kenneth Simons – 07/01/2018
    - k. Timothy Westlake – 07/01/2020
    - l. Robert Zoeller – 07/01/2019
    - m. Robert Zondag – 07/01/2018
  - 3. Wis. Stat. § 15.085 (3)(b) – Affiliated Credentialing Boards’ Biannual Meeting with the Medical Examining Board to Consider Matters of Joint Interest
- F. Federation of State Medical Boards (FSMB) Matters and American Association of Osteopathic Examiners (AAOE) Matters**
  - 1. Testimony at U.S. House of Representatives Committee on Education and Workforce Subcommittee on Higher Education and Workforce Development Hearing on “Occupational Licensing: Reducing Barriers to Economic Mobility and Growth” **(10-15)**

2. 2018 FSMB Annual Meeting Presentations
    - a. State Medical Board Transparency – Mark Bowden, Executive Director, Iowa Board of Medicine **(16-28)**
    - b. Patient/Public Engagement and Transparency in State Medical Board Practice – Carol Cronin, Executive Director, Informed Patient Institute **(29-39)**
  3. Regenerative and Stem Cell Therapy Practices **(40-54)**
- G. Update on Re-Entry to Practice – Lee Ann Lau and Tom Ryan
- H. Legislation and Rule Matters – Discussion and Consideration**
1. Review of Draft Report on Opioid Abuse and the Wisconsin Medical Examining Board Opioid Prescribing Guideline **(55-68)**
  2. Review of Draft Emergency and Proposed Permanent Rules for Med 25, Relating to Sports Physician Licensure Exemption **(69-77)**
  3. Review of Proposed Changes to AT 1 to 4 Relating to Practice of Athletic Trainers **(78-85)**
  4. Update on Legislation and Pending or Possible Rulemaking Projects
- I. Controlled Substances Board Report – Timothy Westlake**
- J. Governor’s Task Force on Opioid Abuse – Timothy Westlake**
- K. Interstate Medical Licensure Compact Commission (IMLCC) – Report from Wisconsin’s Commissioners
- L. Speaking Engagement(s), Travel, or Public Relation Request(s), and Report(s)
- M. Newsletter Matters
- N. Screening Panel Report
- O. Informational Items
- P. Items Added After Preparation of Agenda
1. Introductions, Announcements and Recognition
  2. Administrative Updates
  3. Elections, Appointments, Reappointments, Confirmations, and Committee, Panel and Liaison Appointments
  4. Council Appointment Matters
  5. Education and Examination Matters
  6. Credentialing Matters
  7. Practice Matters
  8. Future Agenda Items
  9. Legislation/Administrative Rule Matters
  10. Liaison Report(s)
  11. Newsletter Matters
  12. Annual Report Matters
  13. Informational Item(s)
  14. Disciplinary Matters
  15. Presentations of Petition(s) for Summary Suspension
  16. Presentation of Proposed Stipulation(s), Final Decision(s) and Order(s)
  17. Presentation of Proposed Decisions
  18. Presentation of Interim Order(s)

19. Petitions for Re-Hearing
20. Petitions for Assessments
21. Petitions to Vacate Order(s)
22. Petitions for Designation of Hearing Examiner
23. Requests for Disciplinary Proceeding Presentations
24. Motions
25. Petitions
26. Appearances from Requests Received or Renewed
27. Speaking Engagement(s), Travel, or Public Relation Request(s), and Reports

Q. Future Agenda Items

**R. Public Comments**

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

**S. Presentation of Petition for Mental Examination**

1. 17 MED 340 – G.Y. **(86-96)**

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

**1. Monitoring**

- a. **8:45 AM APPEARANCE:** Robert DeFatta, M.D. – Requesting Reinstatement of Full Licensure **(97-146)**
- b. Requesting Extension to Petition for Full Licensure - Tammy A. Johnson **(147-161)**

**2. Complaints**

- a. 15 MED 234 – V.F. **(162-165)**
- b. 16 MED 423 – J.D.C. **(166-170)**

**3. Administrative Warnings**

- a. 16 MED 482 – A.M. **(171-173)**
- b. 17 MED 169 – S.C. **(174-175)**
- c. 18 MED 164 – K.B. **(176-177)**

**4. Stipulations, Final Decisions and Orders**

- a. 17 MED 401 – Virginia L. Wiggins, P.A. **(178-182)**
- b. 18 MED 039 – William S. Carpenter, M.D. **(183-188)**

**5. Case Closings**

- a. 14 MED 299 – J.W.H. **(189-191)**
- b. 16 MED 168 – G.M. **(192-206)**
- c. 16 MED 385 – C.M.B. **(207-215)**
- d. 17 MED 422 – L.E.S. **(216-222)**
- e. 17 MED 462 – P.F.F. **(223-231)**
- f. 17 MED 520 – S.E.R. **(232-237)**
- g. 18 MED 146 – D.J.L. **(238-245)**

- U. Open Cases
- V. Consulting with Legal Counsel
- W. 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

**X. RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION**

**Y. Vote on Items Considered or Deliberated Upon in Closed Session, if Voting is Appropriate**

**Z. Open Session Items Noticed Above Not Completed in the Initial Open Session**

**AA. Delegation of Ratification of Examination Results and Ratification of Licenses and Certificates**

**ADJOURNMENT**

**ORAL EXAMINATION OF CANDIDATES FOR LICENSURE  
ROOM 124D/E**

**10:00 A.M., OR IMMEDIATELY FOLLOWING THE FULL BOARD MEETING**

**CLOSED SESSION** – Reviewing Applications and Conducting Oral Examination of Two (at time of agenda publication) Candidates for Licensure – Dr. Padmaja Doniparthi and Dr. Alaa Abd-Elsayed

**NEXT MEETING DATE: AUGUST 15, 2018**

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MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED WITHOUT NOTICE.

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held at 1400 East Washington Avenue, Madison, Wisconsin, unless otherwise noted. In order to confirm a meeting or to request a complete copy of the council’s agenda, please call the listed contact person. The council may consider materials or items filed after the transmission of this notice. Interpreters for the hearing impaired provided upon request by contacting the Affirmative Action Officer, 608-266-2112

**MEDICAL EXAMINING BOARD  
MEETING MINUTES  
JUNE 20, 2018**

**PRESENT:** Alaa Abd-Elseyed, M.D.; David Bryce, M.D.; Mary Jo Capodice, D.O.; Michael Carton (*arrived via GoToMeeting at 8:02 a.m.*); Padmaja Doniparthi, M.D.; Rodney Erickson, M.D.; Lee Ann Lau, M.D.; David Roelke, M.D.; Kenneth Simons, M.D.; Timothy Westlake, M.D.; Robert Zoeller, M.D.; Robert Zondag

**EXCUSED:** Bradley Kudick

**STAFF:** Tom Ryan, Executive Director; Dale Kleven, Rule Coordinator; Kate Stolarzyk, Bureau Assistant; and other Department staff

**CALL TO ORDER**

Kenneth Simons, Chair, called the meeting to order at 8:00 a.m. A quorum of twelve (12) members was confirmed.

**ADOPTION OF AGENDA**

**MOTION:** Lee Ann Lau moved, seconded by Alaa Abd-Elseyed, to adopt the agenda as published. Motion carried unanimously.

**MINUTES OF MAY 16, 2018**

**MOTION:** Robert Zondag moved, seconded by Robert Zoeller, to approve the minutes of May 16, 2018 as published. Motion carried unanimously.

*(Michael Carton arrived via GoToMeeting at 8:02 a.m.)*

**8:00 AM APPEARANCE: DISCUSS REQUESTS FOR PROOF OF CONTINUING  
EDUCATION UPON COMPLAINT TO THE DIVISION OF LEGAL SERVICES AND  
COMPLIANCE**

**MOTION:** David Roelke moved, seconded by Alaa Abd-Elseyed, to delegate to DLSC staff, the authority to prescreen complaints for the purpose of reviewing submitted continuing medical education (CME) materials and to determine if CME requirements are met. If CME requirements are met, then DLSC staff should remove such CME documentation from the screening materials prior to the screening panel meeting. If the submitted documentation does not clearly establish that CME requirements are met, such documentation shall be forwarded to the screening panel for review. Motion carried unanimously.

**CORRESPONDENCE RECEIVED FROM M. VICTORIA MARX, M.D., PRESIDENT,  
SOCIETY OF INTERVENTIONAL RADIOLOGY AND FEDERATION OF STATE MEDICAL  
BOARDS (FSMB) REPORT ON A RECOMMENDED FRAMEWORK FOR A MINIMAL  
PHYSICIAN DATA SET**

**MOTION:** Lee Ann Lau moved, seconded by David Roelke, to approve interventional radiology as an addition to the Board's list of specialties. Motion carried unanimously.

## CLOSED SESSION

**MOTION:** David Bryce moved, seconded by Alaa Abd-Elsayed, 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.). Kenneth Simons, Chair, read the language of the motion aloud for the record. The vote of each member was ascertained by voice vote. Roll Call Vote: Alaa Abd-Elsayed-yes; David Bryce-yes; Mary Jo Capodice-yes; Michael Carton-yes; Padmaja Doniparthi-yes; Rodney Erickson-yes; Lee Ann Lau-yes; David Roelke-yes; Kenneth Simons-yes; Timothy Westlake-yes; Robert Zoeller-yes; and Robert Zondag-yes. Motion carried unanimously.

The Board convened into Closed Session at 9:24 a.m.

## RECONVENE TO OPEN SESSION

**MOTION:** Alaa Abd-Elsayed moved, seconded by Robert Zoeller, to reconvene to Open Session. Motion carried unanimously.

The Board reconvened to Open Session at 10:11 a.m.

## VOTE ON ITEMS CONSIDERED OR DELIBERATED UPON IN CLOSED SESSION

**MOTION:** Padmaja Doniparthi moved, seconded by Mary Jo Capodice, to affirm all motions made and votes taken in Closed Session. Motion carried unanimously.

*(Be advised that any recusals or abstentions reflected in the closed session motions stand for the purposes of the affirmation vote.)*

## EDUCATION AND EXAMINATION MATTERS

### Consideration of Waiver of 24 Months of ACGME/AOA Approved Post-Graduate Training

*Jorge Saucedo, M.D.*

**MOTION:** Padmaja Doniparthi moved, seconded by David Roelke, to grant Jorge Saucedo, M.D. a waiver of the 24 months of ACGME/AOA approved post-graduate training. Motion carried.

**MOTION:** David Roelke moved, seconded by Robert Zoeller, to grant the license to practice medicine and surgery to Jorge Saucedo, M.D., once all requirements are met. Motion carried.

*(Kenneth Simons recused himself and left the room for deliberation and voting in the matter concerning Jorge Saucedo, M.D.)*

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

## Complaints

### *16 MED 207 – J.C.L.*

**MOTION:** David Roelke moved, seconded by Padmaja Doniparthi, to find probable cause to believe that J.C.L., DLSC Case Number 16 MED 207, 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.

*(Lee Ann Lau recused herself and left the room for deliberation and voting in the matter concerning J.C.L., Respondent – DLSC Case Number 16 MED 207.)*

## Administrative Warnings

### *17 MED 204 – H.R.N.*

**MOTION:** Timothy Westlake moved, seconded by Mary Jo Capodice, to issue an Administrative Warning in the matter of DLSC Case Number 17 MED 204. Motion carried unanimously.

## Stipulations, Final Decisions and Orders

### *16 MED 141 – Daniel S. Landdeck, M.D.*

**MOTION:** Timothy Westlake moved, seconded by David Roelke, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Daniel S. Landdeck, M.D., DLSC Case Number 16 MED 141. Motion carried unanimously.

### *18 MED 009 – Kiarash Mirkia, M.D.*

**MOTION:** Lee Ann Lau moved, seconded by Robert Zoeller, to adopt the Findings of Fact, Conclusions of Law and Order in the matter of disciplinary proceedings against Kiarash Mirkia, M.D., DLSC Case Number 18 MED 009. Motion carried unanimously.

## Case Closings

### *16 MED 401*

**MOTION:** David Roelke moved, seconded by Robert Zondag, to refer DLSC Case Number 16 MED 401, against K.M., to DLSC for further information. Motion carried unanimously.

### *16 MED 446*

**MOTION:** Lee Ann Lau moved, seconded by Alaa Abd-Elsayed, to close DLSC Case Number 16 MED 446, against K.S., for Insufficient Evidence. Motion carried unanimously.

### *17 MED 050*

**MOTION:** Robert Zoeller moved, seconded by Lee Ann Lau, to close DLSC Case Number 17 MED 050, against S.L., for No Violation. Motion carried unanimously.

***17 MED 173***

**MOTION:** David Bryce moved, seconded by Robert Zoeller, to close DLSC Case Number 17 MED 173, against D.P.W., for Insufficient Evidence. Motion carried unanimously.

***17 MED 264***

**MOTION:** Robert Zondag moved, seconded by David Roelke, to close DLSC Case Number 17 MED 264, against J.D.O., for No Violation. Motion carried unanimously.

***17 MED 309***

**MOTION:** Lee Ann Lau moved, seconded by Alaa Ebd-Elsayed, to close DLSC Case Number 17 MED 309, against T.F., for No Violation. Motion carried unanimously.

***17 MED 321***

**MOTION:** Robert Zoeller moved, seconded by Lee Ann Lau, to close DLSC Case Number 17 MED 321, against E.K., for No Violation. Motion carried unanimously.

***17 MED 357***

**MOTION:** Lee Ann Lau moved, seconded by Padmaja Doniparthi, to close DLSC Case Number 17 MED 357, against S.E., for No Violation. Motion carried.

*(Kenneth Simons recused himself and left the room for deliberation and voting in the matter concerning DLSC Case Number 17 MED 357.)*

***17 MED 380***

**MOTION:** Robert Zoeller moved, seconded by Lee Ann Lau, to close DLSC Case Number 17 MED 380, against H.T.W., for Insufficient Evidence. Motion carried.

*(Kenneth Simons recused himself and left the room for deliberation and voting in the matter concerning DLSC Case Number 17 MED 380.)*

***17 MED 430***

**MOTION:** Lee Ann Lau moved, seconded by David Bryce, to close DLSC Case Number 17 MED 430, against J.N., for No Violation. Motion carried unanimously.

**REQUEST TO REMOVE LANGUAGE FROM FINAL DECISION AND ORDER  
#LS9802041MED – BRIAN J. EGGNER, M.D.**

**MOTION:** David Roelke moved, seconded by Lee Ann Lau, to deny the request of Brian J. Eggner, M.D., to amend the Final Decision and Order #LS9802041MED. Motion carried unanimously.

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

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

**ADJOURNMENT**

**MOTION:** Robert Zondag moved, seconded by David Roelke, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 10:16 a.m.

