

1 Meeting Report
2 Department of Health
3 Board of Medicine
4 Rules/Legislative Committee Meeting
5 Renaissance Orlando Hotel
6 5445 Forbes Place
7 Orlando, FL 32812
8 (407) 240-1000
9

10 December 2, 2010

11
12 Roll Call 3:51 pm

13
14 **Members Present:**

15 Jason Rosenberg, M.D., Chair
16 Donald Mullins, Consumer Member
17 Steven Rosenberg, M.D.
18 H. Frank Farmer, M.D.
19 Michael Chizner, M.D.
20 Onelia Lage, M.D. (arrived 4:22 pm)
21 Fred Bearison, M.D. (arrived 4:02 pm)

Members Absent:

22
23 **Staff Present:**

24 Larry G. McPherson, Executive Director
25 Ed Tellechea, Board Counsel
26 Donna McNulty, Board Counsel
27 Nancy Murphy, Paralegal
28 Crystal Sanford, Administrator

Others Present:

American Court Reporting

29
30 **Rules Report – Information Only1**

31 No action necessary.

32
33 **Legislative Discussion:**

34
35 **HB 1565..... Supplemental, CD**

36 Mr. Tellechea provided an overview of the changes imposed by HB 1565. He explained the Legislature,
37 during special session, overturned a bill previously vetoed by Governor Crist. These changes were
38 effective November 17, 2010 and have a substantial effect on the rule making process. He further
39 explained the Joint Administrative Procedures Committee (JAPC) reviewed the law and found that any
40 rules not already in effect on November 17th were subject to the changes.

41
42 Mr. Tellechea went on to explain the Board previously drafted statements of estimated regulatory costs
43 (SERCs), pursuant to s. 120.54(3)(a), F.S. as part of the adoption procedures for administrative rules.
44 The changes in law now require the Board to make the following determination regarding any proposed
45 rule:

- 46
47
- 48 • Does the rule have an adverse impact on small business; or
 - 49 • Is the rule likely to “directly or indirectly increase regulatory costs in excess of \$200,000 in the
50 aggregate Florida within one year after the implementation of the rule”.

1 Mr. Tellechea said if the Board found the proposed rule met either of the above criteria, additional
2 economic analysis will be required in the SERC. This analysis would include a determination of
3 whether the proposed rule:

- 4 • Is likely to have an adverse impact on economic growth, private-sector job creation or
5 employment, or private sector investment in excess of \$1 million in the aggregate within 5 years
6 after the implementation of the rule;
- 7 • Is likely to have an adverse impact on business competitiveness, including the ability of persons
8 doing business in the state to compete with persons doing business in other states or domestic
9 markets, productivity or innovation in excess of \$1 million in the aggregate within 5 years after
10 the implementation of the rule;
- 11 • Is likely to increase regulatory costs, including any transactional costs, in excess of \$1 million in
12 the aggregate within 5 years after the implementation of the rule;

13
14 He went on to say if the Board finds the SERC demonstrates the proposed rule has an impact that meets
15 or exceeds the criteria established above, it must be presented to the Florida Legislature by February 4,
16 2011 for ratification. In preparation for this, staff is setting up three conference calls in January to allow
17 the Board to timely review SERCs prepared on proposed rules.

18
19 Dr. S. Rosenberg asked how the change in law effects the inspections of pain management clinics..

20
21 Mr. McPherson stated Department of Health investigators started inspections in November, a month
22 after the on pain clinics, SB 2272, law went into effect. That law provided authority for the Department
23 to inspect pain management clinics for compliance with the statutory provisions and for compliance with
24 standards of practice rules developed by the boards of Medicine and Osteopathic Medicine. The
25 purpose of the inspection going on now is to determine a pain management clinic's compliance with the
26 law (s. 458.3265, F.S.). He said the fee is being charged now.

27
28 Dr. S. Rosenberg asked if a second inspection would be conducted if the rule was ratified by the
29 Legislature and if a second fee would be charged.

30
31 Mr. McPherson stated a second inspection would be conducted to determine a clinic's compliance with
32 the rule. He said a second fee would not be charged.

33
34 Mr. Mullins asked who would be making the decisions necessary to complete the enhanced SERC.

35
36 Mr. McPherson stated the Department is in the process of retaining an economist to draft the enhanced
37 SERCs that would then be presented to the Board for approval.

38
39 Mr. Mullins asked who paid the cost of the economist.

40
41 Mr. McPherson stated if the proposed rule was a Board of Medicine rule, then the Board would bear the
42 cost.

