

1 **Florida Board of Medicine**
2 **Board of Medicine Surgical Care/Quality Assurance Committee**
3 **Meeting Report**
4

5
6 **Marriott Orlando Airport**
7 **7449 Augusta National Drive**
8 **Orlando, FL 32822**
9 **(407) 851-9000**
10

11 **December 1, 2011**
12

13
14 Roll call 4:15 p.m.
15

16 **MEMBERS PRESENT:**

- 17 Jason Rosenberg, M.D., Chair
- 18 James Orr, M.D. (arrived 4:20)
- 19 Trina Espinola, M.D.
- 20 Fred Bearison, M.D.
- 21 Robert Nuss, M.D.
- 22 Nabil El Sanadi, M.D.

MEMBERS NOT PRESENT:

- Brigitte Goersch, Consumer Member

23
24 **STAFF PRESENT:**

- 25 Joy A. Tootle, J.D., Executive Director
- 26 Ed Tellechea, Board Counsel
- 27 Donna McNulty, Board Counsel
- 28 Nancy Murphy, Paralegal
- 29 Crystal Sanford, Program Operations Administrator

OTHERS PRESENT:

- Cindy Green, American Court Reporting

30
31 **PETITION FOR WAIVER/VARIANCE:**

32
33 **Sreenivas Vangara, M.D. RE: Rule 64B8-9.009, FAC1**

34 Dr. Vangara was not present in the room when called. The matter was tabled to allow
35 him time to arrive to the meeting.
36

37 **RULES:**

38
39 **Rule 64B8-9.007, FAC – Standards of Practice (Pause Rule)2**

40 Dr. El Sanadi outlined his presentation to the Committee and recommended changing
41 language in the rule to require the physician to simultaneously confirm the surgery with
42 another member of the surgical team. He then reviewed the form entitled “Universal
43 Protocol for Time-Out” which could be used to confirm the correct patient, the
44 procedure, the side, and the site. The form is then signed by the physician and the RN
45 then reviewed and signed by the charge nurse.
46

1 Dr. Nuss stated he supported the changes but is also concerned about obtaining a verbal
2 confirmation from patients.
3
4 Dr. Rosenberg suggested adding a requirement for patient identification.
5
6 Dr. El Sanadi suggested the requirement not be too specific and require only two items
7 such as the name and something else.
8
9 Dr. Espinola said she liked the concept and the form, but suggested changing the “RN” to
10 “surgical team member”. She also expressed some concern regarding patient
11 identification and suggested not making it too difficult to comply. She provided an
12 example of a police officer being treated under an alias.
13
14 Dr. Orr also liked the form and the concept. His concern centered more on the physician
15 leaving the room after the time-out has been completed. He said the surgeon should not
16 leave the room once the time-out has been performed.
17
18 Mr. Tellechea said the rule requires the time-out to be done immediately prior to the
19 initiation of the surgery.
20
21 Dr. Orr suggested the language be more specific.
22
23 Dr. El Sanadi suggested “simultaneous real time confirmation immediately prior to”.
24
25 Dr. Espinola said the wrong site cases the Board has seen recently involve physicians
26 who did not perform the time-out or the physician left the room. She said the physician
27 should reorient him/herself to the patient upon return. She was not sure the rule needs
28 revising.
29
30 Mr. Tellechea said if the Committee wanted to be more specific he would need language
31 like: to clarify, if at any point the surgeon leaves, he/she must do another time-out before
32 surgery begins.
33
34 Dr. Orr said, do the time-out, leave the room, do it again.
35
36 Mr. Tellechea said he would work on language to present at the next meeting.
37
38 Dr. El Sanadi also suggested changing the verbal confirmation portion of the rule with
39 the language he provided earlier.
40
41 Mr. Tellechea stated “simultaneous” was not clear enough, but he would work on some
42 language for that portion of the rule as well.
43
44 Dr. Nuss said he would like to see the language regarding patient verbal confirmation
45 revised.
46

1 Mr. Tellechea said he would work on language and consult with Dr. El Sanadi.

2

3 Dr. Nuss also suggested the part of the rule regarding a physician delegate, in
4 subparagraph (4), require the delegate accept that delegation in writing.

5

6 Dr. El Sanadi asked how that would affect Fellows or Residents when they take over for
7 the physician during surgery.

8

9 Dr. Nuss explained in those circumstances the Board has been holding the supervising
10 physician responsible for the wrong site surgery.

