

MANHEIM EXHIBIT 5

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**Florida Board of Medicine
Rules/Legislative Committee Meeting
Meeting Report**

**Embassy Suites
1100 SE 17th St
Ft. Lauderdale, FL 33316
(954) 527-2700**

June 2, 2011

13 Roll Call 4:03 pm

14
15 **Members Present:**

16 Jason Rosenberg, M.D., Acting Chair
17 Robert Nuss, M.D.
18 Zachariah P. Zachariah, M.D.

15 **Members Absent:**

16 Fred Bearison, M.D., Chair
17 Don Mullins, Consumer Member

19
20 **Staff Present:**

21 Joy Tootle, J.D., Executive Director
22 Ed Tellechea, J.D., Board Counsel
23 Donna McNulty, J.D., Board Counsel
24 Nancy Murphy, Paralegal
25 Crystal Sanford, Program Operations Administrator

20 **Others Present:**

American Court Reporting

26
27 **Rules Discussion:**

28
29 **Rules Report1**

30 This report is provided for information only.

31
32 No action taken.

33
34 **Development of Board's Annual Regulatory Plan.....2**

35 This matter was deferred until the end of the meeting.

36
37 **Rule 64B8-9.0131(2)(n), FAC – Standards of Practice for Physicians Practicing in
38 Pain Management Clinic (training requirements)3**

39 Mr. Tellechea explained HB 7095 removed rule making authority to develop standard of practice
40 rules for physicians practicing in pain management clinics with the exception of the training
41 requirements. He said the Board's training requirements rule went into effect on May 17, 2011
42 but HB 7095 would require the Board to make some changes to the existing rule to bring the rule
43 into compliance with the statute.

44
45 Mr. Tellechea went on to explain the bill included the Board's proposed standards of practice
46 rules for physicians practicing in pain management clinics with some amendments. He
47 confirmed the Board's rules were not ratified by the Legislature during the 2011 Session.

1 Ms. McNulty stated she would like to operate in conjunction with the Board of Osteopathic
2 Medicine so the language is consistent.

3
4 A motion was made, seconded and carried unanimously to recommend authorizing Mr.
5 Tellechea to amend the rule language in compliance with the statute and to present that language
6 at the next meeting.

7
8 Mr. Tellechea stated the Committee could discuss the statement of estimated regulatory costs
9 (SERC) at the next meeting when the language is presented.

10
11 **Action taken:** amend rule language in compliance with statute and present language at August
12 meeting

13
14 **Rules 64B8-1.007, FAC – Forms4**

15 Mr. Tellechea explained the financial responsibility form was modified to include the language
16 as it appears in the statute. The form was changed to include all the language in the law
17 regarding exemptions.

18
19 A motion was made, seconded and carried unanimously to recommend approval of the changes
20 in the form.

21
22 A motion was made, seconded and carried unanimously to recommend beginning the rulemaking
23 process for Rule 64B8-1.007, FAC.

24
25 The Committee was asked if the changes in this rule would have an economic impact on small
26 business and it was determined these changes would not have an impact.

27
28 Mr. Tellechea explained the first step in this process is to send the rule to the Office of Fiscal
29 Accountability and Regulatory Reform (OFARR).

30
31 A motion was made, seconded and carried unanimously to recommend authorizing conditional
32 approval for Mr. Tellechea to notice this rule for development upon approval by OFARR.

33
34 **Action taken:** form approved; authorized to begin the rule making process; conditional
35 authorization to notice for rule development upon OFARR approval

36
37 **Legislative Discussion:**

38
39 **Summary of Legislation5**

40 This document provides a summary for each of the following bills.

41
42 No action taken.

43
44 **SB 146ER.....6**

45 Ms. Tootle summarized this bill which requires the board to submit a report by December 31,
46 2011, and every four years thereafter to the Governor and the Legislature detailing the following:

- 47
48 (a) Statutes or rules that disqualify from employment or licensure persons convicted of a crime
49 and have completed incarceration and restitution;

1 (b) A determination of whether the disqualifying statutes or rules are readily available to
2 prospective employers and licensees;

3 (c) Identification and evaluation of alternatives to the disqualifying statutes or rules which
4 protect the health, safety, and welfare of the general public without impeding the gainful
5 employment of ex-offenders.
6

7 Ms. Tootle further stated the bill provides that applicants convicted of a felony or first degree
8 misdemeanor may be denied a license if crime is relevant to the standards necessary for
9 protection of the public. However, agencies are prohibited from denying a licensure based solely
10 on an applicant's lack of civil rights.

