VIRGINIA BOARD OF MEDICINE
AD HOC COMMITTEE OF THE BOARD OF MEDICINE ON ETHICS MINUTES

Friday, February 25, 2005 Department of Health Professions Richmond, VA

CALL TO ORDER: The meeting of the Board convened at 1:11 p.m.

MEMBERS PRESENT:
Malcolm Cothran, M.D., Chair
Claudette Dalton, M.D.
Melvin Johnson, M.D.
Shane Kraus, M.D.
Bonnie McQuaid, RRT
Dianne Reynolds-Cane, MD

MEMBERS ABSENT:
Harry C. Beaver, M.D.
Stephen E. Heretick, JD

STAFF PRESENT:
William L. Harp, M.D., Executive Director
Barbara Matusiak, M.D., Medical Review Coordinator
Ola Powers, Deputy Executive Director of Licensure
Karen Perrine, Deputy Executive Director of Discipline
Elaine Yeatts, DHP Senior Policy Analyst
Colanthia Morton Opher, Recording Secretary

OTHERS PRESENT:
Mike Jurgensen, Medical Society of Virginia
Scott Johnson, Medical Society of Virginia

Approval of Minutes of April 9, 2004 Meeting

Dr. Kraus moved to approve the minutes of April 9, 2004. The motion was seconded and carried.

Adoption of Agenda

Dr. Kraus moved to adopt the agenda. The motion was seconded and carried.

Public Comment on Agenda Items

There was no public comment.

Review of Public Comments

Ms. Yeatts provided a summary and copy of all the public comments received. She explained the discrepancy in the numbering of the proposed regulations. Ms. Yeatts advised that there were 14 people that posted comments regarding the off-label use of medication and requested an amendment to the regulations requiring a practitioner to include the disclosure of all notices, warnings, adverse reactions with "off-label" use of such medications and that specific informed consent be obtained prior to their use. Ms. Yeatts also informed the Board that there were two other individuals who posted comments opposing any such amendment by the Board.

First Comment

Dr. Kraus stated that the general public doesn't understand the difference between the medical practice and the FDA marketing allowances for the pharmaceutical industries. Dr. Kraus stated that "off-label" means the pharmaceutical company was directed that they could not use any drug not on the list published for marketing.

Dr. Reynolds-Cane noted that §54.1-3303 deals with prescribing medications in any physician/patient relationship and stated that the language in this code section addresses the "off-label" concern.

After discussion, the Board agreed that it was not necessary to amend the regulations as suggested. Dr. Reynolds-Cane moved that no amendment is necessary based on the comment. The motion was seconded and carried.

Second Comment

Ms. Yeatts advised that the commenter submitted several comments regarding 18VAC 85-20:

(C) <u>The words "properly" and "complete" are vague and ambiguous</u>. Dr. Kraus stated neither needed to be further defined. After discussion of the word "properly" the Board agreed.

(E) <u>Does the proposed "posting" have some more details to it</u>? Dr. Reynolds-Cane advised the intent of the committee was to allow the practitioner to post the information based on reasonable accommodations meeting the Board's requirement. Dr. Dalton moved that the committee has considered the comment and does not feel that there is a need for an amendment. The motion was seconded and carried.

<u>18 VAC 85-20-23 Confidentiality</u> – Ms. Yeatts advised that the commenter is asking the Board to spell out which laws are applicable since there are many regulatory agencies that require the release of information and it is not clearly reflected in this section. Ms. Perrine advised that the Board is unable to spell out which laws are applicable and that laws today could be repealed, amended, etc. and it would be difficult to make sure that this law was all inclusive. Dr. Kraus moved that the committee has considered the comment and does not feel that there is a need for an amendment. The motion was seconded and carried.

18 VAC 85-20-24 Practitioner-Patient Communication – Ms. Yeatts advised that the commenter noted that on many occasions the patient receives an "impression" of what the practitioner believes is going on and the words "impression", "assessment" and "diagnosis" should be included in this section. Dr. Reynolds-Cane moved that the committee has considered the comment and does not feel that there is a need for an amendment. The motion was seconded and carried.

