The Oregon Medical Board (OMB or “Board”) held a regular quarterly meeting on Thursday and Friday, October 5 - 6, 2017, at the OMB offices, 1500 SW 1st Ave. Ste. 620, Portland. Chair Michael Mastrangelo Jr., MD, called the meeting to order at 8:00 a.m. A quorum was present, consisting of the following members:

<table>
<thead>
<tr>
<th>Member Name</th>
<th>City</th>
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<tbody>
<tr>
<td>Michael Mastrangelo, Jr., MD</td>
<td>Bend</td>
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<tr>
<td>K. Dean Gubler, DO, Vice Chair</td>
<td>Beaverton</td>
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<tr>
<td>Lisa M. Lipe, DPM, Secretary</td>
<td>Lake Oswego</td>
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<tr>
<td>Robert M. Cahn, MD</td>
<td>Portland</td>
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<tr>
<td>Paul Chavin, MD</td>
<td>Eugene</td>
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<tr>
<td>Kathrine Fisher, DO</td>
<td>Happy Valley(Thursday only)</td>
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<tr>
<td>Saurabh Gupta, MD</td>
<td>Portland</td>
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<tr>
<td>Kathleen Harder, MD</td>
<td>Salem</td>
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<tr>
<td>James K. Lace, MD</td>
<td>Salem</td>
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<tr>
<td>Jennifer L. Lyons, MD</td>
<td>Portland</td>
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<tr>
<td>Melissa Peng, PA-C</td>
<td>Portland</td>
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<tr>
<td>Chere Pereira*</td>
<td>Corvallis</td>
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</tbody>
</table>

*Public Member

**Staff, consultants and legal counsel present:**

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<thead>
<tr>
<th>Name</th>
<th>Position</th>
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<tr>
<td>Kathleen Haley, JD</td>
<td>Executive Director</td>
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<tr>
<td>Kristina Kallen</td>
<td>Executive Assistant</td>
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<tr>
<td>Joseph Thaler, MD</td>
<td>Medical Director</td>
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<tr>
<td>Nicole Krishnaswami, JD</td>
<td>Operations &amp; Policy Analyst (Thursday only)</td>
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<td>Jessica Bates, HR Director</td>
<td>HR Director (Thursday only)</td>
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<tr>
<td>Theresa Lee, HPSP &amp; Compliance Coordinator</td>
<td>(Friday only)</td>
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<tr>
<td>Carol Brandt, Business Manager</td>
<td>Mark Levy, Senior Software and Systems Administrator</td>
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<tr>
<td>Eric Brown, Chief Investigator</td>
<td>David Lilly, Investigator</td>
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<tr>
<td>Alexander Burt, MD</td>
<td>Psychiatric Consultant (Thursday only)</td>
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<tr>
<td>Kate Lozano, JD</td>
<td>Assistant Attorney General, DOJ, Salem (Thursday only)</td>
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<tr>
<td>Frank Clore, Licensing Assistant &amp; EMS Advisory Committee Coordinator</td>
<td>Laura Mazzucco, Executive Support Specialist</td>
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<tr>
<td>Mohamud Daya, MD</td>
<td>EMS Advisory Committee Member (Friday only)</td>
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<td>Michael Seidel, Investigator</td>
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<tr>
<td>Matt Donahue, Investigator</td>
<td>Michele Sherwood, Investigations Coordinator</td>
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<tr>
<td>Warren Foote, JD</td>
<td>Senior Assistant Attorney General (Thursday only)</td>
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<td>Shane Wright, Investigator</td>
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**OMB Committee members and guests present:**

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<tr>
<th>Name</th>
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<tr>
<td>J. Glenn Forister, PhD, PA-C, Physician Assistant Program, OHSU, Public Guest (Friday only)</td>
<td>Mary Von, DHEd, MS, PA-C, Director of School of Physician Assistants, Pacific University, Public Guest (Friday only)</td>
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<tr>
<td>Ami Kapadia, MD, ABIHM, Kwan-Yin Healing Arts Center (Friday only)</td>
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*Updated November 28, 2017*
Thursday, October 5, 2017

8:00 a.m. – CALL TO ORDER
Michael Mastrangelo, Jr., MD; Chair of the Board

ANNOUNCEMENT OF EXECUTIVE SESSION – Michael Mastrangelo, Jr., MD, Board Chair, announced that pursuant to ORS 192.660(2)(f) and (l), the Oregon Medical Board would convene in Executive Session to consider records that are exempt by law from public disclosure, including information received in confidence by the Board, information of a personal nature the disclosure of which would constitute an invasion of privacy, and records which are otherwise confidential under Oregon law.

EXECUTIVE AND CLOSED SESSIONS – Executive Sessions were conducted pursuant to ORS 192.660(1)(2)(a)(f)(k). Deliberations and Probationer Interviews took place in closed sessions, pursuant to ORS 441.055(9).

PUBLIC SESSIONS AND BOARD ACTIONS – The Board reconvened in Public Session prior to taking any formal, final action (shown in these minutes as BOARD ACTION). Unless otherwise indicated, all matters involving licensee or applicant cases include votes. Vote tallies are shown as follows: Ayes – Nays – Abstentions – Recusals – Absentees.

RECUSALS AND ABSTENTIONS – Where noted, Board members have recused themselves from discussion of any particular case or abstained from the final vote. To recuse means the Board member has actually left the room and not discussed or voted on the disposition of the case. To abstain means the Board member may have taken part in the discussion of the case, but chose to not cast a vote on its disposition.
PUBLIC SESSION
Dr. Mastrangelo took roll. Dr. Gubler, Dr. Gupta, and Dr. Hernandez, PhD, were absent by prior notice.

Dr. Mastrangelo welcomed staff and Board members to the meeting. He invited Mark Levy, Senior Software and Systems Administrator, to give the Board an update on the new Board laptops.

Dr. Gubler joined the meeting at 8:07 a.m.

Swearing in New Board Members
Dr. Mastrangelo swore in new physician Board member, Kathleen Harder, MD, and welcomed her to the Board.

Introduction of Staff Guests
Ms. Haley welcomed Jessica Bates, HR Director, to the Board meeting as an observer.

EXECUTIVE SESSION
Time Certain: 8:45 a.m.
Attorney-Client Session
Kate Lozano, Assistant Attorney General, provided attorney-client advice. Joe Thaler, MD, Oregon Medical Board (OMB) Medical Director, and Warren Foote, JD, Senior Assistant Attorney General, left the room during the attorney-client session.

PUBLIC SESSION
Time Certain: 9:00 a.m.
Dr. Mastrangelo said Dr. Murphy has indicated through the investigators that he will not appear. It is 9:00 a.m. and Dr. Murphy has not appeared.

EXECUTIVE SESSION
ASHAYE, Olurotimi A., MD
Supervision
CS
KDG
Dr. Gubler reviewed the case.

BOARD ACTION: Dr. Gubler moved that in the matter of Olurotimi A. Ashaye, MD, the Board approve Licensee’s request to terminate his 2016 Stipulated Order. Ms. Peng seconded the motion. The motion passed 11-0-0-0-2. Dr. Gupta and Dr. Hernandez, PhD, were absent by prior notice.
CALCAGNO, John A., MD | Supervision | CS | MM
Dr. Mastrangelo reviewed the case.

BOARD ACTION: Dr. Gubler moved that in the matter of John A. Calcagno, MD, the Board approve the IC’s recommendation to modify the Licensee’s 2017 Stipulated Order. Dr. Cahn seconded the motion. The motion passed 10-0-0-0-3. Dr. Gupta, Ms. Pereira, and Dr. Hernandez, PhD, were absent by prior notice.

CROSS, Lorne M., MD | Supervision | CS | RC
Dr. Cahn reviewed the case.

BOARD ACTION: Dr. Cahn moved that in the matter of Lorne M. Cross, MD, the Board approve Licensee’s request to terminate his 2014 Stipulated Order. Dr. Lipe seconded the motion. The motion passed 11-0-0-0-2. Dr. Gupta and Dr. Hernandez, PhD, were absent by prior notice.

PUBLIC SESSION
Dr. Mastrangelo stated for the record that although Deliberation was time certain at 9:00 a.m., Dr. Murphy did not appear before the Board at all. The Board waited until 10:00 a.m. to deliberate this case in respect to Dr. Murphy’s schedule. Deliberation officially commenced at 10:00 a.m.

CLOSED SESSION
DELBERATION
MURPHY, James M., MD | EB | MM
Dr. Mastrangelo reviewed the case.

BOARD ACTION: Dr. Lipe moved that in the matter of James M. Murphy, MD, the Board accept and adopt the findings of facts and conclusions of law in the proposed order. And that we accept and uphold the penalty recommendations made in the proposed order. However, I further move that the Board direct Counsel to amend the basis of the penalties to be imposed include Respondent’s belligerence and failure to cooperate with the investigation and attempts to prevent witnesses from cooperating, but that we do not find the Respondent’s general complaints about the investigation or the complaints and remarks about the Board and staff to be a component of the violation or basis for the penalties. Those opinions and remarks were merely the Respondent’s exercise of his rights to free speech. Dr. Cahn seconded the motion. The motion passed 10-0-0-1-2. Mr. Foote, Dr. Gubler, Dr. Thaler and staff member, Laura Mazzucco, did not participate and left the room. Dr. Hernandez, PhD, and Dr. Gupta were absent by prior notice.

PUBLIC SESSION
Public Comment | MM
No member of the public presented so no public comment was presented.
EXECUTIVE SESSION

**ESTEVEZ, Miguel, MD**

Dr. Gubler reviewed the case.

**BOARD ACTION**: Dr. Gubler moved that in the matter of Miguel Estevez, MD, the Board approve the IC’s recommendation to issue a Complaint & Notice of Proposed Disciplinary Action based on a possible violation of the Medical Practice Act, ORS 677.190(1)(a), as defined in ORS 677.188(4)(a); ORS 677.190(7); ORS 677.190(13); ORS 677.190(23); and ORS 677.190(24). Dr. Lipe seconded the motion. The motion passed 11-0-0-0-2. Dr. Gupta and Dr. Hernandez, PhD, were absent by prior notice.

**HARPER, John S., LAc**

Ms. Pereira reviewed the case.