11
12 Ms. Tootle stated the board will address this report at the August Board Meeting.

13
14 No action required.
15

16 **HB 155ER.....7**

17 Ms. Tootle summarized this bill which creates Section 790.338, F.S. to provide that a health care
18 practitioner or facility shall not ask about firearm ownership or possession unless there is a good
19 faith belief that the information is relevant to a patient's care or safety or the safety of others.

20 The bill also prohibits practitioners from entering firearm ownership information into a patient's
21 medical record unless the information is relevant to patient care or safety, or safety of others. A
22 patient may decline to provide firearm information, and the patient's decision to not answer does
23 not alter existing law regarding a physician's authority to choose his or her patients. A licensee
24 or facility may not discriminate against a patient solely on basis of ownership or possession of a
25 firearm, and shall not harass a patient about firearm ownership during an exam. Violations of this
26 section are grounds for disciplinary action. The Florida Patient's Bill of Rights was expanded to
27 include right to privacy for firearm ownership.
28

29 After discussion, the Committee determined violation of this law falls under failure to comply
30 with a legal obligation and the current disciplinary guidelines for this violation would apply.
31

32 **Action taken:** violation of the this law would be a failure to comply with a legal obligation and
33 current disciplinary guidelines would apply
34

35 **HB 479ER.....8**

36 Ms. Tootle summarized this bill which includes two areas: expert witness and informed consent.
37

38 **Expert Witness Certificates:**

39 The bill requires the Department of Health to issue expert witness certificates authorizing a
40 physician who holds an active and valid license to practice medicine, osteopathic medicine or
41 dentistry in another state to provide expert testimony in Florida, if the applicant submits a
42 complete registration including specified identifying information and a \$50 application fee. The
43 Department of Health must approve the application within 10 business days if the applicant has
44 an active and valid license to practice in another state or Canada and has not had a previous
45 expert witness certificate revoked by the Board, otherwise the applicant can be granted a default
46 certificate. The Expert witness certificates are valid for two years and authorize the holder to
47 provide verified written expert opinion and provide expert testimony in medical negligence
48 litigation cases. It does not authorize the certificate holder to engage in the practice of medicine,
49 osteopathic medicine or dentistry in Florida. Providing deceptive or fraudulent expert witness
50 testimony in the practice of medicine, osteopathic medicine or dentistry is a ground for

1 discipline. In medical malpractice actions, expert testimony about the prevailing professional
2 standard of care can only be offered by an expert licensed under Chapters 458, 459, 466 or in
3 possession of an expert witness certificate.
4

5 **Informed Consent Forms for Cataract Surgery**

6 The bill also requires the Board to adopt rules establishing a standard informed consent form that
7 sets forth recognized specific risks related to cataract surgery. Rules must be proposed within 90
8 days of effective date, October 1, 2011. The Board is required to consider information from
9 physicians regarding recognized risks related to cataract surgery and informed consent forms
10 adopted by other states. The informed consent must be executed by the patient and also signed
11 by a witness. Any incident resulting from a recognized risk specified on the form is not
12 considered an "adverse incident" and in civil actions where it is alleged the physician failed to
13 disclose risks, an executed informed consent is admissible as evidence and creates a rebuttal
14 presumption that the physician did disclose the risk. This bill also requires the Board of
15 Osteopathic Medicine adopt rules establishing a standard informed consent. This bill provides
16 immunity from liability for volunteer team physicians and amends other provisions relating to
17 medical malpractice claims.
18

19 Mr. Tellechea stated the rule requires rulemaking in two areas: disciplinary guidelines for
20 providing deceptive or fraudulent testimony. He said the Board office staff was in the process of
21 setting up joint meetings with the Board of Osteopathic Medicine to develop the informed
22 consent form. He suggested a three member committee with members to be determined by the
23 Chair. He explained the Committee would create the rule and the form then present both to the
24 Board for final approval.
25