43
44 **Rules Discussion:**

45
46 **Rule 64B8-8.001, FAC – Disciplinary Guidelines2**

47 Mr. Tellechea stated the Committee previously approved the rule language which provides disciplinary
48 guidelines for new violations and found that a SERC was necessary because the proposed rule had an

1 economic impact on small business. He explained by statute the Board has authority to set the range of
2 penalties for violations imposed by statute.

3
4 Mr. McPherson asked whether the disciplinary guidelines set a range of penalties within the maximum
5 penalties established by statute constitutes an adverse impact?

6
7 After discussion, a motion was made to recommend rescinding the previous determination this proposed
8 rule imposes an adverse impact on small business and further makes the determination that this proposed
9 rule is not likely to “directly or indirectly increase regulatory costs in excess of \$200,000 in the
10 aggregate Florida within one year after the implementation of the rule” and to request an enhanced
11 SERC.

12
13 Mr. Mullins stated the infrastructure is already in place for the prosecution of practitioners who break
14 the law and no new staff is required as a result of setting penalties for violations of the law.

15
16 The motion was seconded.

17
18 Bradley Levine, Consumer Member on the Board, addressed the Committee and asked for the definition
19 of ‘adverse impact on small business’ because changes in the rule could have a positive impact as well.
20

21 Mr. Tellechea stated the law only addresses adverse impact.

22
23 Mr. Mullins commented that positive impact should be taken into account when determining adverse
24 impact.

25
26 Mr. Tellechea advised the statute does not so provide.

27
28 The motion carried unanimously.
29

30 **Recommendation:** rescinding the previous determination this proposed rule imposes an adverse impact
31 on small business and further makes the determination that this proposed rule is not likely to “directly or
32 indirectly increase regulatory costs in excess of \$200,000 in the aggregate Florida within one year after
33 the implementation of the rule; request enhanced SERC. No SERC is necessary.
34

35 **Rule 64B8-9.0134, FAC – Maximum Number of Prescriptions in Registered Pain**
36 **Management Clinics3**

37 Mr. Tellechea explained this proposed rule was previously approved by the Board of Medicine and
38 Osteopathic Medicine Joint Standards of Practice for Physicians Practicing in Pain Management Clinics
39 Committee. This rule provides the maximum number of controlled substance prescriptions that can be
40 written in a pain management clinic in a 24-hour period of time.
41

42 A motion was made, seconded and carried unanimously to recommend approval of the proposed rule
43 language.
44

45 After discussion, a motion was made, seconded and carried unanimously to recommend rescinding the
46 previous SERC prepared based on prior laws regarding SERC requirements. Finding in the affirmative
47 that this proposed rule imposes either an adverse impact on small business and or this proposed rule is
48 likely to “directly or indirectly increase regulatory costs in excess of \$200,000 in the aggregate Florida
49 within one year after the implementation of the rule” and to request an enhanced SERC.
50

1 **Recommendation:**

- 2 1. Approve language; and
- 3 2. Rescind the previous SERC prepared.
- 4 3. Request enhanced SERC

5
6 **Rule 64B8-9.0133, FAC – Approval of Nationally Recognized Physician Pain**

7 **Management Accrediting Organizations.....4**

8 Mr. Tellechea explained this proposed rule was previously approved by the Board of Medicine and
9 Osteopathic Medicine Joint Standards of Practice for Physicians Practicing in Pain Management Clinics
10 Committee. The rule provides the criteria for which nationally recognized accrediting organizations
11 must meet in order to be approved as an accrediting organization for Florida registered pain
12 management clinics.

13
14 Ms. McNulty advised the Committee that one of the national accrediting organizations stated they would
15 have to have to significantly revise their processes to meet the standards of the proposed rule.

16
17
18 A motion was made, seconded and carried unanimously to recommend approval of the proposed rule
19 language.

20
21 After discussion, a motion was made, seconded and carried unanimously to recommend rescinding the
22 previous SERC prepared based on prior laws regarding SERC requirements. Finding in the affirmative
23 that this proposed rule imposes either an adverse impact on small business and or this proposed rule is
24 likely to “directly or indirectly increase regulatory costs in excess of \$200,000 in the aggregate Florida
25 within one year after the implementation of the rule” and to request an enhanced SERC.

26
27 Mr. Mullins stated he was against the motion because physicians have an option to undergo a
28 Department inspection or be accredited by a national organization.

29
30 After additional discussion, the motion carried unanimously.

31
32 **Recommendation:**

- 33 1. Approve language; and
- 34 2. Rescind the previous SERC prepared.
- 35 3. Request enhanced SERC

36
37 **Rule 64B8-1.007, FAC – Forms (Data Reporting Form for Pain Management Clinics) 5**

38 Mr. Tellechea explained this form was previously approved by the Committee as an option for
39 designated physicians in pain management clinics to utilize when reporting the required data on a
40 quarterly basis. He explained draft rule language will be presented at the next meeting, but asked the
41 Committee to make a recommendation regarding the SERC.