DRAFT

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

**AGENDA REQUEST FORM**

<b>1) Name and Title of Person Submitting the Request:</b>  Dr. Mary Jo Capodice		<b>2) Date When Request Submitted:</b>  6/20/2018  Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting	
<b>3) Name of Board, Committee, Council, Sections:</b>  Medical Examining Board			
<b>4) Meeting Date:</b>  7/11/18	<b>5) Attachments:</b>  <input type="checkbox"/> Yes <input type="checkbox"/> No	<b>6) How should the item be titled on the agenda page?</b>  Federation of State Medical Board (FSMB) and American Association of Osteopathic Examiners (AAOE) Matters: <ul style="list-style-type: none"> <li>• Testimony at US House of Representatives Committee on Education and Workforce Subcommittee on Higher Education and Workforce Development Hearing on "Occupational Licensing: Reducing Barriers to Economic Mobility and Growth"</li> <li>• 2018 FSMB Annual Meeting Presentations                         <ul style="list-style-type: none"> <li>- State Medical Board Transparency – Mark Bowden, Executive Director, Iowa Board of Medicine</li> <li>- Patient/Public Engagement and Transparency in State Medical Board Practice – Carol Cronin, Executive Director, Informed Patient Institute</li> </ul> </li> <li>• Regenerative and Stem Cell Therapy Practices</li> </ul>	
<b>7) Place Item in:</b>  <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session	<b>8) Is an appearance before the Board being scheduled?</b>  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<b>9) Name of Case Advisor(s), if required:</b>	
<b>10) Describe the issue and action that should be addressed:</b>  Board Discussion.			

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

11)	Authorization		
<table style="width: 100%;"><tr><td style="width: 70%;">Signature of person making this request</td><td style="width: 30%;">Date</td></tr></table>		Signature of person making this request	Date
Signature of person making this request	Date		
<table style="width: 100%;"><tr><td style="width: 70%;">Supervisor (if required)</td><td style="width: 30%;">Date</td></tr></table>		Supervisor (if required)	Date
Supervisor (if required)	Date		
<table style="width: 100%;"><tr><td style="width: 70%;">Executive Director signature (indicates approval to add post agenda deadline item to agenda)</td><td style="width: 30%;">Date</td></tr></table>		Executive Director signature (indicates approval to add post agenda deadline item to agenda)	Date
Executive Director signature (indicates approval to add post agenda deadline item to agenda)	Date		
<p><b>Directions for including supporting documents:</b></p> <ol style="list-style-type: none"><li>1. This form should be attached to any documents submitted to the agenda.</li><li>2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.</li><li>3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.</li></ol>			

**United States House of Representatives  
Committee on Education and the Workforce  
Subcommittee on Higher Education and Workforce Development**

**Hearing on  
“Occupational Licensing: Reducing Barriers to Economic Mobility and Growth”**

June 20, 2018

The public is best served when state regulatory boards, duly constituted under state law, are free to make decisions on issues of occupational public health, safety, and welfare, decisions which involve a balancing of multiple values—including the necessity of occupational license, regulatory expediency, and ultimate effect on the economic health of the marketplace. Just as important as these values is the ability to protect their citizens from fraudulent or unsafe practices by unqualified practitioners of vital consumer services.

The undersigned associations of state licensing boards and the organizations representing those licensed professionals serving on these boards have a direct interest in the issues being considered by this Subcommittee. Collectively, our organizations produce uniform examinations and assessment mechanisms to ensure entry level competency, assess domestic and foreign educational programs, draft best practice guidelines and model laws, and manage comprehensive databanks of information crucial to occupational licensure, including information on education, examinations, demographics, post-licensure continuing education and continuing competence. These materials and programs are used by state legislatures and state regulatory boards when contemplating reforms which impact occupational licensure. State governments use occupational licensure to ensure the quality, safety, and integrity of the knowledge-based professions. Licensure and regulation promotes high standards practice and effectuates the state’s primary goal of protecting public health, safety, and welfare.

We urge the Subcommittee to contemplate the unique role of state licensing bodies and occupational licensure in the system of state government. Throughout the history of this country, states have relied upon a system of regulation that includes various approaches to licensure and

have created licensing boards under the auspices of state law to oversee the licensure process and protect the consuming public from harm. We ask you to acknowledge that regulation of certain licensed professional services requires deference to the preferences of the state regarding the type, number, and method of licensure, as well defer to choices of the states on how best to structure occupational licensure and empower regulatory authorities charged with enforcing regulations for the public good.

### The Role of Licensure and Licensing Boards in a Free Market

Professional licensure exists within a system of federalism in which, under the Tenth Amendment, the federal government displays respect for the sovereign decisions made by the states to oversee professionals providing services within their boundaries. State licensing boards limit the ability of unqualified professionals from entering the market and restrict or remove professionals when they do not adhere to the professional standards set by the state or they endanger members of the consuming public. Through promulgation and enforcement of standards of practice, state licensing boards ensure that the skilled professional is acting for the benefit of the consumer, and not at the expense of the consumers. All of these actions are deliberate, and undertaken subject to state laws guaranteeing transparency and public inclusion. In comments at the July 2017 FTC Economic Liberty Taskforce Roundtable, Acting Chairman Maureen Ohlhausen recognized that occupational licensure serves important consumer protection functions, especially in situations where consumers may be vulnerable because they lack sufficient information to evaluate the quality of service providers.

State licensing boards serve an important role in the function of a free market by creating trust between the public consumer of a service and the professional who provides it within a state's borders. Although boards vary in structure and form, the legislatively mandated purview of any state licensing board is to determine whether certain societal values, such as reduction of physical harm or avoidance of deception, outweigh the benefits of unrestricted competition. In addition, state licensing regimes help to level the playing field for persons seeking to enter a particular profession because there are clear requirements and pathways to enter that profession, as opposed to purely relying on access to information and relationships that could otherwise assist in gaining entry into the profession.

The broad generalizations relied upon by critics of state licensing boards assume that consumers can unilaterally distinguish the qualifications necessary to provide a service and characterize the role of licensing boards as superfluous in a modern marketplace. However, it is difficult for a consumer to properly value a market good or service that is based upon the provision of advanced knowledge. Knowledge-based market goods and services lack the purely transparent character that would allow consumers to discern the quality of the goods or services much in the same way they would discern the quality of basic retail goods such as food or clothing. This understanding is implicit in the decision of a state to license a profession and should be reflected in federal competition preferences.

#### Procompetitive Steps to Streamline & Reduce Barriers

It is important for this Subcommittee to recognize the great, procompetitive strides that states and state licensing boards have made in recent years to facilitate and encourage licensed professionals to engage in the delivery of regulated services in a variety of U.S. jurisdictions. These strides have been in the form of interstate compacts, mutual recognition agreements, and various forms of mobility initiatives. These efforts have been coupled with efforts to reduce licensing burdens for veterans and military spouses.

A healthy respect for the ability of states to work together absent federal mandate or interference in the proper functioning of state-based regulation is imperative, as the choices made by the states in structuring its regulatory system are not solely determined by one factor, such as federal competition preferences or economic analysis, when matters of the public health, safety, and welfare of its citizens are at issue. To that end, Congress should be hesitant to enact occupational licensing reforms which would frustrate or impair the ability of state boards to regulate professions in compliance with state law, state policies, and the chosen structures of a state. Congress should continue to defer the primary responsibility to institute occupational licensure reform to the states, as the state regulatory community is better suited to align with multiple aims, including economic outcomes, without sacrificing public protection.

## Conclusion

We appreciate the Subcommittee's attention to this issue, and respectfully urge the Subcommittee to consider devising appropriate policies that balance underlying concerns of competition, economic efficiency, and innovation with the principles of federalism and the good public policy of state regulatory boards as the protector of the health, safety and welfare of the public. We would be pleased to meet with the Subcommittee and its members to discuss these issues further. Thank you.

*Respectfully Submitted,*

**American Association of Osteopathic Examiners**

**American Association of Veterinary State Boards**

**American Council of Engineering Companies**

**American Institute of Certified Public Accountants**

**American Osteopathic Association**

**American Physical Therapy Association**

**American Psychological Association Practice Organization**

**American Society of Anesthesiologists**

**American Society of Civil Engineers**

**American Society of Landscape Architects**

**Association of Social Work Boards**

**Association of State and Provincial Psychology Boards**

**Council of Landscape Architectural Registration Boards**

**Federation of Associations of Regulatory Boards**

**Federation of Podiatric Medical Boards**

**Federation of State Boards of Physical Therapy**

**Federation of State Medical Boards**

**National Association of State Boards of Accountancy**

# State medical board transparency



## Federation of State Medical Boards

MARK BOWDEN, MPA, CMBE  
EXECUTIVE DIRECTOR  
IOWA BOARD OF MEDICINE  
APRIL 27, 2018

# TRANSPARENCY: What do we know?



**“What did the president know, and when did he know it?”** *Sen. Howard Baker, R-Tenn., June 1973, Watergate hearing*

**“There are things we know we know ... we also know there are known unknowns ... but there are also unknown unknowns.”**

*Secretary of Defense Donald Rumsfeld, February 2002, Operation Iraqi Freedom*



# **TRANSPARENCY:** Times are changing



- Media landscape changing - real news, fake news, and otherwise
- Public's interests, expectations can change quickly
- Government's purpose and credibility constantly questioned

# TRANSPARENCY: What is it?

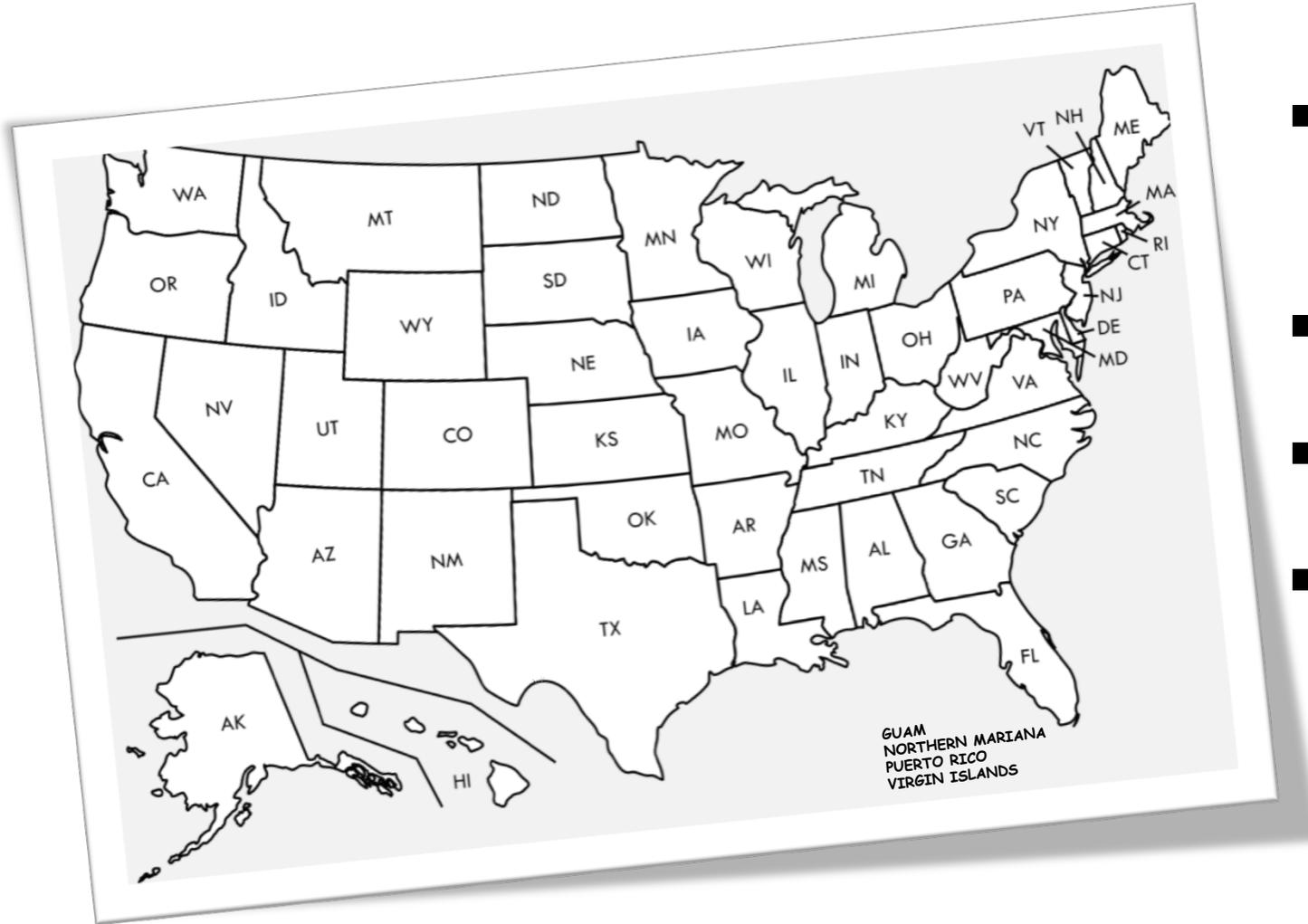
1. Proactive disclosure

2. Requesting public records

3. Campaign finance disclosure



# **TRANSPARENCY:** No exemption for SMBs



- Regulations, legalities abound
- Competing demands
- Not much flexibility
- Many stakeholders

# TRANSPARENCY: Requests for records



- Requests surging
- State laws vary
- Technology helps
- Have a strategy

# **TRANSPARENCY:** Proactive disclosure

- Anticipate
- Prepare
- Stay abreast of trends, issues
- Leverage technology
- Shovel out public information



# TRANSPARENCY: Proactive disclosure



- SMBs are data rich, but information poor
- Ugh

# **TRANSPARENCY:** Be helpful, understanding



- **Be proactive**
- **get the word out**
- **A clear, clean message**
- **Maintain contacts**
- **Make referrals**
- **Maintain, strengthen your processes**

# TRANSPARENCY: Use multiple channels

- Press releases
- Outreach
- Web sites
- Social media
- Education

**Online Services**  
services from the board such as data lists, copies of records,

**About the Board**  
PROTECTING IOWANS' HEALTH

- Rules, laws and policies
- Orders and press releases
- Members and staff
- Agendas, minutes and reports
- Media kit

**IOWA BOARD OF MEDICINE**  
400 SW EIGHTH STREET  
SUITE C  
DES MOINES, IOWA 50309  
PHONE: 515-281-5171  
FAX: 515-281-8641  
Web: [www.medicalboard.iowa.gov](http://www.medicalboard.iowa.gov)

**COMPLAINT FORM**  
Important ways the Iowa Board of Medicine protects  
your health. This form  
**YOUR EXPECTATIONS**  
What would you like the Iowa Board of Medicine to do about your  
complaint?