**BOARD ACTION**: Ms. Pereira moved that in the matter of John S. Harper, LAc, the Board approve the Stipulated Order signed by Licensee on August 1, 2017. Dr. Cahn seconded the motion. The motion passed 11-0-0-0-2. Dr. Gupta and Dr. Hernandez, PhD, were absent by prior notice.

**HENRY, Thomas P., MD**

Dr. Mastrangelo reviewed the case.

**BOARD ACTION**: Dr. Gubler moved that in the matter of Thomas P. Henry, MD, the Board approve the Stipulated Order signed by Licensee on June 19, 2017. Dr. Chavin seconded the motion. The motion passed 11-0-0-0-2. Dr. Gupta and Dr. Hernandez, PhD, were absent by prior notice.

**HICKEN, Michael P., MD**

Dr. Chavin reviewed the case.

**BOARD ACTION**: Dr. Chavin moved that in the matter of Michael P. Hicken, MD, the Board approve the Stipulated Order signed by Licensee on September 1, 2017. Dr. Gubler seconded the motion. The motion passed 11-0-0-0-2. Dr. Gupta and Dr. Hernandez, PhD, were absent by prior notice.

**JOHANSEN, Karen B., MD**

Dr. Lipe reviewed the case.

**BOARD ACTION**: Dr. Lipe moved that in the matter of Karen B. Johansen, MD, the Board approve the IC’s recommendation to accept Applicant’s request to withdraw her license application with a report to the Federation of State Medical Boards (FSMB). Dr. Cahn seconded the motion. The motion passed 11-0-0-0-2. Dr. Gupta and Dr. Hernandez, PhD, were absent by prior notice.

*Updated November 28, 2017*
Approved by the Board on January 5, 2018

Dr. Gupta joined the meeting at 10:42 a.m.

(Name Redacted) MD KDG

Dr. Gubler reviewed the case.

The Board took no official action.

KIMURA, Hidenao, MD SW PC

Dr. Chavin reviewed the case.

BOARD ACTION: Dr. Chavin moved that in the matter of Hidenao Kimura, MD, the Board approve the IC’s recommendation to issue a Complaint & Notice of Proposed Disciplinary Action based on a possible violation of the Medical Practice Act, ORS 677.190(1)(a), as defined in ORS 677.188(4)(a); ORS 677.190(13); and ORS 677.190(24). Dr. Lipe seconded the motion. The motion passed 12-0-0-0-1. Dr. Hernandez, PhD, was absent by prior notice.

Name Redacted 16-0441 #3 SW PC

Dr. Chavin reviewed the case.

BOARD ACTION: Dr. Chavin moved that in the matter of Case #16-0441, the Board issue an Order for Evaluation. Dr. Cahn seconded the motion. The motion passed 12-0-0-0-1. Dr. Hernandez, PhD, was absent by prior notice.

KORT, Daniel D., MD Supervision CS PC

Dr. Chavin reviewed the case.

BOARD ACTION: Dr. Chavin moved that in the matter of Daniel D. Kort, MD, the Board approve the IC’s recommendation to terminate Licensee’s 2015 Stipulated Order. Dr. Gubler seconded the motion. The motion passed 12-0-0-0-1. Dr. Hernandez, PhD, was absent by prior notice.

LARSEN, Lester R., MD SW MM

Dr. Mastrangelo reviewed the case.

BOARD ACTION: Dr. Gubler moved that in the matter of Lester R. Larsen, MD, the Board accept Applicant’s request to withdraw his license application with a report to the FSMB. Dr. Lipe seconded the motion. The motion passed 12-0-0-0-1. Dr. Hernandez, PhD, was absent by prior notice.
**Approved by the Board on January 5, 2018**

<table>
<thead>
<tr>
<th>LE, Christian, MD</th>
<th>WF</th>
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<td>Dr. Gubler reviewed the case.</td>
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**BOARD ACTION:** Dr. Gubler moved that in the matter of Christian Le, MD, the Board approve the Stipulated Order signed by Licensee on September 20, 2017. Dr. Chavin seconded the motion. The motion passed 12-0-0-0-1. Dr. Hernandez, PhD, was absent by prior notice.

<table>
<thead>
<tr>
<th>MAURAS, Kessa, DPM</th>
<th>Supervision</th>
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<td>Dr. Mastrangelo reviewed the case.</td>
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**BOARD ACTION:** Dr. Gubler moved that in the matter of Kessa Mauras, DPM, the Board approve the IC’s recommendation to approve Licensee’s request to terminate her 2014 Stipulated Order. Dr. Chavin seconded the motion. The motion passed 11-0-0-1-1. Dr. Lipe was recused. Dr. Hernandez, PhD, was absent by prior notice.

<table>
<thead>
<tr>
<th>MCCARTHY, Joseph P., MD</th>
<th>MS/SW</th>
<th>PC</th>
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<tr>
<td>Dr. Chavin reviewed the case.</td>
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**BOARD ACTION:** Dr. Chavin moved that in the matter of Joseph P. McCarthy, MD, the Board approve the Stipulated Order signed by Licensee on August 30, 2017. Dr. Cahn seconded the motion. The motion passed 11-0-0-0-2. Dr. Lyons and Dr. Hernandez, PhD, were absent by prior notice.

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<tr>
<th>MCMANAMA, Gerald P., III, MD</th>
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<tr>
<td>Dr. Gubler reviewed the case.</td>
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**BOARD ACTION:** Dr. Gubler moved that in the matter of Gerald P. McManama, III, MD, the Board approve the Stipulated Order signed by Licensee on July 7, 2017. Dr. Chavin seconded the motion. The motion passed 11-0-0-0-2. Dr. Lyons and Dr. Hernandez, PhD, were absent by prior notice.

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<th>McVEY, Douglas K., PA</th>
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<tr>
<td>Dr. Gubler reviewed the case.</td>
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**BOARD ACTION:** Dr. Gubler moved that in the matter of Douglas K. McVey, PA, the Board approve the IC’s recommendation to approve Licensee’s request to terminate his 2015 Stipulated Order. Dr. Chavin seconded the motion. The motion passed 11-0-0-0-2. Dr. Lyons and Dr. Hernandez, PhD, were absent by prior notice.

*Updated November 28, 2017*
MYERS, Larry R., MD

Ms. Pereira reviewed the case.

BOARD ACTION: Ms. Pereira moved that in the matter of Larry R. Myers, MD, the Board approve the Stipulated Order signed by Licensee on September 15, 2017. Ms. Peng seconded the motion. The motion passed 11-0-0-0-2. Dr. Lyons and Dr. Hernandez, PhD, were absent by prior notice.

OTTENHEIMER, Edward J., III, MD

Dr. Chavin reviewed the case.

BOARD ACTION: Dr. Chavin moved that in the matter of Edward J. Ottenheimer, III, MD, the Board approve the IC’s recommendation to issue a Complaint & Notice of Proposed Disciplinary Action based on a possible violation of the Medical Practice Act, ORS 677.190(1)(a), as defined in ORS 677.188(4)(a); and ORS 677.190(13). Dr. Lipe seconded the motion. The motion passed 12-0-0-0-1. Dr. Hernandez, PhD, was absent by prior notice.

REAGAN, Charles P., MD

Dr. Chavin reviewed the case.

BOARD ACTION: Dr. Chavin moved that in the matter of Charles P. Reagan, MD, the Board approve the IC’s recommendation to issue a Complaint & Notice of Proposed Disciplinary Action based on a possible violation of the Medical Practice Act, ORS 677.190(1)(a), as defined in ORS 677.188(4)(a) and (c); ORS 677.190(14); and ORS 677.190(24). Dr. Lipe seconded the motion. The motion passed 12-0-0-0-1. Dr. Hernandez, PhD, was absent by prior notice.

ROBERTS, Brenda D., MD

Dr. Gubler reviewed the case.

BOARD ACTION: Dr. Gubler moved that in the matter of Brenda D. Roberts, MD, the Board approve the IC’s recommendation to issue a Complaint & Notice of Proposed Disciplinary Action based on a possible violation of the Medical Practice Act, ORS 677.190(1)(a), as defined in ORS 677.188(4)(a), (b), and (c); ORS 677.190(8); ORS 677.190(13); ORS 677.190(17); ORS 677.190(23); and ORS 677.190(24). Dr. Chavin seconded the motion. The motion passed 12-0-0-0-1. Dr. Hernandez, PhD, was absent by prior notice.
Approved by the Board on January 5, 2018

ROWLEY, Mark C., MD  Supervision  CS  PC
Dr. Chavin reviewed the case.

BOARD ACTION: Dr. Chavin moved that in the matter of Mark C. Rowley, MD, the Board approve the IC’s recommendation to approve Licensee’s request to terminate his 2015 Stipulated Order. Dr. Gubler seconded the motion. The motion passed 12-0-0-0-1. Dr. Hernandez, PhD, was absent by prior notice.

SALCEDO, Ginamarie G., MD  MD  JLL
Dr. Lyons reviewed the case.

BOARD ACTION: Dr. Lyons moved that in the matter of Ginamarie G. Salcedo, MD, the Board approve Applicant’s request to withdraw her license application with a report to the FSMB. Dr. Gubler seconded the motion. The motion passed 12-0-0-0-1. Dr. Hernandez, PhD, was absent by prior notice.

SASICH, Randy L., MD  Supervision  CS  MM
Dr. Mastrangelo reviewed the case.

BOARD ACTION: Dr. Gubler moved that in the matter of Randy L. Sasich, MD, the Board approve the IC’s recommendation to modify Licensee’s 2013 Consent Agreement. Ms. Peng seconded the motion. The motion passed 12-0-0-0-1. Dr. Hernandez, PhD, was absent by prior notice.

SILLS, Shawn M., MD  Supervision  CS  KDG
Dr. Gubler reviewed the case.

BOARD ACTION: Dr. Gubler moved that in the matter of Shawn M. Sills, MD, the Board approve the IC’s recommendation to approve Licensee’s request to terminate his 2012 Stipulated Order. Dr. Cahn seconded the motion. The motion passed 12-0-0-0-1. Dr. Hernandez, PhD, was absent by prior notice.

TABOR, Mark E., PA  Supervision  CS  RC
Dr. Cahn reviewed the case.