26 Mr. Tellechea said he needed the Committee to provide disciplinary guidelines related to
27 deceptive or fraudulent expert witness testimony.
28

29 Dr. Rosenberg asked if the action would be reciprocal in other states.
30

31 Mr. Tellechea explained that would depend on the legislative language in other states for that
32 type of violation.
33

34 Mr. Tootle stated she would find out if this type of action would be reportable to the Healthcare
35 Integrity Protection Data Bank (HIPDB).
36

37 Dr. Nuss suggested for a first time violation:

- 38 • letter of concern to reprimand
 - 39 • \$1,000 to \$5,000 fine
 - 40 • Laws and rules course
- 41

42 Dr. Zachariah disagreed because these experts make a great deal of money to testify and
43 fraudulent testimony could result in a physician ultimately losing his/her license. He felt a
44 stronger penalty was necessary and suggested the following for a first offense:

- 45 • reprimand to revocation
 - 46 • \$5,000 - \$10,000 fine
- 47

48 Dr. Nuss stated he agreed with Dr. Zachariah but wanted to provide for a gradual increase in the
49 penalty.
50

1 Mr. Tellechea suggested the following for a second offense:

- 2 • suspension to revocation
- 3 • \$7,500 - \$10,000 fine

4
5 A motion was made, seconded and carried unanimously to recommend the following disciplinary
6 guidelines:

7 First offense:

- 8 • reprimand to revocation
- 9 • \$5,000 - \$10,000 fine

10 Second offense:

- 11 • suspension to revocation
- 12 • \$7,500 - \$10,000 fine

13
14 Mr. Tellechea stated he would develop the language and present at the next meeting.
15

16 **Action taken:** set disciplinary guidelines for providing fraudulent or deceptive testimony to
17 include for first offense a reprimand to revocation and a fine of \$5,000 to \$10,000 and for a
18 second offense a suspension to revocation and a fine of \$7,500 to \$10,000
19

20 **HB 935ER.....9**

21 Ms. Tootle summarized this bill which provides that primary care providers may publish a
22 schedule of charges for medical services offered to patients. The schedule must include prices
23 charged to uninsured patients paying by cash, check, credit or debit. The schedule must be posted
24 in a conspicuous place in the reception area and include at a minimum the 50 services most
25 frequently provided on a posting at least 15 square feet in size. If a primary care provider
26 chooses to publish a schedule of charges, he or she is exempt from license fee requirements for a
27 single period of renewal and exempt from CME for a single two year period. However, If the
28 physician takes the exemption and then fails to comply with the related posting requirements, the
29 provider is required to pay the license fee and comply with CME requirements for the period in
30 which the exemption was received. Urgent care centers and clinics are required to publish the
31 schedule of charges and failure to post such a schedule shall result in a maximum fine of \$1,000
32 per day.
33

34 Dr. Nuss asked for the definition of primary care provider.
35

36 Ms. Tootle read the following from the statute:

37 "Primary care provider" means a health care provider licensed under chapter 458, chapter 459, or
38 chapter 464 who provides medical services to patients which are commonly provided without
39 referral from another health care provider, including family and general practice, general
40 pediatrics, and general internal medicine.
41

42 No action taken.
43

44 **HB 993ER.....10**

45 Mr. Tellechea explained this statute requires all state agencies to undergo a rule review exercise.
46 He explained the Board has already been through the review through OFARR and was therefore
47 exempt from undergoing this rule review except there are some additional financial impact
48 related questions that need to be asked when reviewing each rule. He said another review would
49 be done to answer the financial questions.
50

1 No action taken at this time.

2
3 **HB 1127ER.....11**

4 Ms. Tootle explained this bill which requires that an ultrasound be performed on a woman
5 obtaining an abortion and requires that the ultrasound be reviewed with the patient before the
6 patient gives informed consent for the abortion procedure. The patient has right to decline to
7 view and hear explanation of the images and if she refuses, she shall complete a form stating
8 such. An exemption from this requirement is provided if the patient is the victim of rape, incest,
9 domestic violence or human trafficking. Failure to comply with this requirement is grounds for
10 discipline. The Board is required to adopt rules to implement this law.