**Iowa Board of Medicine**  
Published by Chrissy Roberts Greco | April 6 at 4:04pm

**GENETIC COUNSELORS TO BE LICENSED IN IOWA:**  
A new state law will establish the licensure and regulation of genetic counselors under the Iowa Board of Medicine. Click link below for press release:... See More

[medicalboard.iowa.gov](http://medicalboard.iowa.gov)  
MEDICALBOARD.IOWA.GOV

**IOWA BOARD OF MEDICINE**

Practitioners who support:  
• Physicians (M.D. and D.O.)  
• Podiatrists (D.P.M.)  
• Iowa Physician Health Program  
• Data to report

Consumers  
• File a complaint  
• Find a physician  
• Other health-related  
• Consumer information

How may we help:  
• File a complaint  
• Find a physician  
• Other health-related  
• Consumer information

NEWS  
• Health Board News, Summaries  
• Health Board News, Summaries  
• Health Board News, Summaries  
• Health Board News, Summaries

**STATE OF IOWA**  
IOWA BOARD OF MEDICINE  
EXECUTIVE DIRECTOR  
MARK BOWDEN, M.P.A.

**Summary of April 5-6, 2018, Board Meeting**  
April 17, 2018

**Board elects officers, sets 2019 schedule**  
FOR IMMEDIATE RELEASE: April 9, 2018  
CONTACT: Mark Bowden, (515) 494-8344 or  
[mark.bowden@iowa.gov](mailto:mark.bowden@iowa.gov)

**PRESS RELEASE**  
**IOWA BOARD OF MEDICINE**  
(April 11, 2018)

**Comments: Please click on the person's name to access a link to a copy of the**  
Iowa Board of Medicine took the following action:  
A 27-year-old Iowa-licensed physician who practices ophthalmology in Carroll...

# TRANSPARENCY: Explaining the process

**CONSUMER GUIDE**  
**IOWA BOARD OF MEDICINE**



The Iowa Board of Medicine promptly responds to public complaints concerning the competency and conduct of Iowa-licensed physicians and acupuncturists. The Board is committed to protecting the public by ensuring that these health care providers are qualified to practice and that they adhere to laws, rules and standards that regulate their practices.

## WHAT HAPPENS WHEN YOU FILE A COMPLAINT

### FILING



It is the public's right to file a complaint with the Iowa Board of Medicine. Complaints may be submitted online via the Board's website, or can be filed by mail, e-mail, FAX or over the telephone. A form on the website identifies the kind of information that the Board needs to effectively review a complaint. For the Board to consider a complaint, it must include the name of the health care professional, a description of the actions prompting the complaint, the place, date and time of occurrence, and name and telephone number of the complainant. Complaints that do not include the name of the person making the complaint are sometimes difficult to investigate. The identity of the complainant is protected and kept confidential by law.

**Consumers**

**HOW CAN I GET HELP?**

- File a complaint
- Find a physician
- Find an acupuncturist
- Other health site links
- Consumer information

Access this link at: [www.medicalboard.iowa.gov](http://www.medicalboard.iowa.gov)

### INVESTIGATIONS

- All complaints are initially reviewed by agency staff to determine if the matter requires an investigation.
- Complaints that appear to be less serious or outside of the agency's authority are reviewed by the Board to determine if investigations are needed or if these complaints should be referred to another regulatory board.
- All other complaints are immediately assigned to an investigator.
- The complainant is sent a letter with the investigator's name and phone number.
- If it's determined the complaint will not be investigated, the complainant will be notified by letter.
- If the complaint is investigated, the investigator will conduct interviews and collect medical records and prepare a report for review by the Board, which will determine if the case should be closed without action or if the licensee should be disciplined.
- Investigations can take several months, depending on the complexity of the issue.
- Before the Board resolves a case, the licensee may be asked to appear before the Board for a private interview or ordered to undergo a professional evaluation, or the Board may have the case reviewed by qualified members of the profession within the relevant field.

### OUTCOMES

Complaints are most often resolved in one of three ways:

- 1. No formal action.** Typically, this is the result when no violation of laws, rules or medical care standards has occurred. However, the licensee is notified and the information is kept on file. This allows the Board to spot recurrent issues or a pattern of behavior that may cause the Board to intervene in the future.
- 2. Confidential action.** There may be no violation of laws, rules or medical care standards that warrants public action, but the Board is nonetheless concerned about some aspect of the licensee's conduct or performance. In such cases, the Board will issue a confidential letter of education or a confidential letter of warning, cautioning the licensee against repeating similar conduct.
- 3. Public charges filed.** In these cases, the Board determines there is a violation of laws, rules or medical care standards and files public charges and a disciplinary hearing is scheduled. Once the case is resolved, either by settlement agreement or by a disciplinary hearing, the complainant is notified of the outcome.

### PUBLIC DISCIPLINE

Public action against a licensee who has been found to have violated a law, rule or medical care standard may include civil penalties (fines), reprimands, remedial training, limitations or conditions on practice, or suspension or revocation of the license. All disciplined licensees are monitored to ensure they are in compliance with their sanctions. To find out if a public disciplinary action has been imposed, view the licensee's profile on the Board's website or call the Board's office.



### CONFIDENTIAL INFORMATION

The Iowa Board of Medicine is required by state law to maintain the confidentiality of all information related to Board investigations. This includes complaints and investigative reports. Consequently, complainants cannot receive information or be briefed on any aspect of the investigation or how the case is resolved beyond what is presented in public documents about the case.

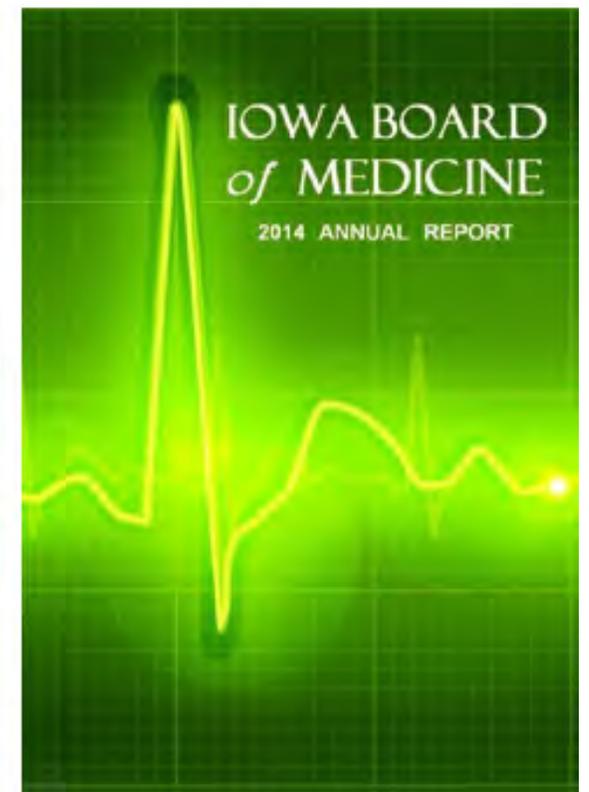
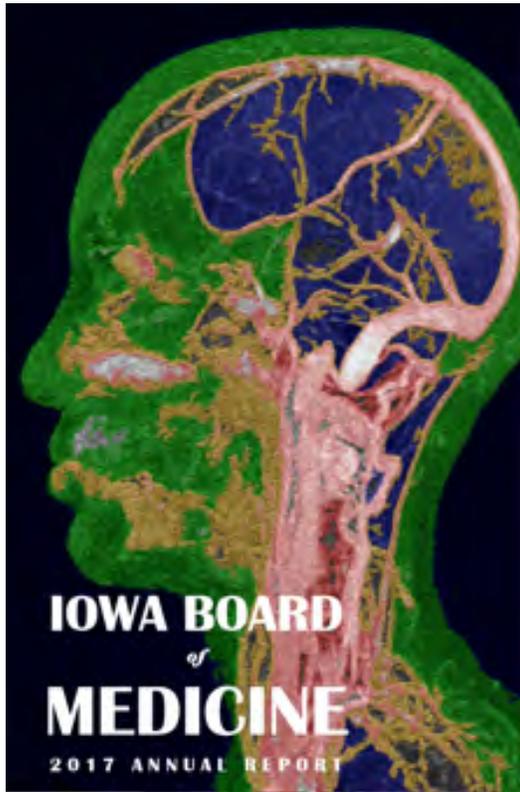
January 2015

BEFORE THE IOWA BOARD OF MEDICINE

IN THE MATTER OF THE STATEMENT OF CHARGES AGAINST  
AN IOWA-LICENSED PHYSICIAN, M.D., RESPONDENT

FILE No. 12-34-267-000

# TRANSPARENCY: Package information



# **TRANSPARENCY:** Take nothing for granted

- Best laid plans can go awry
- A critic can be your best friend
- Information makes public safer



# **Patient/Public Engagement and Transparency in State Medical Board Practice**

Federation of State Medical Boards Annual Meeting  
April 27, 2018

Carol Cronin – Executive Director  
Informed Patient Institute

# IPI Mission & Objectives

- **Mission**
  - To improve the quality of health care by helping the public make more informed choices about their care
- **Objectives**
  - To educate the public about health care quality, patient safety health care costs and patient rights and responsibilities
  - To facilitate access to credible information about health care organizations and professionals
  - To advocate for more, and more useful, health care quality information

# Medical Board Roundtable

- National coalition of patient and consumer advocates interested in increasing public awareness and responsiveness of state medical boards to patients, families and the public
- 25 participants/14 states
- Projects:
  - Review state medical board websites
  - Definition of public member
  - Track policy issues/physician oversight
  - Ten things medical boards can do
  - National Practitioner Data Bank public use files

# Ten Things Medical Boards Should Do To Be More Publicly Accessible

- **Better Understand How to Reach the Public**
  - Research public perceptions
  - Create Consumer Advisory Boards
- **Community Outreach and Awareness**
  - Post information in Dr. offices about medical boards
  - Speakers bureau
  - Subscriptions to online information
  - Use social media

## 10 Things (cont.)

- **Increase Access to Public Meetings**
  - Provide webinar access
  - Provide call-in line for public comment
- **Increase Access to Board Information**
  - Easily found and comprehensive Annual Report
  - Improve accessibility and content of board websites

# IPI/Consumer Reports State Medical Board Website Project (2016)

- Reviewed 65 state medical/osteopathic board websites
- Evaluated 8 categories covering usability & content – 61 criteria
  - Disciplinary information
  - Malpractice information
  - Criminal convictions
  - Search capabilities
- Wide variance in overall rating – highest score (CA – 84 out of 100) and lowest score (MS- 6)
- Part of Consumer Reports cover story on Drs. (April 2016)

# Accessibility & Content of Board Websites

- Understand consumers as your audience:
  - Use easily understandable terms
  - Create a “Consumer Section”
  - Make search process easier to use
- Physician Profiles:
  - Current/historic/other state information on disciplinary actions
  - Plain English descriptions
  - Complete malpractice
  - Hospital actions
  - Criminal actions
  - Federal actions

# Criteria for Public Members on State Health Professional Boards

- Most criteria only talk about disqualifiers (can't be a health provider)
- Affirmative criteria for public members:
  - Track record of consumer/public interest advocacy
  - Connections to grass root organizations representing diverse groups
  - Awareness of health concerns for diverse demographic groups
  - Demonstrated interest in health care safety and quality improvement

# Quotes about State Medical Boards from Consumers

- “Form letters after months of doing nothing...A cruel hoax”
- “For so many reasons, I feel it is a waste of time to report the surgeon..”
- “They do all in their power to silence victims' screams creating the illusion of accountability and independence”
- “They are simply doctors protecting doctors”

## Concluding Observations

- Understand medical boards operate in challenging/complex work within legal, regulatory and budget constraints
- Great deal of frustration now on part of harmed patients and families/nowhere to turn except each other, media, social media, & political process
- Balancing public protection and due process
- Consumer groups as allies if build awareness and trust?

## More Information

Carol Cronin

Executive Director

Informed Patient Institute

[www.informedpatientinstitute.org](http://www.informedpatientinstitute.org)

c.cronin@comcast.net

*Seeking Doctor Information Online: A Survey and  
Ranking of State Medical and Osteopathic Board  
Websites in 2015 (3/16)*

## **Regenerative and Stem Cell Therapy Practices**

*Report and Recommendations of the Workgroup to Study Regenerative and Stem Cell Therapy Practices*

*Adopted as policy by the Federation of State Medical Boards  
April 2018*

### **Section One. Introduction and Charge:**

The Federation of State Medical Boards (FSMB) Workgroup to Study Regenerative and Stem Cell Therapy Practices was convened in May of 2017 by FSMB Chair Gregory B. Snyder, M.D., DABR, in response to a letter (Attachment 1) from U.S. Senator Lamar Alexander (R-TN), Chairman of the U.S. Senate Health, Education, Labor, and Pensions (HELP) Committee, urging the FSMB to develop best practices for state medical and osteopathic boards (hereinafter referred to as “state medical boards”) in regulating the promotion, communication, and practices of treatments received at stem cell clinics in the United States.

In order to address Senator Alexander’s request, Dr. Snyder charged the Workgroup with:

- 1) Evaluating the prevalence, promotional practices, and incidences of patient harm related to regenerative medicine and adult stem cell therapies in the U.S.;
- 2) Evaluating current regulatory approaches that will protect the public, recognizing the potential for improved patient outcomes through health innovation and technology;
- 3) Identifying best practices for state medical and osteopathic boards in investigating complaints of patient harm, fraud, and compliance with licensure requirements; and
- 4) Issuing a report on the Workgroup’s findings from prevailing research and recommending best regulatory practices and guidelines related to physicians’ use of regenerative medicine and adult stem cell therapies in a manner consistent with safe and responsible medicine.

Stem cell and regenerative therapies offer opportunities for advancement in the practice of medicine and the possibility of an array of new treatment options for patients experiencing a variety of symptoms and conditions. Despite significant momentum in research and development, and the potential for such medical advancements, there is reasonable concern about a growing number of providers and clinics in the United States that are undermining the field. Such providers and clinics have been known to apply, prescribe or recommend therapies inappropriately, over-promise without sufficient data to support claims, and exploit patients who are often in desperate circumstances and willing to try any proposed therapy as a last resort, even if there is excessive cost or scant evidence of efficacy.

The following report aims to raise awareness about regenerative and stem cell therapy practices generally, outline their potential benefits and risks, and provide basic guidance for state medical boards and licensed physicians and physician assistants. Central to all of the recommendations provided herein is a range of imperatives, including the importance of protecting the public, respecting patient autonomy, preventing patient exploitation, obtaining informed consent, and appropriately documenting care that is recommended and provided.