BOARD ACTION: Dr. Cahn moved that in the matter of Mark E. Tabor, PA, the Board approve the IC’s recommendation to approve Licensee’s request to terminate his 2014 Corrective Action Agreement. Dr. Lipe seconded the motion. The motion passed 12-0-0-0-1. Dr. Hernandez, PhD, was absent by prior notice.

Updated November 28, 2017
Board Action on Licenses

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<thead>
<tr>
<th>Name Redacted</th>
<th>Name</th>
<th>Supervision</th>
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<tbody>
<tr>
<td>THOMPSON, Albert P., MD</td>
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<tr>
<td>BOARD ACTION: Dr. Cahn moved that in the matter of Albert P. Thompson, MD, the Board approve the IC’s recommendation to approve Licensee’s request to terminate his 2015 Stipulated Order. Dr. Gubler seconded the motion. The motion passed 11-0-0-1-1. Dr. Lipe was recused. Dr. Hernandez, PhD, was absent by prior notice.</td>
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<td>VOGELSANG, Glenn D., MD</td>
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<td>Dr. Chavin reviewed the case.</td>
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<td>BOARD ACTION: Dr. Chavin moved that in the matter of Glenn D. Vogelsang, MD, the Board approve the IC’s recommendation to approve Applicant’s application for licensure. Dr. Harder seconded the motion. The motion passed 11-0-0-2. Dr. Lyons and Dr. Hernandez, PhD, were absent by prior notice.</td>
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<td>YAMANE, Robert Y., MD</td>
<td>Supervision</td>
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<td>BOARD ACTION: Dr. Chavin moved that in the matter of Robert Y. Yamane, MD, the Board approve the IC’s recommendation to approve Licensee’s request to terminate his 2016 Corrective Action Agreement. Ms. Peng seconded the motion. The motion passed 12-0-0-1. Dr. Hernandez, PhD, was absent by prior notice.</td>
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<td>YOON, Justin K., MD</td>
<td>Supervision</td>
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<td>Dr. Gubler reviewed the case.</td>
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<td>BOARD ACTION: Dr. Gubler moved that in the matter of Justin K. Yoon, MD, the Board approve the IC’s recommendation to issue a Complaint &amp; Notice of Proposed Disciplinary Action based on a possible violation of the Medical Practice Act, ORS 677.190(1)(a), as defined in ORS 677.188(4)(a); ORS 677.190(6); and ORS 677.190(15). Dr. Lipe seconded the motion. The motion passed 12-0-0-1. Dr. Hernandez, PhD, was absent by prior notice.</td>
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Dr. Gubler reviewed the case.

**BOARD ACTION:** Dr. Gubler moved that in the matter of Jennifer L. Backman, DO, the Board approve the Stipulated Order signed by Licensee on September 27, 2017. Dr. Chavin seconded the motion. The motion passed 11-0-0-2. Dr. Harder and Dr. Hernandez, PhD, were absent by prior notice.

Dr. Gubler reviewed the case.

**BOARD ACTION:** Dr. Gubler moved that in the matter of Rachel M. Brennan, DO, the Board approve the Stipulated Order signed by Licensee on September 20, 2017. Dr. Chavin seconded the motion. The motion passed 12-0-0-1. Dr. Hernandez, PhD, was absent by prior notice.

Dr. Chavin reviewed the case.

**BOARD ACTION:** Dr. Chavin moved that in the matter of Timothy A. Gallagher, MD, the Board approve the Corrective Action Agreement signed by Licensee on October 2, 2017. Dr. Lipe seconded the motion. The motion passed 12-0-0-1. Dr. Hernandez, PhD, was absent by prior notice.

Dr. Chavin reviewed the case.

**BOARD ACTION:** Dr. Chavin moved that in the matter of Charles S. Graham, DO, the Board approve the Corrective Action Agreement signed by Licensee on September 22, 2017. Dr. Cahn seconded the motion. The motion passed 12-0-0-1. Dr. Hernandez, PhD, was absent by prior notice.

Dr. Chavin reviewed the case.

**BOARD ACTION:** Dr. Chavin moved that in the matter of Stephen A. Hussey, MD, the Board approve the Corrective Action Agreement signed by Licensee on September 19, 2017. Dr. Cahn seconded the motion. The motion passed 12-0-0-1. Dr. Hernandez, PhD, was absent by prior notice.
Approved by the Board on January 5, 2018

KAHN, Heather A., MD  

Dr. Mastrangelo reviewed the case.

BOARD ACTION: Dr. Gubler moved that in the matter of Heather A. Kahn, MD, the Board approve the Stipulated Order signed by Licensee on September 20, 2017. Dr. Chavin seconded the motion. The motion passed 12-0-0-0-1. Dr. Hernandez, PhD, was absent by prior notice.

Investigative Committee Consent Agenda

The Board reviewed the Consent Agenda from September 7, 2017.

BOARD ACTION: Dr. Mastrangelo moved that the Board approve the September 7, 2017, IC Consent Agenda. Dr. Gubler seconded the motion. The motion passed with a voice vote. Dr. Hernandez, PhD, was absent by prior notice.

Dr. Gubler left the meeting at 3:05 p.m.

PUBLIC SESSION

Oregon Medical Board Licensure Count

Dr. Lipe, DPM, reviewed the licensure count between June 30, 2017, and August 22, 2017, of which there were 446.

The Board took no official action.

EXECUTIVE SESSION

Name Redacted

Dr. Lipe reviewed the case.

The Board referred the case to the IC.

Name Redacted

Dr. Lace reviewed the case.

The Board referred the case to the IC.

Name Redacted

Ms. Peng reviewed the case.

The Board referred the case to the IC.

Updated November 28, 2017
Dr. Fisher reviewed the case.

The Board offered Applicant withdrawal or referral of the case to the IC.

Dr. Lipe reviewed the case.

**BOARD ACTION:** Dr. Lipe moved in the matter of Entity 1037603 that the Board require Licensee to participate in the Health Professionals' Services Program (HPSP). Dr. Chavin seconded the motion. The motion passed 9-1-1-0-2. Dr. Lyons voted nay. Ms. Peng abstained. Dr. Gubler and Dr. Hernandez, PhD, were absent by prior notice.

Dr. Lace reviewed the case. Applicant is ineligible for licensure based on OAR 847-020-0170(4)(b).

No official Board action was taken.

Dr. Lipe reviewed the case.

The Board referred the case to the IC.

Dr. Mastrangelo reviewed the case.

The Board offered Applicant withdrawal with a report to the FSMB or referral of the case to the IC.

Dr. Lipe reviewed the case.

The Board offered Applicant withdrawal or referral of the case to the IC.

*Approved by the Board on January 5, 2018*

*Updated November 28, 2017*
Dr. Mastrangelo reviewed the case.

The Board offered Licensee withdrawal or referral of the case to the IC.

CLOSED SESSION

Probability Interviews

The Board members conducted interviews of the following Board licensees/probationers:

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<thead>
<tr>
<th>Board Member</th>
<th>Licensee</th>
<th>Room No.</th>
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<tbody>
<tr>
<td>Dr. Lipe/Dr. Lace</td>
<td>Name Redacted</td>
<td>1</td>
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<tr>
<td>Dr. Cahn</td>
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<tr>
<td>Observer: Ms. Pereira</td>
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<tr>
<td>Ms. Peng</td>
<td>Name Redacted</td>
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<tr>
<td>Observer: Dr. Gupta</td>
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<tr>
<td>Dr. Chavin</td>
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CLOSED SESSION

Probability Interview Reports

The Board members reported on probationer interviews. Dr. Harder and Ms. Peng were absent by prior notice except during the reports for which they were responsible. Dr. Gubler and Dr. Hernandez, PhD, were absent by prior notice.

The Board adjourned at 4:42 p.m.

Board Recessed until 8 a.m. Friday, October 6
6:00 p.m. – Working Board Dinner
Friday, October 6, 2017

8:00 a.m. – CALL TO ORDER
Michael Mastrangelo, Jr., MD; Chair of the Board

ANNOUNCEMENT OF EXECUTIVE SESSION – Michael Mastrangelo, Jr., MD, Board Chair, announced that pursuant to ORS 192.660(2)(f) and (l) the Oregon Medical Board would convene in Executive Session to consider records that are exempt by law from public disclosure, including information received in confidence by the Board, information of a personal nature the disclosure of which would constitute an invasion of privacy, and records which are otherwise confidential under Oregon law.

EXECUTIVE AND CLOSED SESSIONS – Executive Sessions were conducted pursuant to ORS 192.660(1)(2)(a)(f)(k). Deliberations and Probationer Interviews took place in closed sessions, pursuant to ORS 441.055(9).

PUBLIC SESSIONS AND BOARD ACTIONS – The Board reconvened in Public Session prior to taking any formal, final action (shown in these minutes as BOARD ACTION). Unless otherwise indicated, all matters involving licensee or applicant cases include votes. Vote tallies are shown as follows: Ayes – Nays – Abstentions – Recusals – Absentees.

RECUSALS AND ABSTENTIONS – Where noted, Board members have recused themselves from discussion of any particular case or abstained from the final vote. To recuse means the Board member has actually left the room and not discussed or voted on the disposition of the case. To abstain means the Board member may have taken part in the discussion of the case but chose to not cast a vote on its disposition.
PUBLIC SESSION

Mark Levy, Senior Software Systems Administrator, gave an update on the new Board laptops. He explained that the new laptops have a longer battery life which affords increased downloading time.

Dr. Mastrangelo took roll call. Dr. Fisher and Dr. Hernandez, PhD, were absent by prior notice.

Dr. Mastrangelo introduced Dr. de la Torre as the new physician member on the Acupuncture Committee who was observing the Board meeting on Friday.

Dr. Mastrangelo introduced George Koval, MD, an emeritus Board member and the Chair of the new Physician Assistant Workgroup, which will be primarily working on the eight hours per month of onsite supervision issue.

Annual Performance Progress Report, Carol Brandt, Business Manager

Dr. Mastrangelo introduced Ms. Brandt.

Ms. Brandt reported that the Board once again met or exceeded all of the targets of the OMB’s key performance measures (KPMs). There was also a significant increase in the customer satisfaction results, with overall satisfaction increasing by 4% (88% last year to 92% this year). Several other KPMs increased by 5%.