42
43 A motion was made, seconded and carried unanimously to recommend finding this rule has no impact
44 on small business and is not likely to “directly or indirectly increase regulatory costs in excess of
45 \$200,000 in the aggregate Florida within one year after the implementation of the rule”

46
47 **Recommendation:** find this proposed rule does not impose an adverse impact on small business and is
48 not likely to “directly or indirectly increase regulatory costs in excess of \$200,000 in the aggregate
49 Florida within one year after the implementation of the rule” No enhanced SERC.

1 **Area of Critical Need - JAPC Letter.....6**

2 Ms. McNulty summarized issues presented by the JAPC regarding Rules 64B8-4.009 and 64B8-1.007,
3 FAC.

4
5 Mr. McPherson explained that physician assistant applications will be going online, but affidavits can be
6 submitted electronically.

7
8 After discussion, a motion was made, seconded and carried unanimously to recommend finding this rule
9 has no impact on small business and is not likely to “directly or indirectly increase regulatory costs in
10 excess of \$200,000 in the aggregate Florida within one year after the implementation of the rule”

11
12 **Recommendation:** find this proposed rule does not impose an adverse impact on small business and is
13 not likely to “directly or indirectly increase regulatory costs in excess of \$200,000 in the aggregate
14 Florida within one year after the implementation of the rule” No enhanced SERC.

15
16 **Pain Management Clinics Training Requirements Supplemental(1)**

17 Mr. Tellechea reminded the Committee that the Board, following a rule hearing, redacted the training
18 requirements from Rule 64B8-9.0131, FAC Standards of Practice for Physicians Practicing in Pain
19 Management Clinics. He explained the ramifications of not including training requirements in the
20 proposed rule language at this time. He also stated the Board of Osteopathic Medicine rule went into
21 effect on November 8, 2010.

22
23 Dr. Bearison stated the reason the Board redacted the training requirements was to do additional
24 research on the requirements to be become board certified in the four additional specialties added to the
25 Osteopathic companion rule.

26
27 Ms. Sanford stated the research had not been completed.

28
29 Dr. Bearison suggested considering the Osteopathic language.

30
31 Dr. Farmer said he thought the program would be inoperable if the MD and DO rules were not the same.

32
33 A motion was made and seconded to have Mr. Tellechea draft language that would include training
34 requirements similar to the Osteopathic language and to present at one of the January conference calls
35 for approval and to request an enhanced SERC.

36
37 Chris Nuland, Esquire, representing the Florida Chapter of the American College of Physicians,
38 addressed the Committee and supported the motion on the table.

39
40 Mr. McPherson explained the Department’s inspection process. He said that when the inspecting
41 standard of practices rules, Department investigators will go into the clinics and ensure the clinic meets
42 the requirements of the rules. The Department inspection teams are planning to have clinicians assist in
43 reviewing medical records. He updated the Committee on the Department’s recruitment of physicians
44 to serve as clinician inspectors. He explained the Department is looking for active, Medical or
45 Osteopathic physicians who are board certified and have experience in prescribing controlled
46 substances. The physician reviewers would be under contract with the Department.

47
48 Dr. S. Rosenberg asked how many physicians have expressed interest.

1 Mr. McPherson stated over 100 physicians. He said we will be reviewing the applications soon and the
2 Department may determine at a later time that Medical and Osteopathic physicians are not necessary and
3 other professions can be utilized.

4
5 Bob Coats with Symedica addressed the Committee regarding the confusion that could be generated if
6 the Medical rule does not mirror the Osteopathic rule when a Medical doctor and an Osteopathic
7 physician are practicing in the same clinic. The speaker also raised the issue of the Board using an
8 emergency process to put the rule in place.

9
10 The Committee discussed whether the use of emergency rule making would be appropriate. Following a
11 discussion of the requirements for emergency rulemaking including being able to demonstrate whether
12 the situation, which has been in the process of rulemaking and public hearings since August 2009, could
13 now meet the immediate and imminent danger requirements, the Committee did not recommend
14 emergency rulemaking.

15
16 Maureen Kielian representing the Florida Health Information Management Association addressed the
17 Committee and offered the assistance of the Association who are medical record specialists.

18
19 Ms. Kielian was asked to provide written material for the Committee’s consideration.

20
21 The motion carried unanimously.