The Workgroup's deliberations were aided by participants and subject matter experts who brought varying perspectives. For example, Dr. Ronald Domen has expertise in stem cell therapies, bioethics and humanities, and has served on numerous ethics committees at institutional, state, and national levels. Dr. Zubin Master of the Mayo Clinic has extensive training and education in cellular and molecular biology, bioethics and genetics, as well as research and publications on stem cell therapies. Mr. Douglas Oliver became known to the Workgroup through a recommendation by Senator Lamar Alexander of Tennessee, was a recipient of stem cell therapies himself, and has a foundation that advocates for stem cell therapies based on his own experiences and those of others like him. Dr. Bruce White has educational backgrounds in medicine, law, pharmacy and ethics and currently serves as Director of the Alden March Bioethics Institute at Albany Medical College and is Chair of Medical Ethics at the College. The Workgroup also received written comments from several external organizations. The sum of these perspectives aided the Workgroup in producing a balanced report on this emerging issue of national importance.

## **Section Two. Definitions:**

Homologous (Allogeneic) Use: the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with a HCT/P (human cells, tissues, and cellular and tissue-based product) that performs the same basic function or functions in the recipient as in the donor, including when such cells or tissues are for autologous use.<sup>1</sup>

According to the Food and Drug Administration's (FDA) *Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use / Guidance for Industry and Food and Drug Administration Staff (November 2017)*, the FDA "generally considers an HCT/P to be for homologous use when it is used to repair, reconstruct, replace, or supplement:

- Recipient cells or tissues that are identical (e.g., skin for skin) to the donor cells or tissues, and perform one or more of the same basic functions in the recipient as the cells or tissues performed in the donor; or
- Recipient cells or tissues that may not be identical to the donor's cells or tissues, but that perform one or more of the same basic functions in the recipient as the cells or tissues performed in the donor."<sup>2</sup>

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<sup>1</sup> 21 CFR 1271.3(c)

<sup>2</sup>U.S. Food and Drug Administration (November 2017). *Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use Guidance for Industry and Food and Drug Administration Staff*.

Autologous Use: the implantation, transplantation, infusion, or transfer of human cells or tissue back into the individual from whom the cells or tissue were recovered.<sup>3</sup>

Informed and Shared Decision Making: The process by which a physician discusses, in the context of the use of regenerative and stem cell therapies, the risks and benefits of such treatment with the patient.<sup>4</sup> The patient is given an opportunity to express preferences and values before collaboratively evaluating and arriving at treatment decisions.<sup>5</sup>

Informed Consent:<sup>6</sup> Evidence documenting appropriate patient informed consent typically includes the following elements:

- Identification of the patient, the physician, and the physician’s credentials;
- Types of transmissions permitted using regenerative and stem cell therapies (e.g. prescription refills, appointment scheduling, patient education, etc.);
- Agreement from the patient with the physician’s determination about whether or not the condition being diagnosed and/or treated is appropriate for regenerative and stem cell therapy;<sup>7</sup> and
- Express patient consent to forward patient-identifiable information to a third party
- An accurate description of the benefits and risks of treatment or intervention, based on scientific evidence, as well as an explanation of alternatives to treatment or an intervention, and the right to withdraw from treatment or an intervention without denial of standard of care to patients.

Minimal Manipulation: (minor processing including purification, centrifugation, washing, preservation, storage) – the Food and Drug Administration (FDA) argues that it has the authority to regulate anything beyond minimal manipulation and homologous use:

“(1) For structural tissue, processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement; and  
(2) For cells or nonstructural tissues, processing that does not alter the relevant biological characteristics of cells or tissues.”<sup>8</sup>

Unproven Stem Cell Intervention: Stem cell therapy that lacks compelling evidence, based upon scientific studies, to validate its treatment efficacy.<sup>9</sup>

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<sup>3</sup> 21 CFR 1271.3(a)

<sup>4</sup> Federation of State Medical Boards (2016). Model Guidelines for the Recommendation of Marijuana in Patient Care.

<sup>5</sup> Barry, MJ, Edgman-Levitan, S. (2012). Shared Decision Making – The Pinnacle of Patient-Centered Care. *N Engl J Med*, 366:780-781.

<sup>6</sup> With respect to informed consent for the purposes of research studies involving human subjects, researchers should be aware of the basic elements of informed consent outlined in 21 CFR Part 50.25 “Protection of Human Subjects.”

<sup>7</sup> Federation of State Medical Boards (2014). Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine.

<sup>8</sup> 21 CFR 1271.3(f)

<sup>9</sup> Sipp D, et al. (2017). Marketing of Unproven Stem Cell-Based Interventions: A Call to Action. *Science Translational Medicine*, 9:397.

### Section Three. Background, Prevalence and Marketing of Regenerative and Stem Cell Therapies:

Historically, many of the clinics providing unproven stem cell interventions fell under the definition of “stem cell tourism” because most patients seeking such interventions had to travel outside of North American jurisdictions to receive them. The landscape in the United States has evolved considerably over the last few years with hundreds of new clinics opening across the country and many more physicians willing to provide stem cell and regenerative therapies. A study identified 351 U.S. businesses with over 570 clinics engaged in direct-to-consumer (DTC) marketing of stem cell interventions.<sup>10</sup> It has also been suggested that growth in this area of medicine, especially in terms of adult, amniotic, fat-derived and bone marrow stem cell therapies to treat a host of conditions and injuries, is accelerating, both in the U.S. and internationally, and, perhaps counterintuitively, such growth is noted to be most significant in jurisdictions with more stringent regulatory frameworks.<sup>11</sup>

Stem cell clinics typically reach their patients through online DTC marketing, primarily through information provided on company websites. Data purportedly supporting unproven stem cell interventions commonly undermine information about risks and overemphasize information about benefits. Treatment options are described on such websites and are often accompanied by supporting information in the form of journal articles, patient testimonials, and accolades related either to the clinic itself or its affiliated physicians and researchers. Supporting information that accompanies marketing materials can appear to be legitimate, but can also overemphasize, exaggerate, inflate, or misrepresent information derived from legitimate (or even questionable) sources. A physician engaging in such practices of deceptive or false advertising can be in violation of a state’s *Medical Practice Act*. Information provided on clinic websites should be represented accurately and come from reputable peer-reviewed publications or respected external organizations.

Some clinics, however, that are engaged in the provision of treatment modalities that lack evidence – or an appropriate rationale for application of that modality to particular medical conditions – often use what have been described as “tokens of scientific legitimacy” to lend credence to treatments offered or the quality of a clinic and its associated professionals. Examples of such tokens of legitimacy include patient or celebrity testimonials and endorsements, clinician affiliations or memberships in academic or professional societies, registrations in clinical trials, claims of various types of certifications or awards, and others.<sup>12</sup> Further detail and explanations are provided in **Table 1**.

Physicians are ordinarily permitted to advertise themselves, their practice and services offered, provided that such advertisements do not contain claims that may be deceptive or are intentionally false or misleading. Further, physicians should be mindful of ways in which patient

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<sup>10</sup> Turner L, Knoepfler P. (2016). Selling Stem Cells in the USA: Assessing the Direct-to-Consumer Industry *Cell Stem Cell* 19, August 4, 154-7.

<sup>11</sup> Berger, et al. (2016) Global Distribution of Businesses Marketing Stem Cell-Based Interventions. *Cell Stem Cell* 19, August 4, 158-62.

<sup>12</sup> Sipp D, et al. (2017). Marketing of Unproven Stem Cell-based Interventions: A Call to Action. *Sci. Transl. Med.* 9, eaag0426.

testimonials, quality ratings, or other evaluative data is presented to prospective patients through advertisements. In advertising stem cell treatments to potential patients, physicians are responsible for ensuring that all information, especially in terms of risks, benefits and efficacy, is presented in an objective manner. Physicians must not deliberately misrepresent the expected outcomes or results of treatments offered. Physicians should be prepared to support any claims made about benefits of treatment(s) with documented evidence, for example with studies published in peer-reviewed publications.<sup>13</sup>

Physicians must be accurate and not intentionally misleading in providing descriptions of their training, skills, or treatments they are able to competently offer to patients. This includes descriptions of one's specialization and any specialty board certifications.<sup>14</sup>

A recent study on the prevalence and marketing practices of businesses offering stem cell treatments internationally noted the presence of the following elements in their marketing practices:

- Mention of affiliations with a professional society or network
- Claims of partnerships with academic institutions
- Statements of receipt of FDA approval, or explicit mention of exemption from FDA oversight
- Mention of official endorsement from a local or other authority, or professional accreditation
- Listing of patents granted
- Statement that clinical trials of investigational stem cell-based interventions are being conducted<sup>15</sup>

The marketing practices and information found on a business' website can be important sources of data for state medical boards as they investigate complaints made against physicians affiliated with businesses providing regenerative and stem cell treatments. Even where an appropriate informed consent process seems to be in place, deceptive or fraudulent information on clinic websites and other marketing materials could mislead patients into consenting to treatment, thereby invalidating the informed consent process.

Physicians must make accurate claims about the enrollment process of subjects, treatments, and products in clinical trials and are responsible for ensuring that any research conducted and described in marketing materials is carried out according to accepted research protocols and recognized standards. Physicians should consider consulting with Institutional Review Boards (IRBs) to clarify processes and must seek IRB approval, where necessary. The National Institutes of Health (NIH) provides helpful guidance on clinical trials and research methods.<sup>16</sup> Physicians are also encouraged to consult the guidance contained in the *International Conference*

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<sup>13</sup> Federation of State Medical Boards (2016). *Position Statement on Sale of Goods by Physicians and Physician Advertising*.

<sup>14</sup> *Ibid.*

<sup>15</sup> Berger, et al. (2016) Global Distribution of Businesses Marketing Stem Cell-Based Interventions. *Cell Stem Cell* 19, August 4, 158-62.

<sup>16</sup> National Institutes of Health, Office of Science Policy: <https://osp.od.nih.gov/clinical-research/clinical-trials/>

on Harmonisation's Harmonised Tripartite Guideline for Good Clinical Practice to support acceptability of clinical data by patients, state medical boards, and other regulatory authorities.<sup>17</sup>

**Table 1: Co-opted Tokens of Scientific Legitimacy<sup>18</sup>**

Accreditations and awards	Asserting certification of products or practices by international standards organizations or claiming training certification
Boards and advisers	Convening scientific or medical advisory boards featuring prominent business leaders and academic faculty members
Clinical study registration	Registering trials whose apparent purpose is solely to attract patients willing to pay to participate in them
Ethics review	Using the imprimatur of "ethics review" to convey a sense of legitimacy to their products or procedures
Location	Renting of laboratory or business space within a legitimate scientific or government institution
Membership	Joining established academic or professional societies to suggest legitimacy by association
Outcome registries	Publication of open-ended voluntary monitoring data sets rather than undertaking controlled clinical trials
Patenting	Suggesting that patent applications or grants indicate clinical utility rather than initiation of an application process or recognition of novelty and inventiveness
Publication	Publishing research and commentary in journals with limited anonymous peer review
Rationales	Citing preclinical and other research findings to justify clinical application without sufficient efficacy testing in humans
Self-regulation	Forming organizations to self-regulate in ways that support premature commercialization
Technical Language	Using scientific-sounding words that imply academic rigor
Testimonials and Endorsements	Providing expert opinions or celebrity comments on unsupported clinical uses or standing of the provider

#### Section Four. Patient Perceptions:

In seeking treatment for any condition, patients desire safety and efficacy, but may overlook risks to their own safety or a lack of evidence of efficacy in favor of access to treatment, particularly in circumstances where traditional treatment options seem limited or have been exhausted. The power of hope also is known to play a significant role in how patients attempt to gain control over their illness and its potential treatments, thereby putting them in a position of

<sup>17</sup> International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use. (2016). ICH Harmonised Tripartite Guideline for Good Clinical Practice E6(R2).

<sup>18</sup> Sipp D, et al. (2017). Marketing of Unproven Stem Cell-based Interventions: A Call to Action. *Sci. Transl. Med.* 9, eaag0426.

increased vulnerability.<sup>19</sup> This is especially the case when patients and their families have overcome various obstacles on the path to a treatment, including raising large sums of money to pay for it. This can lead to a psychological predisposition to anticipate and assume a positive outcome, regardless of the treatment in question or the availability of compelling evidence.

Given the vulnerable state of some patients who seek regenerative and stem cell therapies, perhaps without the requisite knowledge for making informed decisions, there is increased potential for patient exploitation. Physicians must therefore be mindful of the ways in which at-risk or susceptible patients may process information and arrive at decisions about their treatment options, expectations, and ultimately, the potential for success. A promising way of navigating such difficult circumstances, where treatment options are uncertain or complex, is through the use of shared decision making. This process, whereby the physician describes the risks and benefits of potential treatment options and the patient is given an opportunity to express preferences and values before collaboratively arriving at and evaluating treatment decisions,<sup>20</sup> may help mitigate the risk of patient exploitation and ensure that consent to any treatment option has been provided in an informed manner.

The process of obtaining informed consent and engaging in shared decision making with patients involves conveying information about the reasonable effectiveness of a proposed treatment, as well as its risks and benefits. This can be particularly difficult with respect to regenerative and stem cell therapies, as this is an area of medicine that currently lacks substantive data on efficacy. Generation of relevant data and evidence has not occurred to a sufficient enough degree and this is often blamed on the difficulty involved in organizing large-scale, randomized controlled trials as part of the approval process for novel therapies. However, the FDA has recently argued that a statistically significant 100% improvement in an outcome measure ( $\alpha = 0.05$ ,  $\beta = 0.1$ ) may be detected with a randomized trial involving as few as 42 participants.<sup>21</sup>

The lack of a formal mechanism for reporting outcomes of unproven stem cell interventions, both positive and negative, adds to the difficulty involved in generating data on the effectiveness of such interventions, as does the fact that there is neither a requirement, nor a mechanism, for reporting adverse events related to interventions administered outside of clinical trials and investigations. In the current environment, this increases the importance of appropriate documentation of treatment(s) and ongoing care in patients' medical records. A centralized cell therapy registry for reporting treatment and outcomes may improve the current information available about the effectiveness of such therapies and interventions. It may also dissuade unscrupulous practitioners from engaging in the provision of unproven interventions without an adequate or appropriate basis in theory or peer-acknowledged practice, a pre-requisite for the provision of any intervention, whether proven or not.<sup>22</sup>

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<sup>19</sup> Petersen, et al. (2014). Therapeutic Journeys: The hopeful travails of stem cell tourists, *Sociology of Health & Illness*, 36(5):670-85, pp. 1–16.

<sup>20</sup> Barry, MJ, Edgman-Levitan, S. (2012). Shared Decision Making – The Pinnacle of Patient-Centered Care. *N Engl J Med*, 366:780-781.

<sup>21</sup> Marks PW, et al. (2017). Clarifying Stem-Cell Therapy's Benefits and Risks, *NEJM* 376;11, 1007-9.

<sup>22</sup> White, BD, Gelinas, LC, (2016). "Balancing the Surgeon's Responsibility to Individuals and Society," published in S.C. Stain et al. (eds.), *The SAGES Manual Ethics of Surgical Innovation*, Switzerland: Springer International Publishing, 191-211.