Dr. Dalton stated that she understands where advising a patient of the practitioner's "impression" may be of some protection to the practitioner especially if the results were not what was expected and this practice could possibly prevent the charge of battery.

Dr. Kraus commented that the second sentence of A1, "A practitioner shall not deliberately make a false or misleading statement…" encompasses the concern voiced by the commenter.

Dr. Johnson stated that if the law becomes too specific then the practitioner is restricted in having an ongoing, candid dialogue with a patient.

On another note, Dr. Harp suggested the use of a neutral pronoun in the first sentence to emphasize the practitioner's best analysis of the situation at the time. Dr. Kraus moved to amend the motion to substitute "any" with the word "his". The motion was seconded and carried.

18 VAC 85-20-40 Vitamins, minerals and food supplements – Ms. Yeatts advised that the concern from the commenter is that the recommendation and direction for the use of vitamins, minerals and food supplements states "…it is to be used when a favorable outcome is expected such as preventative practices". The commenter stated that this standard is not applied to the prescribing of controlled substances and therefore should not be applied to vitamins, minerals or food supplements. Ms. Yeatts reminded the Board that this language was drafted by a sub-committee. The sub-committee effort was to remove the absolute language currently in existence requiring the rationale for said use must be therapeutically proven and not experimental.

Dr. Reynolds-Cane moved that the committee has considered the comment and does not feel that there is a need for an amendment. The motion was seconded and carried.

18 VAC 85-20-30 (E) Advertising Ethics – Ms. Yeatts advised that this comment is referring to advertising done on behalf of a practice and the requirement for the practice to designate a person with the specific responsibility and accountability for the content of the ad. Also, that individual's identity should be maintained for at least two years. The commenter feels that this is a different standard for a solo practitioner who remains responsible indefinitely. Ms. Yeatts stated that the regulation's intent is not to imply that a practice has no accountability for an advertisement that is misleading, deceptive, and false past a two year time period but to establish a timeframe for maintaining the identity of the individual responsible for the content of the advertisement must be maintained for that time period.

Dr. Reynolds-Cane moved that the committee has considered the comment and does not feel that there is a need for an amendment. The motion was seconded and carried.

18VAC 85-20-25.1 What constitutes properly trained and supervised - Ms. Yeatts advised that this commenter thinks that "properly trained and supervised" is up to individual interpretation. Dr. Kraus moved that the committee has considered the comment and does not feel that there is a need for an amendment. The motion was seconded and carried.

18VAC 85-20-25.2 What could reasonably be expected to adversely affect patient care, and what is the definition of "egregious"- Ms. Yeatts advised that the language used in the section came directly out of the Federation of State Medical Board's rules. Dr. Kraus moved that the committee has considered the comment and does not feel that there is a need for an amendment. The motion was seconded and carried.

Third Commenter

18 VAC85-20-22 (A) & (B) – Ms. Yeatts advised that this commenter stated that (A) is unnecessary and that (B) covers (A). Ms. Yeatts stated that she and Ms. Perrine discussed this comment and (A) covers the requirements for confidentially and disclosure of records in totality but (B) only points to the provisions in the code section relating to records. In addition, Ms. Yeatts recommended the addition of "legally" to be added in (B) to read …to the patient or his *legally* authorized representative… to be consistent with the terminology used in other parts of the regulations. Dr. Dalton moved that the committee has considered the comment and does not feel that there is a need for an amendment. The motion was seconded. Dr. Kraus moved to amend the motion to add the word "legally" to (B). The motion was seconded and carried.

18 VAC85-20-22 (D) - Ms. Yeatts advised that the commenter did not feel that a physician should be cited for unprofessional conduct for destruction of records for a time period less than six years following the last patient encounter. After discussion, Dr. Dalton moved that the committee has considered the comment and does not feel that there is a need for an amendment.

18 VAC85-20-22 (E) – Ms. Yeatts advised that the commenter suggested that the entire section on posting information on destruction of records be omitted. Dr. Kraus moved that the committee has considered the comment and does not feel that there is a need for an amendment. The motion was seconded and carried.