11
12 Mr. Tellechea suggested the Committee develop disciplinary guidelines for the violation and
13 possibly the form.

14
15 Dr. Rosenberg asked if this would be a failure to comply with a legal obligation.

16
17 Mr. Tellechea recommended the following:

18 First offense: Letter of concern to probation with a \$1,000-2,000 fine.

19 Second offense: Reprimand to suspension with a \$2,500 – 5,000 fine.

20 Third offense: Reprimand to revocation with a \$5,000 – 10,000 fine.

21
22 Dr. Nuss stated it would be valuable to develop the form.

23
24 Dr. Rosenberg suggested Mr. Tellechea work with one of the OB/GYN physicians on the Board
25 to draft the form.

26
27 Dr. Nuss agreed to work with Mr. Tellechea.

28
29 A motion was made, seconded and carried unanimously to recommend authorizing Dr. Nuss and
30 Mr. Tellechea to draft the form and to provide disciplinary guidelines to include:

31 First offense: Letter of concern to probation with a \$1,000-2,000 fine.

32 Second offense: Reprimand to suspension with a \$2,500 – 5,000 fine.

33 Third offense: Reprimand to revocation with a \$5,000 – 10,000 fine.

34
35 **Action taken:** Dr. Nuss and Mr. Tellechea to draft form

36 First offense: Letter of concern to probation with a \$1,000-2,000 fine.

37 Second offense: Reprimand to suspension with a \$2,500 – 5,000 fine.

38 Third offense: Reprimand to revocation with a \$5,000 – 10,000 fine.

39
40 **SB 1676ER.....12**

41 Ms. Tootle summarized the bill which expands sovereign immunity to include certain colleges
42 and universities when providing patient services. Certain colleges and universities that own or
43 operate a medical school, or employees or agents providing patient services pursuant to a
44 contract with a teaching hospital are agents of the teaching hospital and are immune from certain
45 liability for torts.

46
47 No action taken.

48
49 **HB 7095ER.....13**

1 Ms. Tootle summarized this bill which prohibits physicians from dispensing Schedule II or III
2 controlled substances and makes dispensing Schedule II or III controlled substances a third
3 degree felony and a ground for disciplinary action pursuant to 456.072(2).

4
5 This bill creates a new section of law, s. 456.44 dealing with controlled substance prescribing
6 and provides definitions which essentially places the Board's standard of practice for physicians
7 practicing in pain management clinics rules into statute. Physicians licensed under chapters 458,
8 459, 461 or 466 who prescribe controlled substances for the treatment of chronic nonmalignant
9 pain must designate such on the practitioner profile and are required to comply with statutory
10 standards of practice requirements and rules of the boards. The following standards of practice
11 are specified and elaborated on in 456.44(3) for any practitioner who prescribes controlled
12 substances (with the exception of board certified anesthesiologists, physiatrists, neurologists, or
13 board-certified physicians who have surgical privileges at a hospital or ambulatory surgery
14 center and primarily provides surgical services or board-certified medical specialists who also
15 completed fellowship in pain medicine and perform interventional pain procedures):

- 16 (a) Complete medical history and physical examination conducted and documented in the
17 medical record before beginning any treatment including at a minimum certain specified
18 information;
- 19 (b) Development of written individualized treatment plan for each patient with required specified
20 information;
- 21 (c) Discussion of risks and benefits of use of controlled substance and use of written controlled
22 substance agreement between physician and patient including required specified information;
- 23 (d) Regular patient visits and monitoring for evaluation of progress and consideration of risks
24 and indications of abuse or diversion.
- 25 (e) Referral of patient as necessary for additional evaluation and treatment, particularly for
26 patients at risk for misuse or diversion.
- 27 (f) Maintenance of accurate, current and complete records readily available for review which
28 include certain specified information including duplicate of prescriptions;
- 29 (g) Referral of any patient with sign or symptoms of substance abuse to board certified pain
30 management physician, addiction medicine specialist or mental health addiction facility.