The targets changed on a few measures based on Legislative direction. Renewal Efficiency, KPM #6, will have a target of ten days rather than 15 days on license renewal due to consistently achieving the target over the past few years. The Best Practices Measure target is going from 85 to 100%, and the Licensing Efficiency Measure is going from five days to one day based on current performance.

Ms. Brandt said some of these new targets may require stretching, but she assured the Board that public safety will not be shortcut in order to meet these targets. Ms. Brandt said health and public safety remains the primary priority.

Ms. Brandt addressed Dr. Lipe’s concern raised at the previous AAC meeting regarding KPM #1, Licensing Appropriately. Ms. Brandt found that no licenses were denied so KPM #1 does not include licenses that are withdrawn or ineligible or expired.

Annual Review of Agency Head Transactions, Carol Brandt, Business Manager

Ms. Brandt presented to the Board on the 2017 Agency Head Transactions. She said in her role as the Chief Financial Officer, Ms. Brandt audits, reviews, and approves all financial transactions for the agency, including the Executive Director’s timesheet and credit card charges and travel reimbursement.
Approved by the Board on January 5, 2018

Dr. Chavin said kudos to the staff who maintain the website because he finds it very user friendly and well done.

**BOARD ACTION:** Dr. Mastrangelo moved that the Board approve the Agency Head Transactions, as written. Dr. Chavin seconded the motion. The motion passed by voice vote. Dr. Fisher and Dr. Hernandez, PhD, were absent by prior notice.

**Legislatively Adopted Expenditures Budget Summary for 2017-2019, Carol Brandt, Business Manager**

Ms. Brandt reviewed the 2017-2019 legislatively adopted budget. Ms. Brandt explained that the budget for the next biennium is built based on the budget for the previous biennium. Several policy packages were requested: The Interstate Medical Licensure Compact, which was ultimately pulled and not approved; the Board membership package which included additional compensation for Board member meeting preparation time; physician wellness package which was providing funding to The Foundation for Medical Excellence (TFME) for physician and physician assistant wellness; investigative staffing for an additional investigative position; and the licensing staff adjustment to increase a licensing staff position from part time to full time. This budget represents an increase of 8.4%, with no fee increases. There are no fee increases estimated for several biennia.

Dr. Lace asked if there was a rainy day fund. Ms. Brandt said the Legislature approves the OMB’s spending and if the budget is not spent in two years, those approved monies remain in the agency bank account.

Dr. Mastrangelo gave kudos to Ms. Brandt for her exceptional work in managing the budget. He asked Ms. Brandt if the Oregon Wellness Program (OWP) will be paid for from the agency’s legislatively adopted budget. Ms. Brandt said the OWP was granted a one-time expenditure of $175,000.

Ms. Haley added that the OMB has been funding the OWP facilitator for both the executive and full committees, which will continue for this biennium.

Mr. Chavin asked if the OMB would be fundraising for the OWP. Ms. Haley said the OMB will not be fundraising for the OWP. The OWP will be fundraising on its own. The OMB separated the funds and gave the donation to our partner, TFME, because we did not want physician participation deterred by the OMB’s involvement in the OWP.

**Emergency Medical Services (EMS) Advisory Committee**

Dr. Mastrangelo welcomed Mohamud Daya, MD, Emergency Medical Services (EMS) Advisory Committee Chair.

Dr. Daya summarized the EMS Advisory Committee Meeting Minutes from August 18, 2017.
The Committee unanimously approved the proposed rule amendment which required EMS providers to honor Physician Orders for Life-Sustaining Treatment (POLST) orders executed according to the relevant statute, which now includes naturopathic physicians among the health care professionals who may sign POLST orders for a patient. The proposed amendment also allows Emergency Medical Responders (EMRs) to administer epinephrine by subcutaneous or intramuscular injection upon successful completion of an Oregon Health Authority-approved course.

Dr. Daya said the Committee also discussed a Scope of Practice Change Request to add the administration of ipratropium at the Emergency Medical Technician (EMT) level. This request was made by Western Lane Ambulance. This practice is currently allowed by a number of states including Virginia, New Mexico, Wisconsin, and Kentucky. Often the preparation comes as a DuoNeb which includes albuterol and ipratropium which then may be administered simultaneously. The Committee proposed to amend OAR 847-035-0030(9)(d)(D) to read: “Prepare and administer albuterol and ipratropium treatments for known asthmatic and chronic obstructive pulmonary disease (COPD) patients suffering from suspected bronchospasm.”

Furthermore, the Committee reviewed correspondence from Heather Cofer, BSN/RN, Salem Health, who inquired if community Special Weapons and Tactics (SWAT) medics would be able to train within emergency rooms. David Lehrfeld, MD, of the Oregon Health Authority (OHA), stated that the current rules state an EMS provider must work only for an EMS agency and that when an EMS provider works in a hospital or health care setting, the employee may not use his or her license or title as an EMS provider while doing so. Dr. Daya said this policy has been maintained over several years.

Dr. Gubler asked Dr. Daya how this rule was different, since in his experience paramedics were in the operating and emergency rooms retraining on airways.

Dr. Daya said that when EMS providers are a part of a training program, they are not working for an institution. While EMS providers are training on skills at institutions, there are agreements between hospitals or health care institutions and training organizations, which have a stated duration. However, a paramedic certificate or title may not be used to work within the hospital or health care institution. Dr. Daya said the intent of this inquiry was to have paramedics working onsite for an unlimited amount of time.

Dr. Gupta asked if there were institutions which included an EMT role in the emergency department. Dr. Daya said he believed this was not allowed under the OHA and was not permitted by the licensing requirements.

Ms. Haley said this practice originated with an Attorney General opinion from an interpretation of statute.

Dr. Daya said the Committee reviewed the issue of ventilation with a noninvasive positive-pressure delivery device/administration of albuterol treatments and covered the use of Continuous Positive Airway Pressure (CPAP) devices by EMTs. The Committee was concerned with the creep of the Scope of Practice at the EMT level. CPAP is being debated nationally as a
great tool for patients in respiratory distress who cannot maintain oxygenation or (potentially) their ventilatory status. However, it has not crept down into the EMT practice level. Dr. Daya said in most states it remains at the advanced EMT or EMT-I-level practice. The Committee suggested reviewing the CPAP request at a later date after additional materials and findings have been gathered. To clarify that ipratropium or DuoNeb (albuterol/ipratropium combination) may be administered by EMT-level providers, the Committee suggested further amending OAR 847-035-0030(9)(d)(D) to read: “Prepare and administer albuterol and/or ipratropium treatments for known asthmatic and chronic obstructive pulmonary disease (COPD) patients suffering from suspected bronchospasm.”

The Committee also discussed the state’s CHEMPACK cache among first responders. Dr. Daya explained that the Center for Disease Control and Prevention (CDC) and the National Response System keeps CHEMPACKs in certain location for release to hospitals and to EMS agencies for use in a chemical weapons attack or biological weapons attack. Dr. Daya said the challenge has been expiring medication within the auto-injectors inside these CHEMPACKs. Replacement is expensive and required frequently. Many of the CHEMPACKs are being replaced with multi-dose vials which have a longer shelf life. The Committee’s question centered around the specification in the current Scope of Practice per OAR 847-035-0030(9)(L) which states, “In the event of a release of organophosphate agents, the EMT who has completed Authority-approved training may prepare and administer atropine sulfate and pralidoxime chloride by autoinjector, using protocols approved by the Authority and adopted by the supervising physician.” The Committee recommended an inquiry to explore submission of a Scope of Practice Change Request to amend OAR 847-035-0030(9)(L).

Following the discussion at the previous Board meeting in July in which concern was raised over the use of TXA (Tranexamic acid) by emergency medical services, the Committee revisited its use. Dr. Daya said TXA is used nationally in many EMS systems. Regionally TXA has not been deployed because of short transport times to trauma centers where TXA is built into the mass transfusion protocols, but the issue has arisen in rural parts of the state where there are long transport times and possible hypotension in the field with presumed hemorrhagic shock.

Dr. Gubler said he appreciated Dr. Poulsen taking this topic back to the Committee. Dr. Daya said the tri-county protocols used across the state do not include TXA.

Dr. Chavin thanked Dr. Daya for his service. He asked Dr. Daya how the Committee approached a large-scale tragedy such as the type just experienced in Las Vegas.

Dr. Daya said the focus of the Committee’s role is largely on the Scope of Practice to determine what the different levels of providers in the state can do. Dr. Daya said the tri-county area was rich in resources, but in rural parts of the state resources are limited. This creates challenges and raises the Scope of Practice questions. He said locally there was a large amount of training that occurs in the tri-county area about local tragedies or disasters, especially around a potential earthquake.
BOARD ACTION: Dr. Mastrangelo moved that the Board approve OAR 847-035-0030: Scope of Practice, as written. Dr. Gubler seconded the motion. The motion passed by voice vote. Dr. Fisher and Dr. Hernandez, PhD, were absent by prior notice.

BOARD ACTION: Dr. Gubler moved that the Board approve the EMS Advisory Committee Meeting Minutes of August 18, 2017, as written. Dr. Chavin seconded the motion. The motion passed by voice vote. Dr. Fisher and Dr. Hernandez, PhD, were absent by prior notice.

OAR 847-008-0000; 847-008-0005; 847-020-0100; 847-020-0120; 847-020-0160; 847-020-0170; 847-020-0200; 847-035-0001; 847-035-0020; 847-050-0038: Osteopathic Medicine (HB 3363)

The Board reviewed the AAC’s recommendation to move the rule forward as written.

The proposed rule amendments are conforming amendments as required by HB 3363, which clarifies that doctors of osteopathic medicine practice medicine as physicians and eliminates all references to the inappropriate terms “osteopathy” or “osteopath.” HB 3363 becomes effective January 1, 2018.

The Board took no official action.

OAR 847-008-0070: Continuing Medical Competency (Education) (SB 48 and HB 3359)

The Board reviewed the AAC’s recommendation to move the rule forward as written.