18 VAC 85-20-23 – Ms. Yeatts advised that the commenter suggested that it should only be considered unprofessional conduct if the breach of confidentiality is willful or constitutes gross negligence. Dr. Kraus moved to add the words "*or permitted"* to read as …"A breach of confidentiality that is required *or permitted* by applicable law…". The motion was seconded and carried.

18 VAC 85-20-24 (A2)- Ms. Yeatts advised that this commenter addresses the proposed charge of unprofessional conduct to a physician when a good faith attempt has been made to inform the patient consistent with standard of care but the patient does not understand the information.

Ms. Yeatts also advised that this is one of two like comments and suggests the addition of "shall present information relating to a patient's care to a patient or his legally authorized representative in terms that the practitioner believes the patient can understand and would encourage participation in the decision. Dr. Reynolds-Cane moved to amend that language to include "in terms that the practitioner believes the patient could understand and would encourage participation". The motion was seconded and carried.

(A3b) Ms. Yeatts advised that the commenter recommends a language change that addresses emergency situations where a delay in obtaining consent would likely result in harm to the patient to say "may adversely affect the individual's recovery". Dr. Kraus moved that the committee has considered the comment and does not feel that there is a need for an amendment. The motion was seconded and carried.

18 VAC 85-20-24(B) – Ms. Yeatts advised that the commenter stated that it should not be considered unprofessional conduct when a practitioner departs from a group practice without providing notice to the patient as long as continuous treatment is available through the same practice. Dr. Reynolds-Cane moved that the committee has considered the comment and does not feel that there is a need for an amendment. The motion was seconded and carried.

Fourth Commenter

<u>18 VAC 85-20-21(A)</u> – Ms. Yeatts advised that the following comments were compiled by an attorney on behalf of a sub-committee on health records. The first comment relates to the Code's requirement of a physician-patient relationship. Ms. Yeatts advised that the comment and notation acknowledges it is beyond the scope of the regulations therefore no consideration is needed.

<u>18 VAC 85-20-21(B) -</u> Ms. Yeatts advised that the commenter questions what is meant by an emergency, isolated setting or single episode. The commenter suggests further definition of "shall not prescribe unless there is reason to believe that it is an emergency situation or isolated setting". Dr. Reynolds-Cane moved that the committee has considered the comment and does not feel that there is a need for an amendment. The motion was seconded and carried.

<u>18 VAC 85-20-22 (B)</u> – Ms. Yeatts advised that the commenter suggests using "personal representative" instead of "legally authorized". Dr. Dalton moved to add but not define legally authorized representative. The motion was seconded and carried.

Dr. Johnson suggested that if the motion is addressing patient records he recommends a definition be provided for "legally authorized representative". Dr. Kraus called the question.

Ms. Yeatts advised that "legally authorized representative" would be problematic in 18VAC85-20-22(B). Dr. Dalton her withdrew motion after clarification of the use of this language.

Dr. Johnson moved to amend 18VAC85-20-22 (B) to say "*personal* representative" instead of "authorized representative" in all sections referring to patient records. The motion was seconded and carried.

(C) - Ms. Yeatts advised that the commenter suggests adding the word "*materially"* complete. Dr. Kraus moved that the committee has considered the comment and does not feel that there is a need for an amendment. The motion was seconded and carried.

(D1) - Ms. Yeatts advised that the commenter suggests deleting the language "whichever comes first". Dr. Reynolds-Cane moved to accept the language amendment. The motion was seconded and carried.

(D2) - Ms. Yeatts advised the commenter suggests that if a patient's record has been transferred to another practitioner or given to the patient, documentation of that activity should be kept by the original practitioner for at least six years. Ms. Yeatts advised that if the board agrees with this suggestion, she suggests an addition of a subsection be inserted to address this issue. Dr. Reynolds-Cane moved that the committee has considered the comment and does not feel that there is a need for an amendment. The motion was seconded and carried.