31
32 An additional ground for discipline as added for violation of these standards of practice and
33 practitioners found to have inappropriately prescribed or dispensed controlled substances are
34 subject to minimum 6 months suspension and \$10,000 fine per count.

35
36 Prescriptions for controlled substances are required to be written only on a counterfeit-resistant
37 pad produced by an approved vendor or electronically prescribed.

38
39 Section 458.3265, F.S. is amended for regulation and registration of pain management clinics by
40 redefining "pain management clinic" and providing an exemption from registration for clinics
41 owned and operated by physicians or medical specialists meeting certain criteria. It revises the
42 responsibilities of physicians in pain management clinics and allows Physician Assistants (PAs)
43 and Advanced Registered Nurse Practitioners (ARNPs) to perform the physician exams. The bill
44 requires all physicians in pain management clinics to comply with specified facility and
45 operation requirements, infection control requirements, health and safety requirements, quality
46 assurance requirements and data collection and reporting requirements. All Board of Medicine
47 rule making authority and requirements except for training requirements are eliminated.

48
49 Health care practitioners who dispense controlled prescription drugs must report to the PDMP
50 within seven (7) days of dispensing a controlled substance. The bill prohibits a health care

1 practitioner from prescribing a controlled substance not medically necessary through
2 misrepresentation, fraud, etc. A material fact includes whether patient has an existing
3 prescription for a controlled substance issued for the same time period by another practitioner.
4 Penalties are established for violations. Prohibits prescribing practitioners from writing
5 prescriptions for controlled substances for which there is not medical need.

6
7 The bill requires practitioners not exempt from 465.0276 to return Schedule II-III controlled
8 substances purchased for dispensing to wholesale distributor or turn into law enforcement by
9 July 10, 2011. The bill outlines a buy-back program for physicians to sell back controlled
10 substances to wholesale distributors at purchase price paid. Wholesale distributors must report to
11 the Department of Health specified information about activities under this requirement by
12 August 1, 2011. The Surgeon General is required to declare a public health emergency. As a
13 result, the Department of Health is required to identify dispensing practitioners who pose the
14 greatest threat to public health based on non-compliance, purchase amounts and type of medical
15 practice. This must be accomplished by July 2, 2011. The Department of Health in conjunction
16 with the Office of the Attorney General, federal and local law enforcement and the Florida
17 Department of Law Enforcement must coordinate efforts to seize and destroy drug inventories
18 deemed contraband.

19
20 Mr. Tellechea reiterated that the Board’s proposed standards of practice rules for physicians
21 practicing in pain management clinics were included in HB 7095 with a few changes:

- 22 1) The standards of practice rules related only to those physicians practicing in pain
23 management clinics. The new law applies to all physicians treating chronic non-
24 malignant pain.
- 25 2) The standards of practice rule had mandatory urine testing and the law does not.
- 26 3) The law provides for dispensing limitations.
- 27 4) The law exempts certain specialty areas.

28
29 **Development of Board’s Annual Regulatory Plan.....2**

30 Mr. Tellechea explained the Governor’s Executive Order 11-72 required the Board to conduct a
31 complete review of all the Board’s current rules. He stated this review has been completed and a
32 list was provided to the members. He requested Ms. Sanford add the rules discussed at this
33 meeting to the list which include:

- 34
- 35 64B8-8.001, FAC – Disciplinary guidelines
- 36 New rule – informed consent form (to incorporate by reference)
- 37 New rule – form related to abortions (to incorporate by reference)

38
39 Ms. McNulty requested the application rules be added to the list since revisions to the Board’s
40 applications are in the rulemaking process.

41
42 Mr. Tellechea asked the members to review the list of rules provided and approve.

43
44 A motion was made, seconded and carried unanimously to recommend ratification of the rule
45 list.

46
47 A motion was made, seconded and carried unanimously to recommend drafting the regulatory
48 plan and to present it to the Chair for approval so the plan can be presented to the Governor’s
49 Office as required.

- 1 **Action taken:** rule list ratified; draft regulatory plan; obtain approval by Chair and present to
- 2 Governor's Office
- 3
- 4 The meeting adjourned at 5:05 p.m.