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3 **Florida Board of Medicine**
4 **Board of Medicine Surgical Care/Quality Assurance Committee**
5 **Agenda**
6 **Gaylord Palms Resort & Convention Center**
7 **6000 West Osceola Parkway**
8 **Kissimmee, FL 34746**
9 **407-586-0322**
10 **February 2, 2012**

11
12 Roll call 5:00 pm

13
14 **Members Present:**

15 James Orr, M.D., Chairman
16 Fred Bearison, M.D.
17 Robert Nuss, M.D.
18 Brigitte Goersch, Consumer Member (arrived 5:05)
19 Nabil El Sanadi, M.D.

20
21 **Members Absent:**

Trina Espinola, M.D.

22 **Staff Present:**

23 Joy A. Tootle, JD, Executive Director
24 Ed Tellechea, Board Counsel
25 Donna McNulty, Board Counsel
26 Nancy Murphy, Paralegal
27 Crystal A. Sanford, Program Operations Administrator

28 **Others Present:**

American Court Reporting

29
30 **RULES:**

31 **Rule 64B8-9.007, FAC – Standards of Practice (Pause Rule)1**

32 The Committee reviewed proposed draft changes to the rule which would require
33 surgeons to complete a second pause if the surgeon leaves the room after the original
34 pause was completed.

35 Dr. El Sanadi suggested the language in 2(b) be amended to require the licensee
36 completing the procedure plus one additional licensed health care practitioner to
37 simultaneously verify the site, side, person and procedure.

38
39 Dr. Nuss expressed concern regarding the “and in writing” portion of the rule. He said
40 there needs to be documented confirmation.

41
42 Mr. Tellechea confirmed Dr. Nuss was asking for verbal confirmation and documentation
43 of the confirmation. He then confirmed Dr. El Sanadi’s suggestion for two licensees to
44 use two identifiers.

1 Mr. Tellechea stated he would need to work on the language and bring it back at the next
2 meeting.

3
4 A motion was made to table this matter until the next meeting.

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6 Mr. Tellechea asked the Committee if the proposed language in section 2(d) was
7 approved.

8
9 Dr. El Sanadi suggested adding the word ‘if’ so it would read, “... if the physician(s)
10 leaves the room

11
12 Dr. Nuss expressed concern regarding the language in section 4.

13
14 Dr. El Sanadi suggested he work with Mr. Tellechea on 2(b) and Dr. Nuss work with him
15 on section 4.

16
17 Christopher Nuland, Esquire, representing the American College of Surgeons, expressed
18 concern about requiring a licensee, other than a physician, complete the confirmation.

19
20 Mr. Tellechea advised the Committee that section 4 was the subject of a rule challenge
21 when it was promulgated.

22
23 The motion was seconded and carried unanimously.

24
25 **Action taken:** table until next meeting; Mr. Tellechea and Dr. El Sanadi work on
26 language

27
28 **Rule 64B8-9.009, FAC – Standard of Care for Office Surgery2**

29 The Committee review proposed draft changes to the rule which would remove the
30 requirement for offices to maintain 36 vials of dantrolene on the crash cart if the
31 following conditions have been met:

- 32
- 33 • The patient is at least 21 years of age and has a negative family history of
malignant hyperthermia (MH);
 - 34 • The patient has previously been under general anesthesia without having an MH
35 reaction;
 - 36 • The facility does not have an anesthetic machine on premises; and
 - 37 • Succnylcholine, halothane, enflurane, isoflurane, desflurane, sevoflurane, ether,
38 methoxyflurane, and cyclopropane, all MH triggering agents, are not used.
- 39

40 A motion was made, seconded and carried unanimously to recommend approval of the
41 proposed language.

42
43 A motion was made, seconded and carried unanimously to find the proposed changes to
44 the rule would not have an adverse impact on small business nor will it be likely to
45 directly or indirectly increase regulatory costs to any entity in excess of \$200,000 in the
46 aggregate in Florida within one year after the implementation of the rule amendments.

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Dr. Orr said Ms. Tootle received an email from Randy Langsam concerning a national backorder of emergency pharmaceuticals. His email asked whether it was permissible to use expired medications and if a physician could be subject to discipline for having expired medications, using expired medications or having expired medications on the crash cart.

Dr. Nuss said it is challenging, but it happens and physicians deal with it every day.

Dr. El Sanadi agreed and said there is usually more than one medication that can be used.

Mr. Tellechea reminded the Committee the rule provides a list of medications that must be maintained on a crash cart in an office surgery setting. He said if an inspector goes into the office and find medications such as those outlined in the email, the physician would be held accountable.

Dr. Bearison said the Board could not condone the use of expired medications. He said the Board would need to handle that on a case by case basis and could not issue blanket statements in response to the email.

Ms. Tootle advised she would correspond with Mr. Langsam.

Allen Grossman, Esquire, addressed the Committee and asked how long surgical logs were required to be maintained.

Renee Alsobrook, Chief, Prosecution Services Unit, advised the Committee the surgical log could be used in litigation against a physician.

A motion was made to require the logs be maintained for six years. The motion died.

A motion was made and seconded to require the logs be maintained for three years. This motion also failed with only one in support.