11

12 **Action taken:** draft recommended changes to the rule to be presented at the next
13 meeting; Mr. Tellechea will consult with Dr. El Sanadi on rule language

14

15 **PETITION FOR WAIVER/VARIANCE:**

16

17 **Sreenivas Vangara, M.D. RE: Rule 64B8-9.009, FAC1**

18 Dr. Vangara was present but not represented by counsel. He was petitioning for
19 permanent waiver or variance of the rule. He explained his practice and asked that he not
20 be required to maintain the required 36 ampules of dantrolene on his crash cart.

21

22 The Committee questioned Dr. Vangara regarding various aspects of his practice.

23

24 Dr. Espinola did not want to grant the waiver but said she would consider changing the
25 rule.

26

27 A motion was made to deny the petition for waiver or variance of the rule.

28

29 Dr. Rosenberg asked Dr. Vangara to participate in revision of the rule language and told
30 the Committee he wanted to do something to help him. He asked when the dantrolene he
31 has on hand expired.

32

33 Dr. Vangara said it would expire in the next month.

34

35 Mr. Tellechea suggested granting a temporary waiver or variance then go into
36 rulemaking.

37

38 The motion was withdrawn.

39

40 Dr. Bearison asked if anyone knew why it was in the rule in the first place.

41

42 Mr. Tellechea said he was not Board Counsel when the rules went into effect, but it
43 appears that there is new information out now regarding non-triggering agents.

44

1 A motion was made, seconded and carried unanimously to recommend granting the
2 petition with the following restrictions: perform endoscopic procedures only on adults
3 using specific non-triggering agents for one year.

4
5 Mr. Tellechea said he would bring proposed language to the next meeting.

6
7 Dr. Espinola said she would consult with Mr. Tellechea but suggested the language cover
8 three areas:

- 9 • must obtain a detailed family history of the patient
- 10 • perform the procedure on patients over 21 years of age
- 11 • list the specific agents

12
13 Dr. Vangara asked if he would receive something in writing that he could provide to the
14 inspectors.

15
16 Mr. Tellechea informed Dr. Vangara that he would be sent an Order.

17
18 Ms. Sanford said she would ensure the inspectors know his petition for waiver or
19 variance was approved.

20
21 **Action taken:** recommend granting petition with specific conditions, rulemaking to
22 change rule to eliminate requirement for 36 ampules dantrolene in certain circumstances

23
24 **Rule 64B8-9.009, FAC – Standard of Care for Office Surgery3**

25 At a previous meeting, the Committee approved changes to this rule incorporating the
26 American Society of Anesthesiologist’s Standards for Basic Anesthetic Monitoring
27 (Standards) and the latest update was in 2005. In updating the rule, the wrong standards
28 were named in the rule. In addition, Mr. Tellechea needed a physician member to consult
29 with him to ensure the standards in the rule are consistent.

30
31 Mr. Tellechea stated he has not had a chance to work with Dr. Nuss on this matter and
32 asked the Committee to table this until the next meeting.

33
34 **Action taken:** tabled until next meeting

35
36 **DISCUSSION**

37
38 **Provisional Approval of Institute of Medical Quality (IMQ)4**

39 Ms. Sanford explained IMQ was granted a 1-year provisional accreditation status. She
40 said the year is up and none of the registered offices are accredited by this organization.
41 She asked for direction on how to proceed.

42
43 A motion was made, seconded and carried unanimously to recommend the accreditation
44 status expired.

45

1 Mr. Tellechea stated the organization will need to be removed from the rule and asked
2 that it be scheduled for the next meeting.

3
4 **Plastic Surgery Statistics5**

5 Dr. Rosenberg said there have been articles recently regarding surgeries performed in
6 offices resulting in deaths. He asked Board staff to conduct research to determine if the
7 rules are not adequate or the physician did not follow the rules. After receiving the data,
8 he felt the rules were adequate and no additional research needs to be conducted.

9
10 Dr. El Sanadi agreed with Dr. Rosenberg's assessment.

11
12 Dr. Rosenberg thanked Board staff for the extensive research.

13
14 No action necessary.

15
16 **Universal Protocol for Time Out (El Sanadi).....6**

17 This tab was discussed in conjunction with tab 2.

18
19 No action necessary.

20
21 **New Business**

22
23 Ms. Sanford stated she received an email from Rachel Springer, one of the Department's
24 contracted risk managers that perform the office inspections. Ms. Springer wanted
25 clarification on whether the administration of nitrous oxide to administer Botox or dermal
26 fillers like collagen on an anxious patient is considered Level I office surgery.

27
28 Mr. Tellechea said the physician needs to submit a petition for declaratory statement
29 which will include more information on which the Committee can base a decision.

30
31 Dr. Espinola stated the procedures are Level I, but nitrous is more.

32
33 No action necessary.

34
35 The meeting adjourned at 4:58 p.m.