## Section Five. Regulatory Landscape:

The current state of affairs for regulatory oversight on regenerative and stem cell therapies (including human cells and tissues), at both the federal and state level, is evolving and will continue to change in the coming years. In November 2017, the FDA released two guidance documents to explain the Agency’s current thinking on stem cell policy. However, this thinking, as well as the agency’s jurisdiction and authority, may evolve in the future.

Until recently, the regulatory landscape for stem cell and regenerative therapies has been at times restrictive, allowing patients to access stem cell interventions only under the *Expanded Access to Investigational Drugs for Treatment Use* program. Treatments are eligible under this program if they are undergoing testing in a clinical trial and are subject to approval by the FDA. Three-quarters of the states in the nation have passed “Right to Try” legislation, however, which allows terminally ill patients to receive experimental therapies that have passed phase 1 trials without seeking FDA approval.<sup>23</sup> The U.S. Congress is also considering similarly proposed legislation and in August of 2017, the U.S. Senate passed *S. 204, Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017*.

The *21<sup>st</sup> Century Cures Act* (Public Law 114–255), signed into law in December of 2016, represents legislative efforts at the federal level to expand and accelerate patient access to treatment, in addition to promoting innovation in medical products and treatments. With respect to regenerative medicine, the Act amends Section 506 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 356) by requiring expedited review for regenerative medicine therapies, including human cells and tissues, intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition, where there is preliminary clinical evidence indicating that the drug has the potential to address unmet medical needs. There are also ongoing efforts at the federal level to ensure even greater access to treatments that are not subject to FDA approval prior to administration to patients.

Regulation in the regenerative and stem cell therapy arena is continuing to evolve. Human cells, tissues, and cellular or tissue-based products (HCT/Ps) are currently regulated under Sections 351 and 361 of the Public Health Service Act.<sup>24</sup> However, a HCT/P can be regulated solely under Section 361 of the PHS Act if it is:

1. Minimally manipulated,
2. Intended for homologous use only,
3. Not combined with another article, and
4. Either:
  - a. Does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or

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<sup>23</sup>Lancet Commission: Stem Cells and Regenerative Medicine. Published Online October 4, 2017  
[http://dx.doi.org/10.1016/S0140-6736\(17\)31366-1](http://dx.doi.org/10.1016/S0140-6736(17)31366-1)

<sup>24</sup> The Public Health Service Act of 1944 outlines a policy framework for federal and state cooperation in health services and provides for the licensing of biological products.

- b. Has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and is for autologous use, use in a first or second-degree blood relative, or reproductive use.<sup>25</sup>

The difference between an HCT/P that is regulated under both sections of the Public Health Service Act, as opposed to solely under Section 361, is significant for providers of stem cell treatments since the requirements for pre-market authorization of a product are much more stringent under Section 351 and require conducting clinical investigations under an investigational new drug (IND) application and obtaining a biologics license through the FDA, whereas requirements under Section 361 focus only on the prevention of communicable diseases.<sup>26</sup> This represents a lower regulatory threshold for HCT/Ps; their use and transplantation can be considered to fall under the practice of medicine and would, therefore, be regulated by state medical boards.

In regulating this evolving area of medical practice, state medical boards will need to strive to achieve an appropriate balance between respecting the autonomy of patients as they seek viable and reasonable treatment options, and adequately safeguarding them against the risks presented by novel, but often unproven and potentially dangerous, interventions. Results from a 2017 survey of its member boards conducted by the FSMB indicate that a third (n = 17) of the 51 responding boards have investigated complaints against physicians related to regenerative medicine or stem cell therapy, and that eight of those boards have taken disciplinary action against physicians for issues relating to regenerative medicine or stem cell therapy.

In ensuring that physicians offer regenerative and stem cell therapies in a manner that is consistent with safe and responsible practices, state medical boards should ensure that any treatment offered to patients is informed by an appropriate history and physical examination; such informed consent is obtained after an explanation has been provided describing risks, benefits, alternative treatment options, expected convalescence, and expected treatment outcomes; that relevant information about the clinical encounter and ongoing care plans has been documented in the patient's medical record; that the physician is appropriately trained in, and knowledgeable about the proposed treatment; and that the patient has not been coerced in any way into receiving treatment(s) or exploited through the charging of excessive fees.

In order to implement best practices for regenerative and stem cell therapies, physicians must understand the relevant clinical issues and should obtain sufficient targeted continuing education and training.<sup>27</sup>

The recommendations in the final section of this report provide further detail on various requirements that apply to the provision of regenerative and stem cell therapies that state medical boards may wish to consider.

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<sup>25</sup> 21 CFR 1271.10(a)

<sup>26</sup> United States Food and Drug Administration: Regulatory Considerations for Human Cell, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use

<sup>27</sup> Federation of State Medical Boards (2017). *Guidelines for the Chronic Use of Opioid Analgesics*.

## Section Six. Recommendations:

The recommendations that follow address the regulation of the provision of stem cell and regenerative therapies, as well as their promotion and communication to patients, and documentation of treatments provided. The recommendations do not address which uses are appropriate or not for specific conditions or symptoms, as this area of medicine continues to be dynamic and subject to change. Rather, they focus on sensible and necessary principles of patient safety, autonomy, and non-exploitation.

The FSMB recommends that:

1. Where evidence is unavailable for a particular treatment in the form of clinical trials or case studies, physicians must only proceed with an appropriate rationale for the proposed treatment, and justification of its use, in relation to the patient's symptoms or condition. Novel, experimental, and unproven interventions should only be proposed when traditional or accepted proven treatment modalities have been exhausted. In such instances, there must still be a basis in theory or peer-acknowledged practice.<sup>28</sup>
2. State medical boards raise awareness among licensees of applicable federal and state legislation and guidelines regarding regenerative and stem cell therapies, including "right to try" legislation existing or pending at the state and federal levels. State medical boards should also keep their licensees and the public apprised of new developments and regulations in the field of regenerative and stem cell therapies. This may include educational resources, guidance documents, and appropriate industry and stakeholder information on a state medical board's website. State medical boards should further provide information as to reporting procedures of adverse actions related to stem cell interventions.
3. State medical boards should examine their policies and rules addressing informed consent and consider expanding these to include a shared decision making framework that includes the following general elements at a minimum:
  - An explanation, discussion, and comparison of treatment options with the patient
  - An assessment of the patient's values and preferences
  - Arrival at a decision in partnership with the patient
  - An evaluation of the patient's decision in partnership with the patient
4. State medical boards should review professional marketing materials and claims, including any office/clinic and/or doctor websites, and information publicly available about an office/clinic or licensee on online blogs or social media, as information sources in the investigation of complaints made against physicians.
5. State medical boards should pro-actively monitor warning letters sent to licensees that are made publicly available on the FDA website in order to ascertain information, and consider opening an investigation, about licensees who may be engaged in other unscrupulous or

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<sup>28</sup> White, BD, Gelinas, LC, (2016). "Balancing the Surgeon's Responsibility to Individuals and Society," published in S.C. Stain et al. (eds.), *The SAGES Manual Ethics of Surgical Innovation*, Switzerland: Springer International Publishing, 191-211.

unprofessional practices related to the provision of regenerative and stem cell therapy. State medical boards should investigate such practices, when appropriate, in conjunction with applicable state laws, policies, and procedures.<sup>29</sup>

6. Physicians must only offer treatments to patients for which they have a bona fide physician-patient relationship. Physicians must have received adequate and appropriate training, and be able to perform any proposed intervention safely and competently.<sup>30</sup>

7. Physicians should employ a “shared decision making” process when discussing treatment options with patients. Physicians must avoid any claims that may be deceptive or are intentionally or knowingly false or misleading, especially in terms of making promises about uncertain or unrealistic outcomes.

8. Physicians should not use gag orders (rulings that a case must not be discussed publicly) or disclaimers as a way to circumvent liability.

9. Physicians should be prepared to support any claims made about benefits of treatments or devices with documented evidence, for example with studies published in peer-reviewed publications.

10. Physicians should refrain from charging excessive fees for treatments provided. Further, physicians should not recommend, provide, or charge for unnecessary medical services, nor should they make intentional misrepresentations to increase the level of payment they receive.<sup>31</sup>

11. Physicians should consult and educate patients about stem cell interventions and alert them to important resources available to the community. A list of selected resources is provided in **Appendix A**.

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<sup>29</sup> The FDA’s warning letters are available at the following address:

<https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/default.htm>

<sup>30</sup> Federation of State Medical Boards (2014). *Model Policy for the Appropriate Use of Telemedicine Technologies in the Practice of Medicine*.

<sup>31</sup> American Medical Association, *Code of Medical Ethics*, Opinion 11.3.1.

## **WORKGROUP TO STUDY REGENERATIVE AND STEM CELL THERAPY PRACTICES**

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FSMB Director-at-Large  
Past President, Arizona Board of Osteopathic Examiners in Medicine and Surgery

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Former Public Member, Minnesota Board of Medical Practice

Sandra L. Coletta  
Public Member, Rhode Island Board of Medical Licensure and Discipline

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Ronald E. Domen, MD, FACP, FCAP  
Penn State College of Medicine

Zubin Master, PhD  
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Douglas Oliver, MSW  
Patient Appointee  
Founder and Executive Director, Regenerative Outcomes Foundation

Bruce D. White, DO, JD  
Alden March Bioethics Institute

### **EX OFFICIOS**

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Chair, FSMB

Patricia A. King, MD, PhD, FACP  
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Humayun J. Chaudhry, DO, MS, MACP, MACOI  
President and CEO, FSMB

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Jonathan Jagoda, MPP  
Director, Federal Government Relations, FSMB

Mark Staz, MA  
Director, Continuing Professional Development

**APPENDIX A: SAMPLE LIST OF EDUCATIONAL RESOURCES ON REGENERATIVE AND STEM CELL THERAPY PRACTICES**

[The Australian Stem Cell Handbook 2015](#)

[Stem Cell Basics \(National Institutes of Health\)](#)

[Stem Cell Patient booklet \(Albany Medical College\)](#)

[A closer look at Stem Cells \(International Society for Stem Cell Research\)](#)

[Patient Handbook on Stem Cell Therapies \(International Society for Stem Cell Research\)](#)

[Stem Cell Tourism \(California Institute for Regenerative Medicine\)](#)

[The Power of Stem Cells \(California Institute for Regenerative Medicine\)](#)

[SCOPE: Learn About Stem Cells in Your Native Language \(The Niche\)](#)

LAMAR ALEXANDER  
TENNESSEE

## United States Senate

WASHINGTON, DC 20510

April 21, 2017

Gregory B. Snyder, MD, DABR  
Chair-Elect  
Federation of State Medical Boards  
1300 Connecticut Ave NW, Suite 500  
Washington, DC 20036

Dear Dr. Snyder:

Doctors, researchers, and patients have identified regenerative medicine and adult stem cell therapies as potential treatments to heal damaged, diseased, or deteriorated tissues and organs. In recent years, some of that promise has been realized. There are new therapies to treat burn and skin wounds, diabetic ulcers, and damaged knee cartilage, and clinical trials are underway for currently untreatable diseases.<sup>[1]</sup> Doug Oliver, a constituent of mine who was diagnosed with malattia leventinese, a rare form of macular degeneration, participated in a clinical trial that used his own adult bone marrow stem cells to restore his eyesight.<sup>[2]</sup> His remarkable progress is a testament to the potential of these treatments, and one of the reasons it was so important to pass the 21<sup>st</sup> Century Cures Act to provide clarity for regenerative medicine regulated by the Food and Drug Administration.

Unfortunately, recent reports indicate that some patients have been harmed by unproven or investigational treatments received at stem cell clinics. In one evaluation, published in *The New England Journal of Medicine*, three patients developed severe bilateral vision loss as a result of an injection of adult adipose tissue-derived stem cells.<sup>[3]</sup> Other reports find stem clinics advertising their therapies as having the potential to treat diseases like Parkinson's or multiple sclerosis, including in circumstances where little, if any, evidence of their efficacy exists.<sup>[4]</sup> Therefore, I urge your organization to develop best practices for state medical and osteopathic regulatory boards to follow regarding promotion, communication, and practices at stem cell clinics. I also seek information on the following questions:

1. How do state medical boards investigate complaints against stem cell clinics?
2. How are the existing false claims best practices enforced or used by state medical boards?
3. Are there standards or best practices regarding the use and communication of novel technology, such as adult stem cells?

<sup>[1]</sup> <https://report.nih.gov/NIHfactsheets/ViewFactSheet.aspx?csid=62>

<sup>[2]</sup> <http://www.tennessean.com/story/opinion/contributors/2016/06/19/restored-sight-shows-potential-stem-cell-therapy/86042514/>

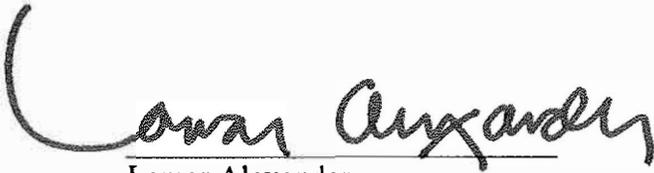
<sup>[3]</sup> <http://www.nejm.org/doi/full/10.1056/NEJMoa1609583>

<sup>[4]</sup> <https://www.nytimes.com/2016/07/28/upshot/stem-cell-therapies-are-still-mostly-theory-yet-clinics-are-flourishing.html>

3. Are there standards or best practices regarding the use and communication of novel technology, such as adult stem cells?
4. Are there standards for education necessary before implementing novel technology, such as adult stem cell procedures?

Thank you.

Sincerely,

A handwritten signature in black ink that reads "Lamar Alexander". The signature is written in a cursive style with a large, sweeping initial "L".