Dr. Bearison suggested it was reasonable to maintain the logs the same time a medical record is required to be maintained.

Mr. Tellechea stated by Board rule, medical records must be maintained for five years; medical malpractice law requires seven years and the statute of limitations to take discipline against a physician is six years.

A motion was made, seconded and carried unanimously to recommend surgical logs be maintained for six years.

Mr. Tellechea advised he would bring proposed language to the next meeting.

1 **Action taken:** proposed language approved, no statement of estimated regulatory costs
2 (SERC) required; amend rule to require surgical logs be maintained for six years; bring
3 language to next meeting

4
5 **ASA Definition of General Anesthesia and Levels of Sedation.....4**

6 Staff has seen an increase in calls regarding the new requirement under Rule 64B8-9.009,
7 FAC related to “any alteration of consciousness”. Staff asked if providing the document
8 entitled, “Continuum of Depth of Sedation: Definition of General Anesthesia and Levels
9 of Sedation/Analgesia”, approved by the ASA House of Delegates in 2004 and amended
10 in 2009 would be permissible and not in contradiction to the rule.

11
12 Mr. Tellechea said that would be non-rule policy.

13
14 Dr. Bearison said the Board needs to give physicians guidance.

15
16 A motion was made and seconded to recommend incorporating the document into the
17 rule.

18
19 Mr. Grossman addressed the Committee and said this would become the standard for
20 altered states.

21
22 Mr. Tellechea suggested tabling this matter until he can consult with an anesthesiologist
23 and will bring language back to the next meeting for discussion.

24
25 The motion carried unanimously but was clarified the changes will make the rule
26 consistent.

27
28 A motion was made, seconded and carried unanimously to recommend authorizing Mr.
29 Tellechea to notice the rule for development.

30
31 **Action taken:** notice rule for development; consult with anesthesiologist regarding
32 incorporating the document, “Continuum of Depth of Sedation: Definition of General
33 Anesthesia and Levels of Sedation/Analgesia” into the rule and bring language back to
34 next meeting

35
36 **Rule 64B8-9.0092, FAC – Approval of Physician Office Accrediting Organizations. 3**

37 The Committee reviewed the draft proposed changes to this rule which would remove the
38 Institute of Medical Quality (IMQ) as an organization approved to accredit offices
39 performing surgery. IMQ was given a one-year temporary approval. During the year,
40 IMQ did not accredit any offices performing surgery in Florida.

41
42 A motion was made, seconded and carried unanimously to recommend removing IMQ
43 from the rule as an approved accrediting organization.

44
45 A motion was made, seconded and carried unanimously to find the proposed change to
46 the rule would not have an adverse impact on small business nor will it be likely to

1 directly or indirectly increase regulatory costs to any entity in excess of \$200,000 in the
2 aggregate in Florida within one year after the implementation of the rule amendment.

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4 **Action taken:** proposed draft language approved; no SERC

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6 **DISCUSSION:**

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8 **Correspondence from Kristal Langner, Health & Safety Institute5**

9 Ms. Langer sent a letter to the Board requesting continued approval of the ACLS and
10 BLS courses offered by the American Health & Safety Institute as meeting the
11 requirements of the office surgery rules.

12
13 A motion was made and seconded to recommend issuing a statement that as long as the
14 courses comply with the American Heart Association standards and guidelines for
15 resuscitation as updated; then the courses meet the requirements of the office surgery
16 rule.

17
18 The motion was later withdrawn.

19
20 Jennifer Benedict, Licensed Risk Manager, addressed the Committee and said the Board
21 approved AHSI in the past and their standards are different than those of the American
22 Heart Association.

23
24 A motion was made, seconded and carried unanimously to recommend tabling this matter
25 until further research can be conducted and to invite a representative from AHSI to
26 explain their standards.

27
28 **Action taken:** table until staff can confirm AHSI meets the American Heart
29 Association's standards and guidelines; representative from AHSI attend next meeting to
30 explain their standards

31
32 **New BusinessNo tab**

33 Dr. El Sanadi asked Ms. Goersch to explain how the pilot and co-pilot interact in a plane
34 related to safety procedures.

35
36 Ms. Goersch explained pilots use the verify action technique. She suggested the use of
37 two separate methods of verification when performing the pause rule.

38
39 **New BusinessNo tab**

40 Dr. Orr discussed the relationship between a proctor and the physician in robotic surgery
41 when one of the two is in another state. He asked if that was the practice of medicine and
42 suggested the Committee look at the telemedicine rule.

43
44 Dr. El Sanadi said it was the practice of medicine.

1 Ms. Goersch suggested the Committee look at what is happening on a national level
2 regarding telemedicine before making changes to the existing rule.

3

4 Mr. Tellechea said there are two issues:

5 1. A physician in another state and telling a Florida physician how to perform a
6 procedure

7 2. A physician comes to Florida and tells a Florida physician how to perform a
8 procedure

9

10 Dr. Orr suggested there was a third issue and that was unlicensed physicians.

11

12 A motion was made, seconded and carried unanimously to recommend tabling this matter
13 until the next meeting.

14

15 **Action taken:** schedule telemedicine rule next meeting; research what is happening on
16 national level

17

18 The meeting adjourned at 6:00 pm