The proposed rule amendment implements HB 3359 (2017), section 34, which requires the Oregon Medical Board to encourage physicians specializing in primary care, geriatrics, or other specialty designated by the Board, to obtain continuing medical education (CME) in the detection and early diagnosis of Alzheimer’s disease and in the appropriate prescribing of antipsychotic drugs to treat patients with Alzheimer’s disease. The bill also specifies that the CME described above is relevant to the practice of all Board licensees and may be used to satisfy CME requirements for maintenance of licensure. HB 3359 becomes effective January 1, 2018.

The proposed rule amendment also implements part of SB 48 (2017), section 1, which requires the Oregon Medical Board to document the completion of any CME in suicide risk assessment, treatment and management and report data to the Oregon Health Authority biennially. SB 48 becomes effective on January 1, 2018.

The Board took no official action.

Updated November 28, 2017
The Board reviewed the AAC’s recommendation to move the rule forward as written.

The proposed rule amendments incorporate changes at the direction of the House Health Care Committee, which specifically asked for additional restrictions on in-office anesthesia.

Four goals were established through a collaborative process with the Nursing and Dental Boards: (1) Require an ASA physical status evaluation and documentation in the patient record; (2) prohibit in-office moderate, deep, or general anesthesia for patients with an ASA physical status of IV or above; (3) specify that only providers who are licensed or permitted to administer anesthesia may provide in-office moderate, deep, or general anesthesia; and (4) require that the facility have an emergency transfer plan or protocol agreement if in-office moderate, deep, or general anesthesia will be administered. After all three boards have adopted rules to achieve these four goals, the boards expect to issue a Joint Statement outlining the goals and providing citations to each board’s relevant rules.

Ms. Haley thanked Ms. Krishnaswami for her great work on this rule and said it has been well received by the Legislature.

Dr. Lace asked if the OMB provided information regarding where licensees can find applicable statutes and rules. Ms. Haley said the first newsletter of 2018 will include information about where to find applicable statutes and rules. Dr. Mastrangelo said that was a great idea.

Discussion ensued regarding moderate sedation and the ASA levels.

Dr. Thaler provided a brief history of this rule. For the creation of this rule, Dr. Thaler explained there was public commentary for six months by plastic surgeons, dermatologists, surgeons, and oral surgeons who came to the OMB and testified about this rule. They went through the entire rule process to craft these rules. Changing rules is wise but involves a whole process with public testimony. Since these rules were adopted (which were adopted because of the death of a patient) five years ago, there have been no other major issues.

Dr. Mastrangelo said the changes to the rule are appropriate and the Board feels comfortable with the changes presented by Ms. Krishnaswami.

The Board took no official action.
The Board reviewed the AAC’s recommendation to move the rule forward as written.

The proposed rule amendment is necessary to allow podiatric physicians and surgeons to become Board-approved supervising physicians for PAs as required by SB 831 (2017). SB 831 becomes effective January 1, 2018.

Dr. Gubler said inpatient general medicine training has increased tremendously. The PA may have had much more general medical training than the podiatrist.

The Board took no official action.

The Board reviewed the AAC’s recommendation to move the rule forward as written.

The proposed rule amendment is necessary to align physician assistant dispensing privileges with those outlined in SB 423 (2017), which allows physician assistants who are practicing outside of rural or underserved areas to dispense Schedule III-IV controlled substances. SB 423 becomes effective January 1, 2018.

The Board took no official action.

J. Glenn Forister, PhD, PA-C, Physician Assistant Program, OHSU, presented public comment. He said he had been authorized by OHSU Governmental Affairs to represent the entire institution on this matter. Dr. Forister, PhD, said OHSU was in opposition to the proposed amendment to change the PA preceptorship rule which would require preceptors to take an exam and pay a fee to precept PA students. Dr. Forister, PhD, said their opposition stems from the standing rule being fairly adequate in controlling the activities of PA learners across the state. He said there is difficulty getting preceptorships due to competition for clinical learners. With 224 PA programs in the country, the two Oregon programs would follow the new rule, but Dr. Forister, PhD, was not sure the other PA programs would do so. This dynamic presents the concern of a competitive advantage to other learners for preceptor spots.

Dr. Mastrangelo said if a provider was going to be a preceptor for a PA, the provider should understand the rules in Oregon to supervise a PA. He asked Dr. Forister, PhD, if he was asking for a waiver of the requirement or a waiver of the fee for that requirement.

Dr. Forister, PhD, said he was asking that the amendment not be adopted in addition to the already-standing rules. There are already significant rules that limit the use of students in the clinical setting. Dr. Forister, PhD, said the issue with this rule is only for the activities of
students before they become graduates, before they become PAs. He said he has no problem with the rule requiring people who are hiring PAs to understand fully all the stipulations of the rule for PA practice by the OMB. The student issue creates a significant hardship for OHSU and would damage OHSU’s ability to place students across Oregon.

Dr. Lyons asked the role of students who are with physicians and if PA students shadowing physicians, see patients, etc.

Dr. Forister, PhD, said the students participate in patient care. The only thing PA students can do on their own that can be entered into the medical record for the purpose of billing is to take a review of systems and a social history. All other parts of the history must be attended by the physician, verified for accuracy by the physician, and the patient must be seen by the physician. Dr. Forister, PhD, said PA practice is different because PAs may see patients without a supervising physician in attendance and only check in with a supervisor occasionally.

Dr. Lyons asked if PA students do any procedures. Mr. Forister said they do procedures under direct supervision.

Dr. Forister, PhD, said the two programs in the state, OHSU and Pacific University oppose this rule amendment. He said Pacific University is planning on submitting an opposition letter with their stipulated reasons.

Regarding out-of-state PA programs who may decide to send a PA to Oregon, that program probably will not even know about this rule or follow the rule, said Dr. Forister, PhD.

Dr. Mastrangelo said he takes exception to that statement. He has been a preceptor from out of state and he has had deans interview him to ensure he is a competent preceptor. Additionally, Dr. Mastrangelo has had students from other programs just show up and the student’s program knows, or wants to know, very little about what the student participated in while under his tutelage. Dr. Mastrangelo said this rule addresses the issue that could come up with those programs. Also, as a supervisor of PA students, Dr. Mastrangelo said it was important for him as a preceptor and supervisor to understand how PAs work within the system and the applicable rules. He asked Dr. Forister, PhD, how a preceptor could adequately, competently, and appropriately preceptor a student if the preceptor does not understand the rules in Oregon.

Dr. Forister, PhD, said he understands and appreciates Dr. Mastrangelo’s experience and his preceptor role. Dr. Forister, PhD, said the Board had advised PA programs to submit the names of all students practicing in Oregon when they arrive in Oregon. OHSU, as an Oregon program, submitted the names as well as Pacific University. He said it was probably true, however, that not all PA programs submitted the names of the learners even though it was required.

Dr. Gupta asked Dr. Forister, PhD, if it was in the best interest of the patients to place a student with a Board-approved preceptor.

Dr. Forister, PhD, said he would like the Board to consider the best approach to rules for all students, not just PA students. He said this rule creates an extra barrier to learning. Dr. Forister,
PhD, said he also believes the Board could require the PA school to attest that the preceptor has signed off on an understanding of the rules.

Dr. Lyons said she would appreciate nurse practitioners and PA students coming through Ophthalmology to acquire knowledge, but she is not going to become a supervising physician because it is too onerous. Dr. Lyons does not want a PA working for her because she has optometrists. She would like PAs to learn within specialties because she believes it is very important.

Dr. Gubler said if you do not have time to take a test and learn the rules, you do not have time to be a decent preceptor. If this keeps people from being a preceptor, that is good.

Dr. Forister, PhD, said if the Board feels that way, it would be appropriate to recommend that all learners who work with licensees, whether they be nurse practitioners or physician students, would also be subject to the same policy so that understanding how to precept the student is clear and not ambiguous.

Dr. Chavin summarized OHSU’s opposition which was the Board is creating an unlevel playing field which really disadvantages PAs. He asked Dr. Forister, PhD, if that was a correct summation. Dr. Forister, PhD, said it was. He said the OHSU PA program feels that the PA student status is very similar to the student status of other learners and that the current rules have worked well for over 20 years.

Dr. Cahn said PA student status is not the same. PAs are a unique group who work under physicians who are supervising them and are certified or qualified to do so. It is not the same relationship. Dr. Cahn said he understood Dr. Forister’s, PhD, argument that PA students are somehow disadvantaged in terms of finding adequate numbers of preceptors, but he thinks Dr. Gubler hit the nail on the head in terms of finding people who are interested and qualified to do that training and recognize the special relationship that PAs and physicians have.

Dr. Mastrangelo told Dr. Forister, PhD, that his arguments are great, and he understands his position. He said the last thing he wants to do is set up a barrier to PA education. Students and PAs are integral to the delivery of health care in this state. However, Dr. Mastrangelo feels it is more important for someone teaching PA students to understand the rules in the state regarding the use of PAs and the use of PA students. The Board needs to hold the standard that if someone is teaching, that teacher is held to at least the same standard, if not a higher standard, as someone who is practicing. Dr. Mastrangelo said he has great respect for Dr. Forister, PhD, in what he does for students and with teaching. He would challenge Dr. Forister, PhD, to work with the Board to examine the onerousness of the process, such as cost, the difficulty of the questions, or the number of questions, for example. Dr. Mastrangelo wants preceptors to read and understand the material. Hospitals are required by the Joint Commission on the Accreditation of Hospitals Organization (JCAHO) to complete computer-based learning (CBL) with physicians.

Discussion ensued regarding testing of preceptors and the fee.
Dr. Lace said he has been involved with PAs for 37 years. His practice is a supervising physician organization (SPO). Dr. Lace shared the experience of the PAs who work in his practice. The supervising physician must enter the information into the electronic medical record (EMR). Dr. Lace said his practice was happy to provide a PA site for the PA schools based on their experience and history.

Dr. Lipe asked if OHSU provided a stipend for the preceptors. Dr. Forister, PhD, they do not directly, but OHSU has affiliation agreements with some places to cover administrative costs. The DO programs and the MD programs do provide payments. Dr. Forister, PhD, said this is why he wants to work with the Board to reduce barriers to preceptors precepting their students.

Dr. Mastrangelo asked how Dr. Forister’s, PhD, program orients the preceptors.