Lamar Alexander  
U.S. Senator

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

**AGENDA REQUEST FORM**

<b>1) Name and Title of Person Submitting the Request:</b>  <b>Dale Kleven</b> <b>Administrative Rules Coordinator</b>		<b>2) Date When Request Submitted:</b>  <b>6/27/18</b>  Items will be considered late if submitted after 12:00 p.m. on the deadline date: ▪ 8 business days before the meeting	
<b>3) Name of Board, Committee, Council, Sections:</b>  <b>Medical Examining Board</b>			
<b>4) Meeting Date:</b>  7/11/18	<b>5) Attachments:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	<b>6) How should the item be titled on the agenda page?</b> <b>Legislative/Administrative Rule Matters:</b> 1. Review of Draft Report on Opioid Abuse and the Wisconsin Medical Examining Board Opioid Prescribing Guideline 2. Review of Draft Emergency and Proposed Permanent Rules for Med 25 Relating to Sports Physician Licensure Exemption 3. Review of Proposed Changes to AT 1 to 4 Relating to Practice of Athletic Trainers 4. Update on Other Legislation and Pending or Possible Rulemaking Projects	
<b>7) Place Item in:</b> <input checked="" type="checkbox"/> Open Session <input type="checkbox"/> Closed Session <input type="checkbox"/> Both	<b>8) Is an appearance before the Board being scheduled?</b>  <input type="checkbox"/> Yes ( <a href="#">Fill out Board Appearance Request</a> ) <input checked="" type="checkbox"/> No	<b>9) Name of Case Advisor(s), if required:</b>	
<b>10) Describe the issue and action that should be addressed:</b>  3. Under s. 15.085 (5), Stats., the Athletic Trainers Affiliated Credentialing Board is required to submit a proposed rule to the Medical Examining Board for comment at least 60 days before the proposed rule is submitted to the Legislative Clearinghouse. Any comments on the proposed rule must be considered by the Athletic Trainers Affiliated Credentialing Board and included in the report on the proposed rule submitted to the Legislature.			
<b>11)</b> <i>Dale Kleven</i>		Authorization  <i>June 27, 2018</i>	
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	
<b>Directions for including supporting documents:</b> 1. This form should be attached to any documents submitted to the agenda. 2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director. 3. If necessary, Provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.			

**Kenneth Simons**  
Chairperson

**WISCONSIN MEDICAL EXAMINING BOARD**

1400 E Washington Ave  
PO Box 8366  
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**Timothy Westlake**  
Vice Chairperson



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**Mary Jo Capodice**  
Secretary

**Wisconsin Medical Examining Board Report on Opioid Abuse – October 2018**

**Scope and purpose of the report:** 2017 Wisconsin Act 262 requires the Medical Examining Board to annually submit a report related to opioid abuse to the Legislature and Governor’s Office. This preliminary report must include proactive efforts taken by the Board to address the issue of opioid abuse and goals for addressing the issue of opioid abuse as it relates to the practice of medicine and surgery in Wisconsin. Future reports must also include actions taken by the Board to achieve the goals identified in previous reports, and whether those goals have been achieved.

**Proactive efforts taken by the Board to address the issue of opioid abuse:**

**Statewide Outreach**

As vice chair of the Medical Examining Board and a member of the Controlled Substances Board and Governor’s Task Force on Opioid Abuse, Dr. Timothy Westlake has worked with the Governor’s Office, the Legislature, the Wisconsin Medical Society, the state’s two medical schools, and hospital and clinic systems to ensure the Board is an effective partner in statewide efforts to enhance the physician workforce’s knowledge concerning the appropriate use and best prescriptive practices with opioids.

Doctor Westlake also was instrumental in Wisconsin’s passage of [Act 60](#) this legislative session—the new law allows law enforcement to pursue cases involving a fentanyl analog not yet specifically included in the state’s controlled substances act.

**National Outreach and Leadership**

In May 2018, Dr. Westlake highlighted in testimony before the U.S. House Judiciary Committee the extreme dangers of illegal fentanyl use and urged the federal government to use as an example a Wisconsin law that could help federal law enforcement better prosecute drug crimes involving fentanyl analogues.

Doctor Kenneth Simons, Chair of the Medical Examining Board, serves on the Board of Directors for the Federation of State Medical Boards (FSMB). During his term, the FSMB has undertaken several initiatives related to opioid abuse, including adoption of the Guidelines for the Chronic Use of Opioid Analgesics and publication of several articles in the Journal of Medical Regulation.

**Opioid Prescribing Guideline**

In July 2016, the Board issued its Opioid Prescribing Guideline. The Guideline, which encourages providers to implement best practices for responsible prescribing, was developed using the Centers for Disease Control and Prevention’s Guideline for Prescribing Opioids for Chronic Pain and the Wisconsin Department of Workforce Development’s Chronic Opioid Clinical Management Guidelines for Wisconsin Worker’s Compensation Patient Care as primary resources. The Board has continually monitored and periodically updated the Guideline, most recently in April of 2018.

### **Continuing Education Related to Prescribing Controlled Substances**

The Board revised its administrative rules to require both MD and DO physicians to take two of the required 30 hours of continuing medical education via an approved course on the Board's Opioid Prescribing Guideline. Physicians who do not hold a U.S. Drug Enforcement Administration number to prescribe controlled substances are exempted from the requirement. The requirement first applied to renewals in 2017 and 2018 and will sunset with the renewal on November 1, 2019.

### **Goals for addressing the issue of opioid abuse as it relates to the practice of medicine and surgery in Wisconsin:**

#### **Continuing Education Related to Prescribing Controlled Substances**

As the current requirement for continuing medical education related to the Opioid Prescribing Guideline expires after the current biennium, the Board has started the process for a rule revision that would define future requirements for the completion of continuing medical education related to prescribing controlled substances. The Board's goal is to have the rules in place at the beginning of the 2019-2021 biennium.

#### **Enforcement Action**

Currently, if an investigation of a physician's prescriptive practices occurs, it is done in response to a complaint filed against the physician. The Board's goal is to, in partnership with the Controlled Substances Board, begin proactively investigating physicians whose prescriptive practices with controlled substances may be inconsistent with the standard of minimally competent medical practice. The Controlled Substances Board will use reports generated from the Prescription Drug Monitoring Program to refer physicians to the Board for possible investigation.

#### **Opioid Prescribing Guideline**

The Board will continue to monitor the Guideline and make updates as needed to keep it current and relevant to physicians and their patients.

#### **Continued Outreach and Leadership**

It is the Board's goal to continue its active participation in the statewide and national efforts to combat opioid abuse.

**Kenneth Simons**  
Chairperson

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**Mary Jo Capodice**  
Secretary

**Wisconsin Medical Examining Board Opioid Prescribing Guideline – April 19, 2018**

**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.

**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.

**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.

**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 re-uptake 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 strongly discouraged in patients taking benzodiazepines or other respiratory depressants. Benzodiazepines triple the already high increases in respiratory depression and 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, chronic obstructive pulmonary disease (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, attention deficit disorders (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.** Violations of the opioid agreement.
    - iv.** Periodic pill counts may also be considered for high risk patients.

- 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. It is also recommended practitioners discuss with patients the effect opioid use may have on the ability to safely operate machinery or a vehicle in any mode of transportation.
  - 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, when possible, should assist the patient in obtaining addiction treatment, either by providing it directly (buprenorphine, naltrexone, etc. plus behavioral therapy) or referring them to an appropriate treatment center or provider willing to accept the patient. Discharging a patient from the provider's practice solely due to an 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.
  - i.** Opioid weaning can be performed by reducing the MED by 10% weekly until 5-10 mg MED remain at which time the opioid can be fully discontinued.
  - ii.** Prescription of clonidine 0.2 mg po BID or tizanidine 2 mg 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.
  - i.** Opioid weaning can be performed by reducing the MED by 25% weekly until 5-10 mg MED remain at which time the opioid can be fully discontinued.
  - ii.** Prescription of clonidine 0.2 mg po BID or tizanidine 2 mg po TID can be provided to patients complaining of opioid withdrawal related symptoms.
  - iii.** 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.

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.

**23.** Current HIPAA Guidance for the Sharing of Protected Health Information with a Patient's Family Members and Loved Ones Irrespective of Patient Wishes.

[Interpretive guidance](#) from the US Department of Health and Human Services Office of Civil Rights, indicates that HIPAA regulations allow health professionals to share health information with a patient's loved ones in emergency or dangerous situations such as opioid overdose. HIPAA allows health care professionals to disclose some health information without a patient's permission under certain circumstances, including: in cases where the patient is incapacitated or unconscious, or where a serious and imminent threat to a patient's health or safety exists. For example, a doctor whose patient has overdosed on opioids is presumed to have complied with HIPAA if the doctor informs family, friends, or caregivers of the opioid abuse after determining, based on the facts and circumstances, that the patient poses a serious and imminent threat to his or her health through continued opioid abuse upon discharge.

## 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/>

The Wisconsin prescription guidelines appropriately address the dangers of opioid and the concurrent use of medications IE benzodiazepines. The guidelines also define the upper limits of opioid dosing that will keep many patients safe from opioid addiction. However, these guidelines do not discuss tapering of opioids or provide guidance on alternatives to controlling the patients' pain.

Further, while it is recognized that opioids can lead to hyperalgesia, overdose and deaths, the strategies to recognize the risk patients to avert these unintended sequela are not explored.

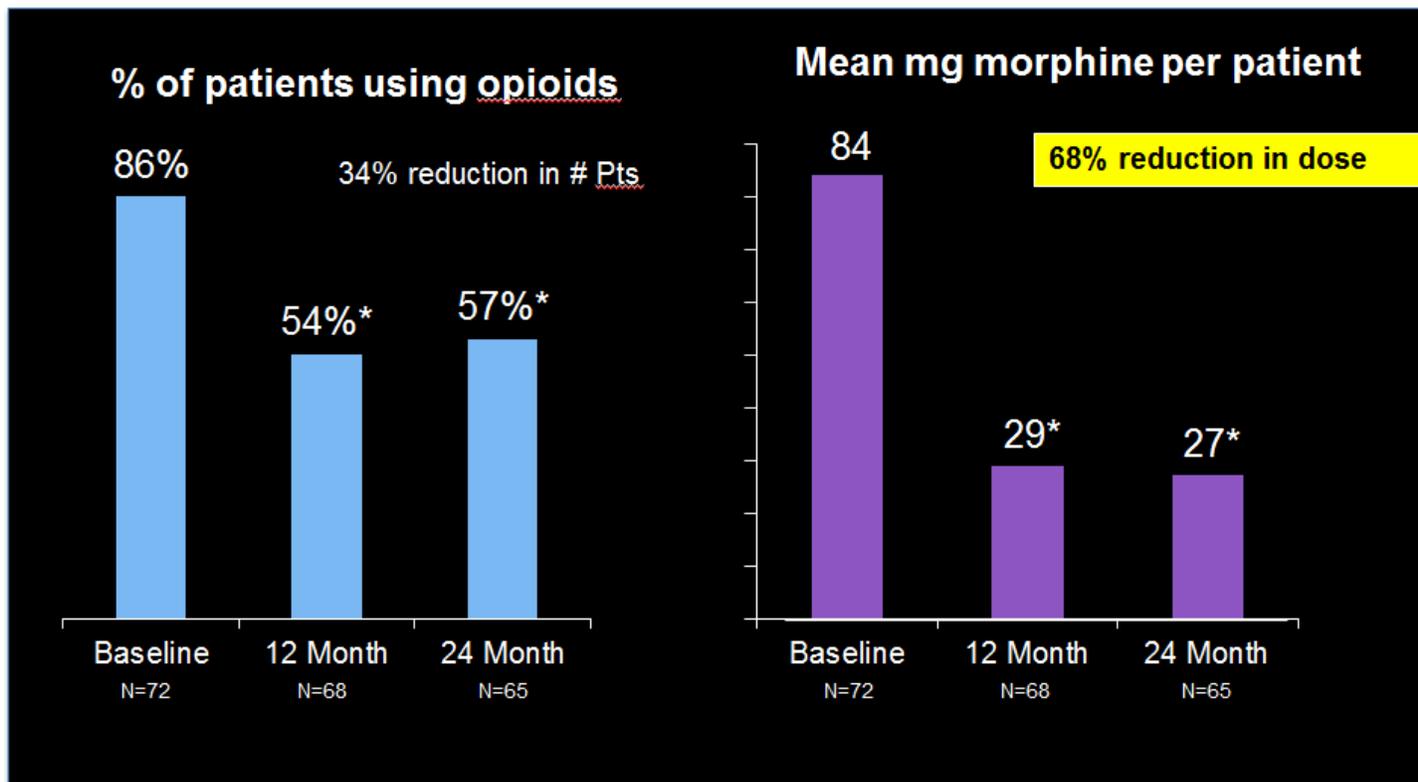
In June 2018, at the Midwest Society of Interventional Pain Physicians meeting in Chicago IL, a Wisconsin Boarded physician, Dr. Nilesh Patel delivered an excellent lecture which categorized modalities for the management of chronic pain. He used the data from multiple sources including Finnerup et al (Lancet), Cochrane collaborative data base, as well as the US Agency for Health Care which categorized *relative effectiveness* of various modalities. Patel used a scale that demonstrated how many patients have to be treated in order that the treatment be effective in at least one patient. He specifically dissected the data on the various therapeutic options advocated by the MEB and CDC to decrease the use of opiates. For example, one has to treat at least 6 patients with Duloxetine and 7 patients with Gabapentin or Pregabalin to have one patient respond at least 50%. The high numbers needed to treat (NNT) are obviously the reasons why patients discontinue these medications. Dr. Patel reviewed the literature and found that the data is sparse for modalities that are commonly included in a treatment program IE non-opiate medications, physical therapy,

acupuncture, and cognitive behavioral therapy. Also the Agency for Health Care showed that there was a moderate response to physical treatments for low back pain. Of even greater concern, per US government reviews, many complimentary therapies, or non-medical treatments have not gone through vigorous scientific testing to determine efficacy, yet these are advocated widely in various guidelines IE Cochrane.