(E) Ms. Yeatts advised the commenter suggests language regarding the destruction of patient records be amended to say, "Patient records shall only be destroyed in a manner reasonably calculated to protect patient confidentiality such as by incineration or shredding." Dr. Kraus moved that the committee has considered the comment and does not feel that there is a need for an amendment. The motion was seconded and carried.

(F) - Ms. Yeatts advised that the commenter addresses the requirements of §54.1-2405 and asks the Board to expound in more detail what the notification requirements are to a patient from a practitioner in the closing, selling or relocation of a practice. Dr. Reynolds-Cane moved that the committee has considered the comment and does not feel that there is a need for an amendment. The motion was seconded and carried.

<u>18VAC85-20-23</u> – Motion previously made on comments to this code section. No additional comments or motion made under this commentator.

<u>18VAC85-20-24(A1)</u> Ms. Yeatts advised that the commentator suggests the two sentences be separated for clarification. Dr. Kraus moved that the committee has considered the comment and does not feel that there is a need for an amendment. The motion was seconded and carried.

<u>18VAC85-20-24(A2)</u> - Motion previously made on comments to this code section. No additional comments or motion made under this commentator.

<u>18VAC 85-20-24(A3)</u> – Ms. Yeatts advised that this comment and concern was that the section only applied to those with a specialty. Ms. Yeatts suggested adding language to say "…same or a similar *area of practice* or specialty… Dr. Kraus moved to add language to say "that a reasonably prudent practitioner in a similar practice in Virginia would tell a patient." The motion was seconded and carried.

(3A) – Ms. Yeatts advised that this comment addressed whether there should be acknowledgment that consent may not be granted. Ms. Yeatts explained that if the legally authorized person refuses to give consent then the practitioner would need to document and advise the Board of the refusal in writing. Dr. Kraus moved that the committee has considered the comment and does not feel that there is a need for an amendment. The motion was seconded and carried.

(4) – Ms. Yeatts advised that the commenter suggested the deletion of the language "that affects their care". Dr. Reynolds-Cane moved to accept the proposed amendment as suggested. The motion was seconded and carried.

<u>18 VAC 85-20-24(B)</u> Ms. Yeatts advised the commenter suggested adding language that allows the practitioner to terminate a relationship with a patient provided the termination does not constitute patient abandonment. Dr. Kraus moved that the committee has considered the comment and does not feel that there is a need for an amendment. The motion was seconded and carried.

Ms. Yeatts also advised that the commenter points out that §54.1-2962.2 is referenced in this section and suggests that explanatory language be added. Dr. Reynolds-Cane moved that the committee has considered the comment and does not feel that there is a need for an amendment. The motion was seconded and carried.

18VAC 85-20-30 – Ms. Yeatts advised that the advertising comments were on sections that had not been amended. Dr. Kraus moved that the committee has considered the comment and does not feel that there is a need for an amendment. The motion was seconded and carried.

18VAC85-20-40 – Ms. Yeatts advised that this comment is suggesting a language change to the last sentence … be expected without such use to now read "… be expected *without the use of the vitamins, minerals or food supplements so recommended*." Dr. Kraus moved that the committee has considered the comment and does not feel that there is a need for an amendment. The motion was seconded and carried.

Fifth Comment

Ms. Yeatts advised that this commenter asked for a definition of a family member. Dr. Dalton suggested defining family member as 1st or 2nd degree relative by blood or marriage. Dr. Reynolds-Cane stated that even though the definition would offer some guidance, it would be difficult to produce an all inclusive definition. Dr. Reynolds-Cane moved that the committee has considered the comment and does not feel that there is a need for an amendment. The motion was seconded and carried.

Next Steps in the Process

Ms. Yeatts advised that the Ad Hoc's recommendations, summary of the comments and the Ad Hoc's response to those comments will be presented for review to the Legislative Committee April 22, 2005 and to the Advisory Boards the first week in April.

Announcements
With no other business, the meeting adjourned at 4:30 p.m.

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Malcolm L. Cothran, MD
Chair

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William L. Harp, M.D.
Executive Director

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Colanthia Morton Opher
Recording Secretary