Dr. Forister, PhD, said there is a clinical coordinator and hub coordinators who are in different parts of the state who are practicing PAs working with the OHSU program. When the coordinators vet a site, by OHSU’s accreditation standards, they have to review everything to ensure all CVs meet the requirements of the accrediting body. Everything must be signed off before taking a student. OHSU also provides site visits which entails the coordinators going back to the sites. Site visits occur frequency. Each student can expect between two and eight site visits a year in which faculty is going onsite to ensure sound relationships.

Dr. Mastrangelo asked if the Board rules regarding PA supervision and PA practice are given during orientation. Dr. Forister, PhD, said not currently, but he would be happy to do so.

Dr. Lipe asked the percentage of preceptors that would be reduced if this amendment passed and how difficult it would be to include an affidavit in the preceptor paperwork certifying the preceptor read the rules. Dr. Forister, PhD, said it would depend on how the rule was applied by the Board. If only one person was required to sign off on the rule, that would be agreeable. Dr. Forister, PhD, said including an affidavit into the preceptorship paperwork was a slam dunk and could be completed immediately.

Dr. Mastrangelo asked if Dr. Forister, PhD, would be willing to make the paperwork and the instructions part of the orientation paperwork rather than simply including the affidavit in the packet.

Dr. Forister, PhD, said the course P3, which is Principles of Professional Practice, already includes the instructions on all of the rules.

Dr. Mastrangelo asked if it was reasonable to add into the preceptor paperwork an attestation that the preceptor understands the rules. Discussion ensued.

Dr. Mastrangelo clarified that this process would not be a backdoor for becoming a supervising physician. If someone wants to be a supervising physician, he or she would still have to go through the process and the exam. This attestation would mean the preceptor would be approved.
to supervise students. He asked Dr. Forister, PhD, if that would be something that he could support.

Dr. Forister, PhD, said he could support that idea.

Dr. Lipe said in subsection C, rather than and it should say or and then had paragraph D, that might be an option. Either you have to be approved by the Board as a supervising physician or you have to be approved by an accredited facility. Dr. Forister, PhD, clarified you would have to sign an affidavit and be trained by the school.

Dr. Gubler said the rules are different. Having a student is not the same as supervising a PA in a clinical practice. He said we are talking about the uniqueness of what a student can and cannot do and should ensure the preceptor is really committed to education.

Dr. Mastrangelo said if the facility includes the materials that we have for our test in the preceptor orientation packet and the preceptor signs off as having read, understood, and agreed with these rules, he did not see why this could not supersede the amendment, with the caveat that it does not allow preceptors to supervise PAs. That is a separate process. This would remove the $100 fee and remove the onerousness of the actual exam.

Dr. Forister, PhD, said the OHSU PA program accrediting body requires that the majority of its preceptors, but not all, have to be MDs, DOs, or PAs. That does not preclude Dr. Forister, PhD, from bringing in other types of instructors in the clinical instruction.

Dr. Chavin asked the Chair to please invite the other guest from Pacific University.

Dr. Forister, PhD, said he appreciated the Board’s time.

Dr. Mastrangelo thanked Dr. Forister, PhD, for coming to the Board. He then welcomed the waiting guest to the Board and asked her to please introduce herself.

Mary Von, DHEd, MS, PA-C, is the Director of the School of PA Studies at Pacific University and the Associate Dean of Faculty Affairs for the College of Health Professions. She has been with Pacific University since 2003, and she has been the program director since 2014. Ms. Von said she hoped the Board had received the letter with signatures from Pacific’s executive dean and vice provost and the President, Lesley M. Hallick. Ms. Von said Pacific concurs with Dr. Forister, PhD. She said on this 50th anniversary of PA day, she appreciated the Board’s points. She would appreciate the opportunity to discuss the costs involved, and she supports putting some of the onus on the program. Costs are presently borne by the students and are one more impediment to students. Ms. Von said she would strongly support the two different ways to validate the rules.

Dr. Gupta asked the annual tuition cost for Pacific’s PA program.
Ms. Von said the total program cost was $91K. Average student indebtedness at the time of graduation is approximately $120,000 to $140,000 for 27 months. Dr. Mastrangelo said medical school was approximately $200,000 to $250,000.

Dr. Chavin asked if Pacific sends its students to other states, if PA students come from out of state, and, if so, how are the out-of-state students placed.

Ms. Von said Pacific does send its students out of state and throughout the world, as Pacific offers international rotations; however, the bulk of Pacific’s students are trained within the United States. Ms. Von said Oregon is a very hot commodity presently. She said hundreds of PA students are coming to Oregon monthly. Pacific receives calls from Pennsylvania, New York, and throughout the east coast asking for rotations in Oregon. Competition is stiff outside of Oregon’s borders.

Dr. Chavin asked if PA students who are interested in coming to Oregon go through Ms. Von, Pacific, or the medical school. Ms. Von said no, students call the administrators directly. She said there are some schools, such as A.T. Still and Western, who have hub coordinators in Portland who work with PA students to place students in Oregon.

Dr. Mastrangelo asked about Pacific’s orientation process.

Ms. Von said the Pacific orientation process is very similar to OHSU’s orientation process. Pacific does not include the Board rules in the orientation packet. Orientation is very strict. There are four different forms that are completed as they vet sites. Pacific reviews everyone’s licenses, board certification, and go through each state’s separate boards to ensure there are no negative rulings on record. Ms. Von said there are times in which the licensee is not chosen as a preceptor due to negative information found in the licensee’s file.

Dr. Mastrangelo asked if Pacific specifically addressed the rules for PA supervision and PA practice in Oregon through adding preceptorship rules and Board rules in the orientation packet.

Ms. Von said presently the rules are not included in orientation packets, but she would add the rules if it would assist with the PA student process. Additionally, Ms. Von said it would give Pacific an opportunity to see how invested preceptors are in teaching PAs.

Dr. Gubler said if he asked Ms. Von to supply a list of disqualified preceptors in the last two years, how long would the list be.

Ms. Von said she does keep track of disqualified preceptors, and it would be a short list. Across the United States it would be a long list, but in Oregon the list would be very short.

Dr. Gubler said in the last 17 years, there has been progressive pressure to take more students at all levels. He questions how carefully the approved preceptors are supervised. Dr. Gubler said the preceptors are educating people who will be providing health care to the public, and it is not wrapped as tight as it could be. He does not understand the push to avoid wrapping it just a little bit tighter to make sure people know the rules. He asked what the major obstacle was.
Ms. Von said the major obstacle was it was just one more obstacle.

Dr. Gubler said there should be one more obstacle to ensure quality. Ms. Von said she would be happy to produce the forms, criteria, and packets used and the documentation Pacific goes through.

Dr. Mastrangelo thanked Ms. Von and Dr. Forister, PhD. He said the Board feels it is very important that health care providers who are precepting PAs understand the rules for supervising PAs in Oregon. The Board is not going to back down from that. The Board also is sympathetic to the rule being an impediment to expanding the number of available PA preceptor positions, and the Board will take this under consideration to work with Pacific and OHSU for an alternative solution, such as some of the things mentioned earlier. Dr. Mastrangelo said the next steps were to have Dr. Thaler and Ms. Haley work with Pacific and OHSU to see what the Board can do.

Ms. Von said she was happy to provide any helpful information at any time.

The Board reviewed the AAC’s recommendation to move the rule forward as written.

The proposed rule amendment specifies that physician assistant students may participate in preceptorships when the preceptor is qualified and competent, a Board-approved supervising physician supervises the preceptorship, and the care is delivered in the course of an accredited PA training program. Prior notification to the Oregon Medical Board is not required.

The Board took no official action.

The Board went into Executive Session to discuss Entity #1037603. Discussion ensued.

No official Board action was taken.

Dr. Mastrangelo introduced Ami Kapadia, MD, from Kwan-Yin Healing Arts Center. Dr. Kapadia combines western and complimentary diagnostics and therapies to assist patients in reaching their health goals.
Dr. Kapadia thanked the Board for the invitation. Dr. Kapadia trained on the east coast in family medicine and has been in Portland for approximately seven years. She has a private practice at Kwan-Yin Healing Arts Center where she practices integrative medicine, and she works part-time at the Veteran’s Administration (VA) Hospital and with Providence Urgent Care.

Dr. Kapadia said her presentation will include the following:

- General description of functional medicine and epigenetics and environmental factors that affect humans’ predispositions;
- Key aspects of a functional medicine workup;
- Two case studies.

Functional medicine is not meant to replace conventional medicine but to augment and build upon it, said Dr. Kapadia. She shared a summary by the Institute of Functional Medicine:

Functional medicine is not a replacement for traditional family medicine. It encompasses and is a deep dive into what family medicine is and always has been. As in traditional family medicine, a functional medicine practitioner looks closely at the myriad interactions among genetic, environmental, and lifestyle factors that can influence long-term health and complex chronic disease. A major premise of functional medicine is that with science, clinical wisdom, and a deep empathy for the patient, many of the underlying causes of chronic disease can be identified, and interventions to remediate those causes can be addressed earlier and more effectively. The modalities that functional medicine uses always start with the foundational lifestyle factors of diet, rest, relationships, stress, movement, and exercise. The modalities taught in functional medicine are all focused on safety and efficacy with a deep underpinning in the peer-reviewed literature. In fact, functional medicine relies on and uses evidence-based medicine as originally conceived, which was to combine peer-reviewed clinical evidence, the clinical expertise of the physician, and patient motivations and preferences. These are all in alignment with traditional family medicine.

Epigenetics or environmental factors are the focus of functional medicine. This is the triad of the environment and genes and how they interact in a general phenotype.

*The Journal of Exposure Science and Environmental Epidemiology* in 2011 said that 90 percent of chronic disease is driven by the environment. Dr. Kapadia said these factors are modifiable and what she works on with patients.