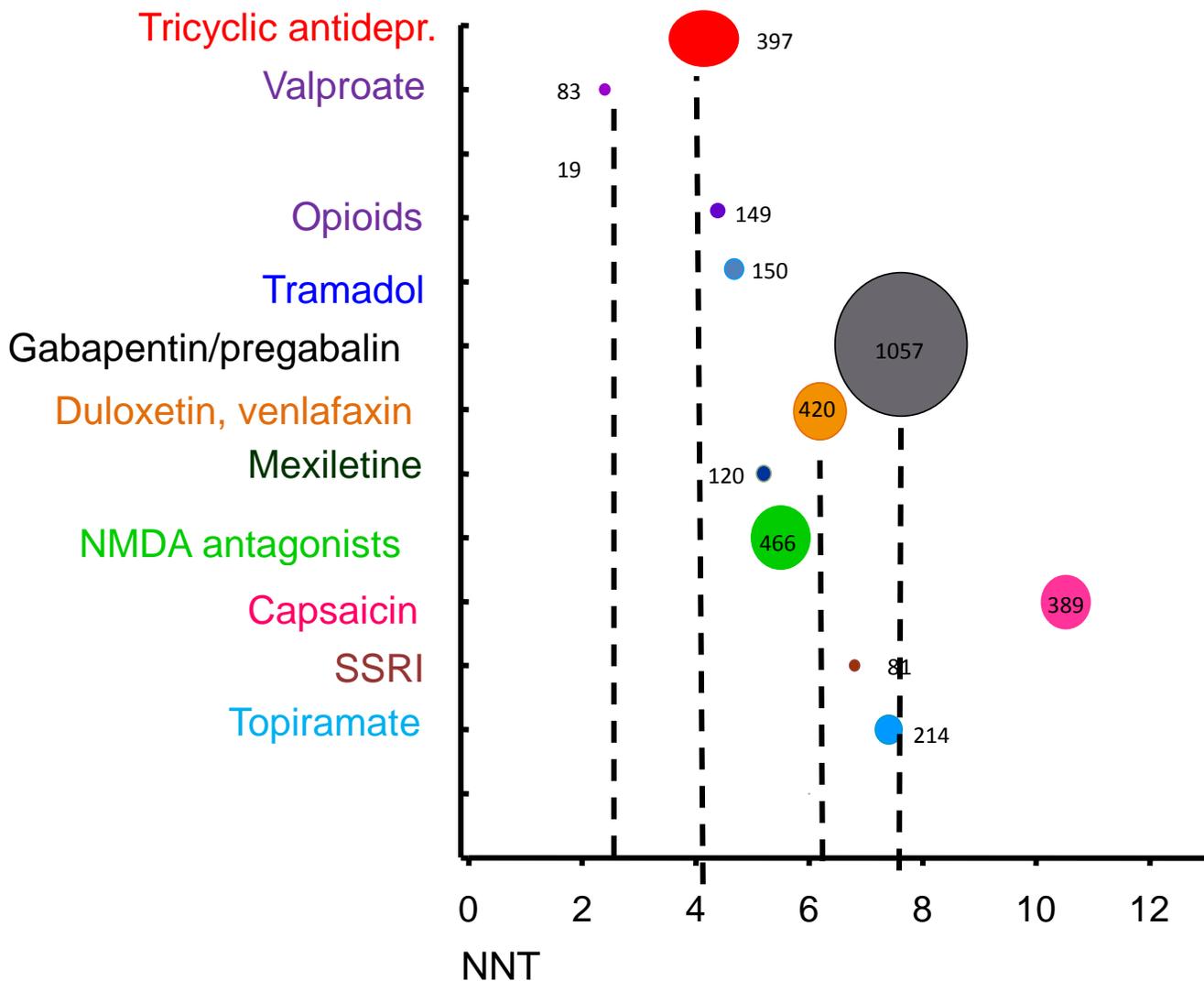
For instance, a patient with disc herniation's may not find relief with non- opiate medication, physical and cognitive therapy, but will respond to epidural steroids, particularly if the goal is to provide pain relief, improving function, decreasing costs and avoiding surgery. The NNT of transforaminal epidurals for radiculopathy is 4 for a minimum 50% relief of pain and the NNT of transformational epidurals is 3 for avoidance of surgery in the patient with lumbar disc herniation. The prospective multicenter US and European trials data, for the patient with previous back surgery also demonstrate a consistent reduction in opiate use and in many cases complete discontinuation of opiates while increasing function and decreasing pain scores at 2 and three years follow up.

In sum, when advocating, treatments we should include effective and opioid sparing modalities. Interventional approaches including transforaminal epidurals and spinal cord stimulation are effective an opioid sparing. More work has to be done regarding cost effectiveness.

## Multicenter HF Spinal Stimulation Decreased Opioid Use from 84mg to 27mg



(At two year follow up, there was improvement in pain, function and a decrease in morphine equivalent daily dose to below the MEB and CDC guidance of 50 MEDD **Al-Kaisey et al Pain Medicine 2014**; In a follow up 36 month cohort, the same authors demonstrated that 92% started on opiates but 36 months after implantation, only 12% patients needed any opiate. *Al Kaisey A et al. Pain Medicine 2017*)



NNT  
 (The lower the NNT the more effective the therapy. Finnerup et al. Lancet 2015)

STATE OF WISCONSIN  
MEDICAL EXAMINING BOARD

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

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The statement of scope for this rule, SS 063-18, was approved by the Governor on May 18, 2018, published in Register 749B on May 29, 2018, and approved by the Medical Examining Board on June 8, 2018.

This emergency rule was approved by the Governor on (date)

ORDER

An order of the Medical Examining Board to create ch. Med 25, relating to sports physician licensure exemption.

Analysis prepared by the Department of Safety and Professional Services.

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FINDING OF EMERGENCY

The Legislature by SECTION 5g of 2017 Wisconsin Act 341 provides an exemption from providing evidence that promulgating this rule as an emergency rule is necessary for the preservation of the public peace, health, safety, or welfare and an exemption from a finding of emergency for the promulgation of this rule.

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ANALYSIS

**Statutes interpreted:**

Section 448.03 (2m), Stats.

**Statutory authority:**

Sections 15.08 (5) (b) and 448.03 (2m) (e), Stats.

**Explanation of agency authority:**

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

Section 448.03 (2m) (e), Stats., requires the Medical Examining Board promulgate rules to implement the sports physician licensure exemption under s. 448.03 (2m), Stats.

**Related statute or rule:**

None.

**Plain language analysis:**

The proposed rules create ch. Med 25 to implement the sports physician licensure exemption under s. 448.03 (2m), Stats., as created by 2017 Wisconsin Act 341. Specifically, s. Med 25.03 (2) provides the requirements for requesting the extension the Board may grant under s. 448.03 (2m) (c) 1. b., Stats. The remainder of the chapter provides physicians and others with clear and concise guidance concerning the exemption's conditions and limitations.

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

None.

**Comparison with rules in adjacent states:****Illinois:**

Illinois statutes and rules do not provide a licensure exemption for sports medicine physicians practicing medicine and surgery on a limited or short-term basis at sporting events or facilities.

**Iowa:**

Rules of the Iowa Board of Medicine provide a licensure exemption for physicians and surgeons from out of state who hold a current, active license in good standing in another United States jurisdiction and who accompany one or more individuals into Iowa for the purpose of providing medical care to the individuals on a short-term basis (653 IAC 9.2 (2) f.).

**Michigan:**

Michigan statutes provide a licensure exemption for individuals authorized to practice a health profession in another state or territory of the United States who are appointed by the United States Olympic Committee to provide health services exclusively to team personnel and athletes at a training site or event [MCL 333.16171 (i)]. The exemption applies to the individual while performing the duties assigned in the course of the sanctioned training program or event and for the time period specified by the United States Olympic Committee.

An exemption is also provided for individuals currently authorized to practice a health profession in another state and providing health services for an athletic team [MCL 333.16171 (j)]. The exemption is subject to the following conditions:

- The individual may provide only those health services permitted if the individual were licensed to practice in Michigan.
- The athletic team must be from the same state that authorized the individual to practice the health profession.
- The individual must provide health services under the terms of a written agreement with the athletic team.

- The individual may only provide health services while the athletic team is traveling to or from or participating in a sporting event in Michigan.
- Health services may only be provided to a member of the athletic team; a member of the athletic team's coaching, communications, equipment, or sports medicine staff; a member of a band or cheerleading squad that is accompanying the athletic team; or the athletic team's mascot.
- The individual may not provide health services at a health care facility or agency located in Michigan.

**Minnesota:**

Minnesota statutes and rules do not provide a licensure exemption for sports medicine physicians practicing medicine and surgery on a limited or short-term basis at sporting events or facilities.

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

The rules were developed by reviewing the provisions of 2017 Wisconsin Act 341 and obtaining input and feedback from the Medical Examining Board.

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

The rules do not have an effect on small business beyond any effect associated with the legislation creating the sports physician licensure exemption (2017 Wisconsin Act 341).

**Fiscal estimate:**

[To be determined]

**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 [Kirsten.Reader@wisconsin.gov](mailto:Kirsten.Reader@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, P.O. Box 8366, Madison, Wisconsin 53708-8366; telephone 608-261-4472; email at [DSPSAdminRules@wisconsin.gov](mailto:DSPSAdminRules@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, P.O. Box 8366, Madison, Wisconsin 53708-8366, or by email to [DSPSAdminRules@wisconsin.gov](mailto:DSPSAdminRules@wisconsin.gov). Comments must be submitted by the date and time at which the public hearing on these rules is conducted. Information as to the place, date, and time of the public hearing will be published on the Legislative Reference Bureau's website and in the Wisconsin Administrative Register.

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TEXT OF RULE

SECTION 1. Chapter Med 25 is created to read:

CHAPTER MED 25

SPORTS PHYSICIAN LICENSURE EXEMPTION

**Med 25.01 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) (b) and 448.03 (2m) (e), Stats., and implement the sports physician licensure exemption under s. 448.03 (2m), Stats.

**Med 25.02 Exemption.** Subject to s. 448.03 (2m), Stats., and ss. Med 25.03 and 25.04, a physician who is licensed in good standing to practice medicine and surgery in another state may practice medicine and surgery in this state without a license granted by the board if the physician has one of the following:

(1) A written agreement with a sports team to provide care to team members and coaching staff traveling with the team for a specific sporting event to take place in this state.

(2) An invitation from a national sport governing body to provide services to team members and coaching staff at a national sport training center in this state or to provide services to athletes and coaching staff at an event or competition in this state that is sanctioned by the national sport governing body.

**Med 25.03 Expiration and extension of an exemption. (1)** An exemption under s. Med 25.02 (1) is valid only while the physician is traveling with the sports team, and, except as provided under sub. (2), is subject to a limit of 10 days.

(2) The board may extend an exemption under s. Med 25.02 (1) for up to 20 days. As provided under s. 448.03 (2m) (c) 1. b., Stats., the total extensions granted a physician under this subsection may not exceed 30 days in a given calendar year. A request for extension shall be submitted to the board at least 10 days prior to the expiration date under sub. (1), and include all the following:

(a) A completed application on a form provided by the board.

(b) A verified copy of the written agreement between the applicant and the sports team under s. 448.03 (2m) (a) 1., Stats.

(c) A verified copy of a license to practice medicine and surgery in another state issued to the applicant and verified documentary evidence of the applicant's current eligibility to practice under that license in that state.

**Note:** An application for extension may be obtained from the Department of Safety and Professional Services at (608) 261-2112 or from the Department's website at <http://dsps.wi.gov>.

(3) An exemption under s. Med 25.02 (2) is valid during the time certified by the national sport governing body, subject to a limit of 30 days.

**Med 25.04 Practice limitations.** As provided under s. 448.03 (2m) (b), Stats., a physician may not do any of the following while practicing under s. Med 25.02:

(1) Provide care or consultation to any person residing in this state, other than an athlete, team member, or member of a coaching staff specified under s. Med 25.02 (1) and (2).

(2) Practice at a health care facility, as defined in s. 146.997 (1) (c), Stats., or a clinic, as defined in s. 146.903 (1) (b), Stats.

(3) Prescribe drugs.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on November 1, 2018, pursuant to s. 227.24 (1) (c), Stats.

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(END OF TEXT OF RULE)

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STATE OF WISCONSIN  
MEDICAL EXAMINING BOARD

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

---

PROPOSED ORDER

An order of the Medical Examining Board to create ch. Med 25, relating to sports physician licensure exemption.

Analysis prepared by the Department of Safety and Professional Services.

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ANALYSIS

**Statutes interpreted:**

Section 448.03 (2m), Stats.

**Statutory authority:**

Sections 15.08 (5) (b) and 448.03 (2m) (e), Stats.

**Explanation of agency authority:**

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

Section 448.03 (2m) (e), Stats., requires the Medical Examining Board promulgate rules to implement the sports physician licensure exemption under s. 448.03 (2m), Stats.

**Related statute or rule:**

None.

**Plain language analysis:**

The proposed rules create ch. Med 25 to implement the sports physician licensure exemption under s. 448.03 (2m), Stats., as created by 2017 Wisconsin Act 341. Specifically, s. Med 25.03 (2) provides the requirements for requesting the extension the Board may grant under s. 448.03 (2m) (c) 1. b., Stats. The remainder of the chapter provides physicians and others with clear and concise guidance concerning the exemption’s conditions and limitations.

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

None.

## **Comparison with rules in adjacent states:**

### **Illinois:**

Illinois statutes and rules do not provide a licensure exemption for sports medicine physicians practicing medicine and surgery on a limited or short-term basis at sporting events or facilities.

### **Iowa:**

Rules of the Iowa Board of Medicine provide a licensure exemption for physicians and surgeons from out of state who hold a current, active license in good standing in another United States jurisdiction and who accompany one or more individuals into Iowa for the purpose of providing medical care to the individuals on a short-term basis (653 IAC 9.2 (2) f.).

### **Michigan:**

Michigan statutes provide a licensure exemption for individuals authorized to practice a health profession in another state or territory of the United States who are appointed by the United States Olympic Committee to provide health services exclusively to team personnel and athletes at a training site or event [MCL 333.16171 (i)]. The exemption applies to the individual while performing the duties assigned in the course of the sanctioned training program or event and for the time period specified by the United States Olympic Committee.

An exemption is also provided for individuals currently authorized to practice a health profession in another state and providing health services for an athletic team [MCL 333.16171 (j)]. The exemption is subject to the following conditions:

- The individual may provide only those health services permitted if the individual were licensed to practice in Michigan.
- The athletic team must be from the same state that authorized the individual to practice the health profession.
- The individual must provide health services under the terms of a written agreement with the athletic team.
- The individual may only provide health services while the athletic team is traveling to or from or participating in a sporting event in Michigan.
- Health services may only be provided to a member of the athletic team; a member of the athletic team's coaching, communications, equipment, or sports medicine staff; a member of a band or cheerleading squad that is accompanying the athletic team; or the athletic team's mascot.
- The individual may not provide health services at a health care facility or agency located in Michigan.

**Minnesota:**

Minnesota statutes and rules do not provide a licensure exemption for sports medicine physicians practicing medicine and surgery on a limited or short-term basis at sporting events or facilities.

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

The proposed rules were developed by reviewing the provisions of 2017 Wisconsin Act 341 and obtaining input and feedback from the Medical Examining Board.

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

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

**Effect on small business:**

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department’s Regulatory Review Coordinator may be contacted by email at Kirsten.Reader@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, P.O. Box 8366, Madison, Wisconsin 53708-8366; telephone 608-261-4472; email at DSPSAdminRules@wisconsin.gov.

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TEXT OF RULE

SECTION 1. Chapter Med 25 is created to read:

CHAPTER MED 25

SPORTS PHYSICIAN LICENSURE EXEMPTION

**Med 25.01 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) (b) and 448.03 (2m) (e), Stats., and implement the sports physician licensure exemption under s. 448.03 (2m), Stats.

**Med 25.02 Exemption.** Subject to s. 448.03 (2m), Stats., and ss. Med 25.03 and 25.04, a physician who is licensed in good standing to practice medicine and surgery in another state may practice medicine and surgery in this state without a license granted by the board if the physician has one of the following:

- (1) A written agreement with a sports team to provide care to team members and coaching staff traveling with the team for a specific sporting event to take place in this state.

(2) An invitation from a national sport governing body to provide services to team members and coaching staff at a national sport training center in this state or to provide services to athletes and coaching staff at an event or competition in this state that is sanctioned by the national sport governing body.

**Med 25.03 Expiration and extension of an exemption.** (1) An exemption under s. Med 25.02 (1) is valid only while the physician is traveling with the sports team, and, except as provided under sub. (2), is subject to a limit of 10 days.