22
23 **Recommendation:** draft language that would include training requirements similar to the Osteopathic
24 companion language and to present at one of the January conference calls for approval and to request an
25 enhanced SERC

26
27 **DISCUSSION REGARDING SERCS:**

28
29 Mr. Tellechea explained the following proposed rules were previously approved by the Committee and
30 were being returned for the Committee to make a determination about the enhanced SERC for each
31 proposed rule.

32
33 **Rule 64B84.029, FAC - Registration as a Dispensing Physician; Delegation of Dispensing**
34 **to Prescribing Physician Assistants..... Supplemental (2)**

35 Mr. Tellechea explained this proposed rule amendment language incorporates with reference a form
36 used for supervising physicians to advise the Board dispensing authority has been delegated to a
37 physician assistant that he/she supervises.

38
39 A motion was made, seconded and carried unanimously to recommend finding this rule has no impact
40 on small business and is not likely to “directly or indirectly increase regulatory costs in excess of
41 \$200,000 in the aggregate Florida within one year after the implementation of the rule”

42
43 **Recommendation:** find this proposed rule does not impose an adverse impact on small business and is
44 not likely to “directly or indirectly increase regulatory costs in excess of \$200,000 in the aggregate
45 Florida within one year after the implementation of the rule”

46
47 **Rule64B8-1.007, FAC – List of Approved Forms; Incorporation..... Supplemental (2)**

48 Mr. Tellechea explained this proposed rule amendment accomplishes the same task in the previous tab
49 but incorporates the form into the forms rule.

1 A motion was made, seconded and carried unanimously to recommend finding this rule has no impact
2 on small business and is not likely to “directly or indirectly increase regulatory costs in excess of
3 \$200,000 in the aggregate Florida within one year after the implementation of the rule”
4

5 **Recommendation:** find this proposed rule does not impose an adverse impact on small business and is
6 not likely to “directly or indirectly increase regulatory costs in excess of \$200,000 in the aggregate
7 Florida within one year after the implementation of the rule” No enhanced SERC.
8

9 **Rule 64B8-30.00, FAC – Physician Assistant Licensure Supplemental (2)**

10 Mr. Tellechea explained this proposed rule amendment also accomplishes the same task in the previous
11 tab but incorporates the form into the PA licensure rule.
12

13 A motion was made, seconded and carried unanimously to recommend finding this rule has no impact
14 on small business and is not likely to “directly or indirectly increase regulatory costs in excess of
15 \$200,000 in the aggregate Florida within one year after the implementation of the rule”
16

17 **Recommendation:** find this proposed rule does not impose an adverse impact on small business and is
18 not likely to “directly or indirectly increase regulatory costs in excess of \$200,000 in the aggregate
19 Florida within one year after the implementation of the rule” No enhanced SERC.
20

21 **Rule 64B8-8.018, FAC – Voluntary Relinquishment of License Supplemental (2)**

22 Mr. Tellechea explained this proposed rule amendment adds obligations as a basis for denying a
23 physician’s request to administratively voluntarily relinquish his/her license.
24

25 A motion was made, seconded and carried unanimously to recommend finding this rule has no impact
26 on small business and is not likely to “directly or indirectly increase regulatory costs in excess of
27 \$200,000 in the aggregate Florida within one year after the implementation of the rule”
28

29 **Recommendation:** find this proposed rule does not impose an adverse impact on small business and is
30 not likely to “directly or indirectly increase regulatory costs in excess of \$200,000 in the aggregate
31 Florida within one year after the implementation of the rule” No enhanced SERC.
32

33 **Rule 64B8-31.010, FAC – AA Disciplinary Guidelines Supplemental (2)**

34 Mr. Tellechea explained the Anesthesiology Assistant Joint Committee had previously approved
35 proposed language that set forth disciplinary guidelines for new violations imposed by statute.
36

37 A motion was made, seconded and carried unanimously to recommend finding this rule has no impact
38 on small business and is not likely to “directly or indirectly increase regulatory costs in excess of
39 \$200,000 in the aggregate Florida within one year after the implementation of the rule”
40

41 **Recommendation:** find this proposed rule does not impose an adverse impact on small business and is
42 not likely to “directly or indirectly increase regulatory costs in excess of \$200,000 in the aggregate
43 Florida within one year after the implementation of the rule” No enhanced SERC.
44

45 **Legislative Discussion:**

46
47 **HB 25 Supplemental**

48 Mr. McPherson summarized the bill which relates to mammography reports reflecting a finding of dense
49 breast tissue and information that must be included if a copy is provided to the patient.
50

1 After discussion, a motion was made, seconded and carried unanimously to recommend remaining
2 neutral on this bill.

3

4 **Recommendation:** remain neutral

5

6 **New Business** **No tab**

7 There being no further business, the meeting adjourned at 5:28 p.m.