Functional medicine always asks two key questions to identify imbalances regardless of the patient’s diagnosis. 1) Does this person need to be rid of something that is making the person sick? The five areas that are explored are environmental toxins, allergens, infections, poor diet, and stress. 2) Does this person have an unmet need or an individual requirement for something necessary for optimal function for the patient?
Causes for imbalance in a patient include toxins which are pesticides, lead in drinking water, microtoxins from water-damaged buildings; allergens are environmental and/or in the patient’s diet; microbes, nutrition, and stress; unmet needs for optimal health are foods and if the patient is receiving the macronutrients needed, vitamins, minerals, nutrients, fresh air, drinking clean water, getting outside and moving, getting appropriate sleep, connection to the patient’s community. By looking into these possible causes of imbalance in a patient’s life, Dr. Kapadia said they are working to provide what can create balance for the patient.

Two case studies were provided with one being generic and one being a specific patient who Dr. Kapadia has in her practice. To combine the two approaches to a patient, everyone receives a full routine workup as well as the functional medicine workup. The patient is offered the standard of care treatment and the functional medicine treatment options.

Dr. Kapadia shared a diagram of the differential diagnosis. Looking at the traditional allopathic model that has the ICD-10 diagnostic codes, the symptoms of the patient, associated pathology, and the medications or surgery that could help the patient. Under the differential diagnosis, the functional medicine will examine the patient’s biological systems, potential imbalances in function, the root causes of those imbalances, and things that can be added to promote health and things that can be removed that are potentially impeding the patient’s health.

As a generic example, Dr. Kapadia sees many patients with irritable bowel syndrome who have already received a conventional workup. However, she always does a complete history and physical, and she always rules out more serious pathology when necessary and makes appropriate referrals. Dr. Kapadia said appropriate referrals are a premise of functional medicine and ensuring the patient has already had a standard workup completed.

Additionally, Dr. Kapadia provided a summary of the courses of action she would take with patients with irritable bowel syndrome: Elimination challenge diets, which is the gold standard for determining what foods are irritating; screen for nutritional deficiencies (with zinc, magnesium, and B12 deficiencies being the most common) and try to ensure the patient is eating a nutritionally dense diet; identify sources of stress and options for treatment; and a wide-ranging search for possible intestinal microbes that could be out of balance including the microbiome, the mycobiome, or the yeast species in the gut. In Portland she is seeing a lot of protozoa with cryptosporidium and Giardia because Portland does not currently filter its water supply for those organisms. Dr. Kapadia sometimes does specialized testing to look for those protozoa. Finally, she assesses for any exposures to environmental toxins such as exposure to heavy metals, exposure to water-damaged buildings, chemicals at work, etc.

Treatment strategies in a patient with irritable bowel syndrome involve removing certain foods, replacing nutrients that were out of balance, referrals for counseling and other recommendations for stress management, offering potential pharmaceutical and herbal therapies for underlying imbalances in the gut flora, and identifying and eliminating the source of exposure to any environmental toxins. She works with industrial hygienists who go to and evaluate the patient’s house to identify any potential exposures in the home, and she works on nutrient strategies to assist the patient in detoxifying if needed.
Dr. Kapadia provided a clinical example of her approach to treatment, specifically treatment of irritable bowel syndrome. The patient is a 47-year-old RN who was diagnosed with an autoimmune small-fiber neuropathy about 7 years ago. Her symptoms are severe foot pain, fatigue, irritable bowel syndrome, and insomnia. Dr. Kapadia took away the patient’s processed food, potential food intolerances, intestinal imbalances, toxicity from her environment, as able, nutrients to help her detoxify, and tried to ensure she had clean air, water, and food. Dr. Kapadia also added whole real food nutrients, healthy gut bacteria promoted by certain herbs, and probiotics. Dr. Kapadia said after about six months, the patient’s overall symptoms improved. The patient’s fatigue, bloating, and constipation were all improved, although not completely gone. She could spend more time with her family and do more activities with her family. Her neuropathy had improved, although she still had some symptoms, and she said she could live with where her symptoms were at the time. Dr. Kapadia provided a graph of the patient’s initial autoimmune neuropathy markers which were from her neurologist who diagnosed the patient with small-fiber neuropathy. The graph illustrated a significant decrease in the autoimmune markers.

Dr. Lace asked what natural herbs are and if they are United States Pharmacopeia (USP) approved. Dr. Kapadia said she uses many different herbs with many of them based out of Ayurvedic medicine and traditional Chinese medicine. These herbs have been used for thousands of years, which is where much of the data surrounding their use comes from. She said the herbs were GMP approved, but she said she was unsure if they were USP approved but would get back to him with that information.

Dr. Lace asked how Dr. Kapadia keeps from being anecdotal in her practice to provide objective data. Dr. Kapadia said that gets back to the art of medicine. There are studies for certain herbs to help with certain conditions. Also, there is combining as much science as she can with remedies that have been shown to be safe through clinical experience and studies used together. Dr. Lace asked who pays for all of the testing. Dr. Kapadia said she begins with the tests that are covered by the patient’s insurance. She does not require much out-of-pocket expense to the patient because she recognizes it is expensive. She offers patients the option for more testing to see the data. Environmental Protection Agency (EPA) studies show that people have hundreds of chemicals in their blood so she offers to empirically work on liver Phase I and Phase II detoxification, add a nutrient-dense diet, and other things that help detoxification without showing it on paper, unless the patient wants it. She does not do chelation.

Dr. Thaler asked if there was a standard of care for the field of functional medicine. Dr. Kapadia said there is the Institute for Functional Medicine that many providers have trained with, but there is a generally accepted knowledge base among doctors who have studied functional medicine that they would consider appropriate. Dr. Thaler asked if thyroid function studies in functional medicine had a standard of care. Dr. Kapadia said it is accepted in functional medicine to carefully consider a trial of thyroid hormone in a patient who has received other treatments in functional medicine but has not responded, and who seems to fit the picture in case the patient has thyroid resistance at their receptor sites or other mechanisms where the patient’s thyroid-stimulating hormone (TSH) could be normal. Dr. Thaler asked about cortisol as well.
Dr. Kapadia said she has asked her colleagues about this. Cortisol is accepted in functional medicine, but it is definitely not the first thing that is tried. The studies that were quoted to Dr. Kapadia were from Dr. William Jeffries who wrote a book on cortisol replacement.

Dr. Gubler asked why many herbal medicines over the years have not gone through a similar process such as foxglove.

Dr. Kapadia said she thought it was a financial issue. Pharmaceutical companies are not sponsoring trials so much of the data is in Chinese or has been studied in India. The US has not spent the money to do research trials to have these herbs Food and Drug Administration (FDA) approved. Thorne Research has spent the money on research trials on Sulforaphane.

Dr. Koval said researching and testing was very expensive. He was the principal investigator for 150 to 200 clinical trials looking at agents trying to treat disease states. Dr. Koval learned that in diseases that have been confirmed objectively and there are agents that seem to work, it does not mean that agent works better than time. Once a provider starts giving things to a patient or doing something to a patient, it must be measured against not doing something to see what is truly effective.

Dr. Lyons said if there was a positive effect of something that is given to a patient, there can be negative effects, too. She said that speaks to the evidence-based medicine. Although it is expensive, it is safer to look at the downside of something that is going to have an effect.

Dr. Mastrangelo asked who regulates the herbs and supplements. While researching information for a talk he gave recently, he came across an article about grizzly bear gallbladders and poaching in the Pacific Northwest. The gallbladders are worth $10,000 to $12,000 each because they are so sought after. There is also cruelty to these grizzly bears as they are kept in small cages with tubes in their bile ducts to harvest their Ursodiol or Actigall which dissolves gallstones. Again, he would ask who regulates these agents and why go to that extent to get it when it is available in a pill form.

Dr. Kapadia said GMP is the standard for supplements in this country, but not all supplements meet that. She also uses Thorne Research and Pure Encapsulations and an additional one or two for herbal formulations. *(Attachment I)*

Dr. Mastrangelo thanked Dr. Kapadia for her presentation.
The Board reviewed the AAC’s recommendation to adopt the rule as written.

The rule amendment in OAR 847-010-0090 will update the requirements for clinical clerkships and preceptorships in line with current medical education programs. The rules being repealed will remove outdated, unneeded, and duplicative language.

**BOARD ACTION:** Dr. Lipe moved that the Board adopt OAR 847-010-0005; 847-010-0010; 847-010-0025; 847-010-0030; 847-010-0035; 847-010-0038; 847-010-0045; 847-010-0090: Division 010 Updates and Hospital Clinical Clerkships, as written. Dr. Chavin seconded the motion. The motion passed by voice vote. Dr. Fisher and Dr. Hernandez, PhD, were absent by prior notice.

The Board reviewed the AAC’s recommendation to adopt the rule as written.

The rule amendment clarifies that applicants for initial licensure must report during the application process any changes in information previously provided or any new information that becomes available. Updates must be made within ten business days. Such new information may include newly filed or resolved malpractice claims, adverse actions taken by health systems or regulatory bodies, arrests or convictions, and other information that would be relevant to the license application.

**BOARD ACTION:** Dr. Lace moved that the Board adopt OAR 847-008-0010: Initial Registration, as written. Dr. Gubler seconded the motion. The motion passed by voice vote. Dr. Fisher and Dr. Hernandez, PhD, were absent by prior notice.
The Board reviewed the AAC’s recommendation to adopt the rule as written.

The rule amendments and new rules specify that an applicant (1) who has withdrawn an application for licensure that may contain evidence of a violation of the Medical Practice Act, or (2) whose application has been denied by the Board may submit a new application for licensure two years after the date of withdrawal or denial.

BOARD ACTION: Dr. Gubler moved that the Board adopt OAR 847-020-0185; 847-020-0190; 847-050-0065; 847-070-0060; 847-080-0028; 847-080-0030: Application Withdrawals and License Denials, as written. Dr. Chavin seconded the motion. The motion passed by voice vote. Dr. Fisher and Dr. Hernandez, PhD, were absent by prior notice.

Public Health & Pharmacy Formulary Advisory Committee (HB 2397)

Dr. Lipe said the Public Health & Pharmacy Formulary Advisory Committee was in response to HB 2397. This creates a new committee that advises what drug and devices a pharmacist can prescribe with a diagnosis from a health care provider. The Committee will consist of seven members, two of whom are MDs or DOs, two nurse practitioners and three pharmacists. The Committee will be operative as of January 2018. The Governor’s office has asked the OMB to recommend three or more physicians for the two seats on the Committee. Ms. Krishnaswami and Ms. Haley have been working on staffing the Committee.