(2) The board may extend an exemption under s. Med 25.02 (1) for up to 20 days. As provided under s. 448.03 (2m) (c) 1. b., Stats., the total extensions granted a physician under this subsection may not exceed 30 days in a given calendar year. A request for extension shall be submitted to the board at least 10 days prior to the expiration date under sub. (1), and include all the following:

(a) A completed application on a form provided by the board.

(b) A verified copy of the written agreement between the applicant and the sports team under s. 448.03 (2m) (a) 1., Stats.

(c) A verified copy of a license to practice medicine and surgery in another state issued to the applicant and verified documentary evidence of the applicant's current eligibility to practice under that license in that state.

**Note:** An application for extension may be obtained from the Department of Safety and Professional Services at (608) 261-2112 or from the Department's website at <http://dsps.wi.gov>.

(3) An exemption under s. Med 25.02 (2) is valid during the time certified by the national sport governing body, subject to a limit of 30 days.

**Med 25.04 Practice limitations.** As provided under s. 448.03 (2m) (b), Stats., a physician may not do any of the following while practicing under s. Med 25.02:

(1) Provide care or consultation to any person residing in this state, other than an athlete, team member, or member of a coaching staff specified under s. Med 25.02 (1) and (2).

(2) Practice at a health care facility, as defined in s. 146.997 (1) (c), Stats., or a clinic, as defined in s. 146.903 (1) (b), Stats.

(3) Prescribe drugs.

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.

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(END OF TEXT OF RULE)

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STATE OF WISCONSIN  
ATHLETIC TRAINERS AFFILIATED CREDENTIALING BOARD

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IN THE MATTER OF RULEMAKING : PROPOSED ORDER OF THE  
PROCEEDINGS BEFORE THE : ATHLETIC TRAINERS AFFILIATED  
ATHLETIC TRAINERS AFFILIATED : CREDENTIALING BOARD  
CREDENTIALING BOARD : ADOPTING RULES  
: (CLEARINGHOUSE RULE )

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PROPOSED ORDER

An order of the Athletic Trainers Affiliated Credentialing Board to repeal AT 2.02 (2) (Note), 2.03, 2.04, 2.05, 4.01 (Note), and 4.02 (1); to renumber and amend AT 1.02 (1); to amend AT 1.02 (5), 1.05, 2.02 (2), 3.01, 3.03, 3.05, and 4.01 (1) (intro.), (2) (intro.), (3) (intro.), (4) (intro.), and (5); and to create AT 1.02 (1g) and (5m), relating to practice of athletic trainers.

Analysis prepared by the Department of Safety and Professional Services.

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ANALYSIS

**Statutes interpreted:**

None.

**Statutory authority:**

Sections 15.085 (5) (b) and 448.9525 (2), Stats.

**Explanation of agency authority:**

Section 15.085 (5) (b), Stats., provides an affiliated credentialing board “[s]hall promulgate rules for its own guidance and for the guidance of the trade or profession to which it pertains. . .”

Section 448.9525 (2), Stats., provides that, subject to s. 448.956 (1), (4), and (5), Stats., the Athletic Trainers Affiliated Credentialing Board and the Medical Examining Board shall jointly promulgate rules relating to the minimum requirements of a protocol required under s. 448.956 (1), Stats.

**Related statute or rule:**

None.

**Plain language analysis:**

The proposed rules make the following changes to provide clarity and reflect the provisions of 2009 Wisconsin Act 162 and 2017 Wisconsin Act 59, which made various changes to the practice of athletic trainers and the duties and powers of the Athletic Trainers Affiliated Credentialing Board:

- Chapter AT 1:

- The definitions of “NATABOC” and “board” are revised and the definitions of “athletic training” and “physical activity” are created based on the respective statutory definitions.
- Section AT 1.05 is revised to specify the Board may accept the results of a credentialing examination administered by a successor agency of the National Athletic Trainers’ Association Board of Certification, Inc. (NATABOC)
- Chapter AT 2:
  - Section AT 2.02 (2) is revised to specify a successor agency of NATABOC may provide required certifications.
  - References to application for and renewal of temporary licenses are removed by repealing ss. AT 2.03, 2.04, and 2.05. 2009 Wisconsin Act 162 eliminated the Board’s authority to issue temporary licenses.
- Chapter AT 3:
  - Sections AT 3.01 and 3.03 are revised to specify a successor agency of NATABOC may provide required approvals and certifications.
  - Sections AT 3.03 and 3.05 are revised to reflect s. 440.035 (2), Stats., as created by 2017 Wisconsin Act 59, concerning the Board’s authority to require a credential holder to submit proof of completion of continuing education programs or courses.
- Chapter AT 4:
  - 2009 Wisconsin Act 162 replaced the term “athletic injury” with “injury or illness sustained while participating in physical activity.” Sections AT 4.01 (1) (intro.), (2) (intro.), (3) (intro.), and (4) (intro.) are revised to reflect this change in terminology.
  - A note in s. AT 4.01 that includes substantive requirements for referrals is repealed. Requirements for referrals are specified in s. 448.956 (1m), Stats., as created by 2009 Wisconsin Act 162.
  - Section AT 4.02 (1), which provides a protocol must require an athletic trainer to notify the consulting physician as soon as possible if a person being treated sustains new injuries, is repealed. 2009 Wisconsin Act 162 eliminated this protocol requirement.

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

None.

**Comparison with rules in adjacent states:**

**Illinois:**

Rules of the Illinois Department of Financial and Professional Regulation establish requirements for licensure as an athletic trainer in Illinois and the approval of athletic training programs (68 Ill. Adm. Code 1160.20 to 1160.80).

**Iowa:**

Rules of the Iowa Board of Athletic Training establish requirements for licensure as an athletic trainer in Iowa (645 IAC 351.1 to 353.5).

**Michigan:**

Rules of the Michigan Department of Licensing and Regulatory Affairs establish requirements for licensure as an athletic trainer in Michigan, a plan of care for certain athletic training services, and delegation of acts related to the practice of athletic training (Mich Admin Code, R 338.1301 to R 338.1377).

**Minnesota:**

The Minnesota Statutes, sections 148.7801 to 148.7815, establish requirements for licensure as an athletic trainer in Minnesota and define the scope of athletic training.

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

The proposed rules were developed by reviewing the provisions of 2009 Wisconsin Act 162 and 2017 Wisconsin Act 59 in conjunction with current rules relating to athletic trainers under chs. AT 1 to 4 and obtaining input and feedback from the Athletic Trainers Affiliated Credentialing Board.

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

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

**Effect on small business:**

These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department’s Regulatory Review Coordinator may be contacted by email at Kirsten.Reader@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, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-261-4472; email at DSPSAdminRules@wisconsin.gov.

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TEXT OF RULE

SECTION 1. AT 1.02 (1) is renumbered AT 1.02 (1r) and amended to read:

**AT 1.02 (1r)** “Board” means the athletic trainers affiliated credentialing board.

SECTION 2. AT 1.02 (1g) is created to read:

**AT 1.02 (1g)** “Athletic training” has the meaning given in s. 448.95 (5), Stats.

SECTION 3. AT 1.02 (5) is amended to read:

**AT 1.02 (5)** “NATABOC” means the ~~national athletic trainers association board of certification~~ National Athletic Trainers’ Association Board of Certification, Inc.

SECTION 4. AT 1.02 (5m) is created to read:

**AT 1.02 (5m)** "Physical activity" has the meaning given in s. 448.95 (7), Stats.

SECTION 5. AT 1.05 is amended to read:

**AT 1.05 Required examinations.** For purposes of satisfying the ~~examination requirement~~ requirements of ss. 448.953 (1) (f) and (h) and 448.954, Stats., the board accepts the results of a credentialing examination administered by ~~the~~ NATABOC or its successor agency.

SECTION 6. AT 2.02 (2) is amended to read:

**AT 2.02 (2)** ~~Unless applying for a temporary license under s. 448.953 (4) (a), Stats., official certification~~ Verification attested to and submitted directly to the board by NATABOC or its successor agency that the applicant has met ~~the~~ all requirements for certification ~~of the~~ NATABOC ~~and has passed the certification examination administered by the~~ NATABOC.

SECTION 7. AT 2.02 (2) (Note) is repealed.

SECTION 8. AT 2.03, 2.04, and 2.05 are repealed.

SECTION 9. AT 3.01 is amended to read:

**AT 3.01 Approved courses of study.** For purposes of satisfying the ~~continuing education requirement~~ requirements of s. 448.9545, Stats., ~~the board shall approve~~ a course of study ~~approved by the board is a course~~ that has been approved for continuing education credit by NATABOC or its successor agency.

SECTION 10. AT 3.03 is amended to read:

**AT 3.03 Evidence of compliance.** ~~For the renewal of any license granted under subch. VI of ch. 448, Stats., the~~ The board will shall accept as evidence of compliance with this chapter certification by ~~the~~ NATABOC or its successor agency that the licensee has attended and completed continuing education programs approved under ~~the provisions of~~ s. AT 3.01.

SECTION 11. AT 3.05 is amended to read:

**AT 3.05 Audit.** The board ~~may require~~ shall audit any licensee ~~to submit his or her evidence of~~ who is under investigation by the board for alleged misconduct for compliance with the continuing education requirements ~~to audit compliance~~.

SECTION 12. AT 4.01 (1) (intro.), (2) (intro.), (3) (intro.), (4) (intro.), and (5) are amended to read:

**AT 4.01 (1) (intro.)** ~~Authorization for taking~~ Taking a basic medical history when necessary for evaluation and treatment of an athletic injury or illness sustained while participating in physical activity. ~~that~~ A basic medical history may include any of the following:

**(2) (intro.)** ~~Authorization to evaluate the athletic~~ Evaluating an injury utilizing or illness sustained while participating in physical activity. An evaluation may include any of the following procedures:

~~(3) (intro.) Authorization to utilize treatment procedures to treat~~ Treating an athletic injury including or illness sustained while participating in physical activity. Treatment may include any of the following procedures:

~~(4) (intro.) Authorization to utilize rehabilitation procedures to rehabilitate~~ Rehabilitating an athletic injury including or illness sustained while participating in physical activity. Rehabilitation may include any of the following procedures:

(5) ~~Authorization to administer~~ Administering specifically enumerated drugs.

SECTION 13. AT 4.01 (Note) is repealed.

SECTION 14. AT 4.02 (1) is repealed.

SECTION 15. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

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(END OF TEXT OF RULE)

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## ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

<b>1. Type of Estimate and Analysis</b> <input checked="" type="checkbox"/> Original <input type="checkbox"/> Updated <input type="checkbox"/> Corrected	<b>2. Date</b> June 7, 2018
<b>3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)</b> AT 1 to 4	
<b>4. Subject</b> Practice of athletic trainers	
<b>5. Fund Sources Affected</b> <input type="checkbox"/> GPR <input type="checkbox"/> FED <input type="checkbox"/> PRO <input type="checkbox"/> PRS <input type="checkbox"/> SEG <input type="checkbox"/> SEG-S	<b>6. Chapter 20, Stats. Appropriations Affected</b>
<b>7. Fiscal Effect of Implementing the Rule</b> <input checked="" type="checkbox"/> No Fiscal Effect <input type="checkbox"/> Increase Existing Revenues <input type="checkbox"/> Increase Costs <input type="checkbox"/> Decrease Costs <input type="checkbox"/> Indeterminate <input type="checkbox"/> Decrease Existing Revenues <input type="checkbox"/> Could Absorb Within Agency's Budget	
<b>8. The Rule Will Impact the Following (Check All That Apply)</b> <input type="checkbox"/> State's Economy <input type="checkbox"/> Specific Businesses/Sectors <input type="checkbox"/> Local Government Units <input type="checkbox"/> Public Utility Rate Payers <input type="checkbox"/> Small Businesses <b>(if checked, complete Attachment A)</b>	
<b>9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).</b> \$0	
<b>10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be \$10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	
<b>11. Policy Problem Addressed by the Rule</b> The proposed rules make changes to provide clarity and reflect the provisions of 2009 Wisconsin Act 162 and 2017 Wisconsin Act 59, which made various changes to the practice of athletic trainers and the duties and powers of the Athletic Trainers Affiliated Credentialing Board.	
<b>12. 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.</b> The proposed rules were posted on the Department of Safety and Professional Services' website for 14 days in order to solicit comments from businesses, representative associations, local governmental units, and individuals that may be affected by the rule. No comments were received.	
<b>13. Identify the Local Governmental Units that Participated in the Development of this EIA.</b> No local governmental units participated in the development of this EIA.	
<b>14. 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)</b> The proposed rule will not have a significant impact on specific businesses, business sectors, public utility rate payers, local governmental units, or the state's economy as a whole.	
<b>15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule</b> The benefit to implementing the rule is providing clarity and conformity with the Wisconsin Statutes. If the rule is not implemented, it will continue to contain outdated and incorrect notes and references.	
<b>16. Long Range Implications of Implementing the Rule</b> The long range implication of implementing the rule is clarity, updated references, and conformity with the Wisconsin Statutes.	
<b>17. Compare With Approaches Being Used by Federal Government</b> None	
<b>18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)</b>	

## ADMINISTRATIVE RULES Fiscal Estimate & Economic Impact Analysis

**Illinois:**

Rules of the Illinois Department of Financial and Professional Regulation establish requirements for licensure as an athletic trainer in Illinois and the approval of athletic training programs (68 Ill. Adm. Code 1160.20 to 1160.80).

**Iowa:**

Rules of the Iowa Board of Athletic Training establish requirements for licensure as an athletic trainer in Iowa (645 IAC 351.1 to 353.5).

**Michigan:**

Rules of the Michigan Department of Licensing and Regulatory Affairs establish requirements for licensure as an athletic trainer in Michigan, a plan of care for certain athletic training services, and delegation of acts related to the practice of athletic training (Mich Admin Code, R 338.1301 to R 338.1377).

**Minnesota:**

The Minnesota Statutes, sections 148.7801 to 148.7815, establish requirements for licensure as an athletic trainer in Minnesota and define the scope of athletic training.

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19. Contact Name

Dale Kleven

20. Contact Phone Number

(608) 261-4472

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

**ADMINISTRATIVE RULES**  
**Fiscal Estimate & Economic Impact Analysis**

**ATTACHMENT A**

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1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

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2. Summary of the data sources used to measure the Rule's impact on Small Businesses

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3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?

- Less Stringent Compliance or Reporting Requirements
  - Less Stringent Schedules or Deadlines for Compliance or Reporting
  - Consolidation or Simplification of Reporting Requirements
  - Establishment of performance standards in lieu of Design or Operational Standards
  - Exemption of Small Businesses from some or all requirements
  - Other, describe:
- 

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

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5. Describe the Rule's Enforcement Provisions

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6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)

- Yes    No
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