Ms. Haley said she and Ms. Krishnaswami have been working with the OMA and the Governor’s office, and they have the names moving forward.

No official Board action was taken.

Columbia Care Services Request for Waiver of the 8-Hour On-Site Supervision Requirement

Ms. Peng said Columbia Care Services is planning on hiring a PA to work in Medford in mental health. The PA will be working initially ten (10) hours per week, potentially increasing to 20 hours per week. Columbia Care is requesting four hours of monthly onsite supervision rather than eight based on the 10-hours-per-week work schedule. The PA graduated from Yale, has experience in the mental health field and speaks Spanish. The discussion is whether the Board can make an exception to the eight hours of onsite supervision for someone working quarter time, eventually possibly halftime. Discussion ensued.

BOARD ACTION: Dr. Lipe moved that the Board approve delegating to Ms. Peng once the additional information is obtained from Columbia Care regarding their supervision waiver request. Dr. Gubler seconded the motion. The motion passed 11-0-0-0-2. Dr. Fisher and Dr. Hernandez, PhD, were absent by prior notice.
Workgroup on Supervision of Physician Assistant

Ms. Peng deferred to Ms. Haley for any updates. Ms. Haley said the OMB is working with the OMA, Dr. Lace, and other folks in the physician community to come up with another physician who will be available to commit to three meetings. Ms. Haley said Dr. Koval graciously agreed to chair the Workgroup. She said there was a new PA member as well, Jon Gietzen, PA. Ms. Haley said she is optimistic the Workgroup will come forth with a great product. Ms. Haley said if anyone knows a physician who supervises a PA in the community who would like to participate, please contact her.

April 2018 Board Retreat, Memo from Kathleen Haley, JD, Executive Director

Dr. Lipe presented the information about the Board retreat. Dr. Mastrangelo and Dr. Koval shared how valuable the previous retreat was to solidify the Board. Ms. Haley said she will present the Board with other dates and gather feedback.

International Association of Medical Regulatory Association (IAMRA) Independence of Regulation: The Primacy of Patient Safety

Dr. Lace updated the Board on International Association of Medical Regulatory Agencies (IAMRA) and their mission.

Ms. Haley said the OMB has worked with IAMRA for many years, and it has been a valuable relationship with learning and sharing opportunities.

Investigative Case Review

Dr. Gubler asked Ms. Haley to give information about data regarding applicants and investigative cases involving DUIs.

Ms. Haley said Ms. Sherwood and Ms. Kallen helped gather data around licensee and applicant substance abuse and case resolution.

No official Board action was taken.

Emeritus Board Members (SB 60) Informational Only

Dr. Mastrangelo updated the Board on the Emeritus Board Member law which will go into effect January 1, 2018.

No official Board action was taken.
The Board reviewed the proposed Board and Committee meeting dates for 2018-2019.

Ms. Haley said she would like to move the Board meetings toward a single-day format, which she will present to the AAC for discussion.

**BOARD ACTION:** Dr. Lipe moved that the Board approve the proposed 2018-2019 Board and Committee meeting dates. Dr. Cahn seconded the motion. The motion passed with a voice vote. Dr. Fisher and Dr. Hernandez, PhD, were absent by prior notice.

The Board reviewed the September 13, 2017, Administrative Affairs Committee meeting minutes.

**BOARD ACTION:** Dr. Lipe moved that the Board approve the September 13, 2017, Administrative Affairs Committee meeting minutes, as written. Ms. Peng seconded the motion. The motion passed with a voice vote. Dr. Fisher and Dr. Hernandez, PhD, were absent by prior notice.

The Board reviewed the July 13 - 14, 2017, Board meeting minutes.

**BOARD ACTION:** Dr. Gubler moved that the Board approve the July 13 - 14, 2017, Board meeting minutes, as written. Dr. Lipe seconded the motion. The motion passed with a voice vote. Dr. Fisher and Dr. Hernandez, PhD, were absent by prior notice.

The Board acknowledged the following Interim Stipulated Orders (ISO) and Automatic Suspension:

- CARLSON, Bruce D., MD – *ISO Effective September 1, 2017*
- GIRARD, Ryan J., LAc – *Automatic Suspension Effective October 2, 2017*
- GRIFFIN, John W., MD – *ISO Effective September 17, 2017*
- POPOWICH, Yale S., MD – *ISO Effective September 14, 2017*

Dr. Mastrangelo recognized Dr. Lipe for her years of service to the Board and Committees.

_The Board adjourned at 12:58 p.m._
In response to Dr. Lace’s questions about safety of herbs/supplements:

**Issue #1: How are herbal/nutritional supplements manufactured/regulated?**

- I would not trust herbal medicines sold in other countries that do not meet guidelines followed in US

- All of the companies in the US are now required to follow GMP guidelines as required by FDA (GMP=good manufacturing practices)

- What GMP means in practice:
  - Rules created by FDA to ensure manufacturers produce unadulterated and properly labeled supplements: requires proper controls in place for dietary supplements so they are processed in consistent manner and meet quality standards for identity, purity, strength, composition
  - Includes inspection of physical plants/facilities, cleaning, testing final product or incoming and in process materials
  - Facilities subject to inspection by FDA

- One of the main companies we use (Thorne Research) also follows the Government of Australia’s Therapeutic Goods Administration guidelines which impose the same manufacturing standards for nutritional supplements as they do for pharmaceuticals

Reference: https://www.fda.gov/food/guidanceregulation/cgmp/ucm079496.htm

**Issue #2: Even if manufactured appropriately, how do we ensure safety of the actual herbal medicine / ingredient(s) being used?**

- Most of us who use natural/herbal medicines subscribe to the “Natural Medicines Standard Database” which is basically the “gold standard” for evidence based information on natural medicines used by medical schools, universities, and practitioners. It is free from commercial bias and requires a subscription to use.

- On next page, I am pasting some excerpts from the Natural Medicines Standard Database to show the depth of what is available regarding safety data, etc. on natural/herbal medicines. I am using “Coptis” as an example of a natural medicine/herbal that we use.
EXCERPT FROM NATURAL MEDICINE STANDARD DATABASE FOR COPTIS HERBAL MEDICINE:

Safety

CHILDREN: **LIKELY UNSAFE** ...when used orally in newborns. The berberine constituent of coptis can cause kernicterus in newborns, particularly preterm neonates with hyperbilirubinemia (2589).

PREGNANCY: **LIKELY UNSAFE** ...when used orally. Berberine is thought to cross the placenta and may cause harm to the fetus. Kernicterus has developed in newborn infants exposed to berberine (2589). Preliminary evidence suggests that maternal intake of goldthread during the first trimester increases the risk of congenital malformations of the central nervous system (15129).

LACTATION: **LIKELY UNSAFE** ...when used orally. Berberine and other harmful constituents can be transferred to the infant through breast milk (2589).

Adverse Effects

**General:** Orally, use of coptis and other berberine-containing herbs during pregnancy, lactation, or in newborn infants can cause kernicterus, and several resulting fatalities have been reported (2589). Berberine has been used orally in adults in doses up to 2 grams per day for 8 weeks with no adverse effects reported (13520).

Topically, berberine has been used with for up to 20 days with no adverse effects reported (13526).

Interactions with Drugs

**CYCLOSPORINE (Neoral, Sandimmune)**

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<th>Occurrence</th>
<th>Level of Evidence</th>
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<tr>
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<td>High</td>
<td>Possible</td>
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Berberine, a constituent of coptis, can reduce metabolism of cyclosporine and increase serum levels. It might inhibit cytochrome P450 3A4 (CYP3A4), which metabolizes cyclosporine (13524).

**CYTOCHROME P450 3A4 (CYP3A4) SUBSTRATES**

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There's very preliminary evidence that berberine, a constituent of coptis, might inhibit cytochrome P450 3A4 (CYP3A4) enzyme (13524). So far, this interaction has not been reported in humans. However, watch for an increase in the levels of drugs metabolized by CYP3A4 in patients taking goldthread. Some drugs metabolized by CYP3A4 include lovastatin (Mevacor), clarithromycin (Biaxin), indinavir (Crixivan), sildenafil (Viagra), triazolam (Halcion), and numerous others. Use goldthread cautiously or avoid in patients taking these drugs.

Reference: https://naturalmedicines.therapeuticresearch.com/
In response to Dr. Lyons’ questions about evidence based medicine when using herbal/natural medicines:

• I would be able to provide as needed 15+ references for each of the main herbs I use in practice. These are available through Natural Medicine Standard Database and other resources.

• As an example, we use “neem” frequently to help with digestive symptoms. Below are some examples of such references regarding various properties of neem:


Questions about thyroid hormone and hydrocortisone use:

- I meet with several functional medicine physicians in the area periodically and I am hoping to gather more data on what others are doing with thyroid and hydrocortisone replacement. I can get back to you regarding evidence/research supporting their practices.

**THYROID HORMONE**

- Functional medicine practitioners may use slightly different upper limits of normal than what is recommended by the American College of Endocrinology (some endocrinologists are also using different ULN than ACE). If the TSH is close to upper limit of normal, patient is symptomatic, and they have exhausted looking at other causes of their symptoms, they may consider a cautious trial of thyroid medication.

- Podcast I found useful to understand current issues in defining appropriate upper limit of normal for TSH: Dr. Antonio Bianco, MD, PhD endocrinologist from Rush University:
  

**LOW DOSE HYDROCORTISONE**

- I found 2 main studies cited in the literature for use in patients with chronic fatigue syndrome:

  1. McKenzie et al, 1998 JAMA article: Concluded that low dose hydrocortisone therapy resulted in some improvement in symptoms but clinical use was not recommended due to adrenal suppression.
     a. They used 25-35mg of hydrocortisone per day. I have never seen any functional medicine docs or naturopathic docs use such a high dose.

  2. Cleare et al., 1999 Lancet: Concluded that low dose hydrocortisone therapy resulted in significant improvement in fatigue and did NOT cause adrenal suppression over course of 1 month of study.
     a. They used much lower doses of 5-10mg of hydrocortisone per day (this is equivalent to 1.25-2.50mg of prednisone per day).

References:

1. McKenzie et al article: https://jamanetwork.com/journals/jama/fullarticle/188004