

BOARD OF MEDICAL PRACTICE
PROPOSED PERMANENT RULES RELATING TO
CONTINUING MEDICAL EDUCATION

RULE 5605

STATEMENT OF NEED AND REASONABLENESS

Purpose of Amendments

The proposed rules: 1) eliminate the Board's approval of Continuing Medical Education (CME) courses; 2) eliminate all categories of CME for physicians except Category 1, and; 3) increase the required number of Category 1 CME hours for physicians from 45 to 75 for a three year cycle.

Statutory Authority

Minn. Stat. § 147.01, subd. 1 (Creation; Terms) provides that "the setting of board fees and other provisions relating to board operations are as provided in chapter 214."

Minn. Stat. § 147.01, subd. 3 (Board Administration) provides that "the Board shall have the authority to adopt rules as may be necessary to carry out the purposes of this chapter."

Minn. Stat. § 214.12, subd. 1 (Continuing education) provides that "the health-related licensing boards may promulgate by rule requirements for renewal of licenses designed to promote the continuing professional competency of licensees. These requirements of continuing professional education or training shall be designed solely to improve skills and shall not exceed an average attendance requirement of 50 clock hours per year. All requirements promulgated by the boards shall be effective ... [at a date] as the board may determine."

Minn. Stat. § 214.06, subd. 2 (Renewal) provides that "notwithstanding any law to the contrary, each health-related licensing board ... shall promulgate rules providing for the renewal of licenses. The rules shall specify the period of time for which a license is valid, procedures and information required for renewal, and renewal fees to be set pursuant to subdivision 1."

Rule Development Process

The Board began the process of developing the proposed rule by publishing in the December 20, 1993 edition of the State Register notice seeking information or opinions from sources outside the Board in preparing to propose non-controversial amendments. (Appendix A).

The Board developed the proposed amendments on the basis of needs identified by the Board. After compiling a list of suggested changes, the Board surveyed the Minnesota Medical Association (MMA) and other medical related organizations for advice. The Board's Licensure and Public Policy committees held public meetings on October 27, 1993; January 6, 1994; and February 23, 1994 to review changes proposed by the MMA and other groups. Based on comments received and input through the committee meetings, the full Board approved changes to the CME rules on March 12, 1994. (Appendix B). Pursuant to Minn. Stat. § 14.32, the Board has prepared this Statement of Need and Reasonableness and made it available to the public as of July 11, 1994.

The Board has published in the State Register the proposed rules and the Notice of Intent to Adopt Rules. (Appendix C). The Board will also mail copies of the Notice to persons registered with the Board pursuant to Minn. Stat. § 14.22, as well as others who the Board believes may have an interest in the rules. The Notice will comply with the requirements of Minn. Stat. § 14.22 and Minn. R. § 2010.0300, item E. The rules will be phased in over a three year period, beginning January 1, 1995 and effective thereafter based on individual licensee renewal cycles.

Discussion of Proposed Amendment

Under Minnesota Rule, Chapter 5605, the Board has the authority to approve continuing medical courses. CME approval is also conducted by national accrediting organizations for physicians (Accreditation Council for Continuing Medical Education (ACCME) or the American Osteopathic Association (AOA)) through review by the American Medical Association (AMA). The current Board review and approval is not as rigorous as that of the national accrediting organizations. The demands on Board staff to conduct such reviews would be cost prohibitive and would take existing staff away from other licensure responsibilities.

The Board's Public Policy Committee and Licensure Committee recommended that the Board amend the CME rules to discontinue Board review/approval of CME courses and recognize only courses approved by nationally recognized CME course accreditation organizations or by recognized medical specialty boards. These recognized organizations include the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association Bureau of Professional Education (AOA-BPE) and the Royal College of Physicians and Surgeons of Canada.

The Committees recommended the rule change because of the growing complexity and specialization of CME courses which is requiring more expertise to review. Also, the number of organizations requesting approval of courses has grown. This combination of an increased number of more complex courses will soon exceed the capabilities of Board staff to adequately credential appropriate coursework.

The Board by removing itself from approving CME courses simplifies the rule by providing one recognized standard for accepted CME coursework. These courses have been found acceptable by organizations in the business of being current in medical education and have clear standards on what is required for an acceptable program. A benefit for physicians in using nationally recognized CME programs is that the coursework is transferable for national accreditation purposes, specialty board certification and/or CME requirements of other states' licensing boards. Under the current rules, the coursework would only be accepted in Minnesota unless otherwise nationally recognized.

The Board, with the proposed rule change, would be deleting credits allowed for educational activities such as teaching, publishing, professional reading and programs sponsored in-house by hospitals and clinics. However, the nationally recognized organizations, such as the Accreditation Council for Continuing Medical Education of the American Medical Association do recognize such programs so long as the programs meet the standards set forth in their guidelines. Thus, these less traditional CME programs could still exist under the rules as proposed here, as long as they are accredited by the appropriate organization.

The proposed rule change provides that the Board will retain its requirement that physicians complete 75 hours of continuing medical education within a three year cycle. However, the rule will now require that all coursework to have been approved by a nationally recognized CME accreditation organization. Before the rule required at least 45 hours of Board approved coursework and would allow up to 10 - 20 hours of alternative coursework from each category activity such as professional readings, papers, teaching and in-house programs at clinics or

hospitals. Thus, the number of CME hours of coursework to be submitted within a three year cycle is still the same at 75 hours, but it is now up to the licensee to choose appropriately credentialed programs, whether they are traditional courses or alternative programs (i.e. readings) that are under CME accreditation organizations recognized by the Board under the proposed rules.

The rule changes do not affect Minn. Statute §214.12 subd. 1, which states that: "These requirements of continuing professional education or training shall be designed solely to improve skills and shall not exceed an average attendance requirement of 50 clock hours per year". The 75 hour requirement translates to about 25 hours per year.

The rule changes will become effective on January 1, 1995. Organizations that currently have courses approved by the Board would be notified of the rule change in October 1994, assuming approval of the rule, to allow them time to contact appropriate CME credentialing organizations to get course approval. The rule change does not affect courses approved by the Board prior to January 1, 1995 for CME reporting purposes.

The Board believes the proposed rule changes will enhance the protection of the public by raising the quality of continuing education programs, since the standards will be those recognized by nationally recognized CME accreditation organizations. Physicians will also benefit by a greater transferability of CME credits and by having one CME standard to follow, rather than hoping less traditional CME coursework will be found acceptable by the Board. The Board itself will also have more staff time available to conduct audits on individual licensees to insure that they are attending CME programs which will improve their skills, rather than dividing time between audits and screening of courses.

Expenditure of Public Money by Local Public Bodies

Minn. Stat. § 14.11, subd. 1 requires that "if the adoption of a rule by an agency will require the expenditure of public money by local public bodies, the appropriate notice of the agency's intent to adopt a rule shall be accompanied by a written statement giving the agency's reasonable estimate of the total cost to all local public bodies." The Board does not anticipate that the proposed amendments will require the expenditure of public money by local public bodies.

Impact on Agricultural Land

Minn. Stat. § 14.11, subd. 2 requires that "if the agency proposing the adoption of the rule determines that the rule may have a direct and substantial adverse impact on agriculture land in the state, the agency shall comply with the requirements of sections 17.80 to 17.84." The Board does not anticipate that the proposed amendments will have a direct and substantial adverse impact on agricultural land in the state.

Small Business Considerations

Minn. Stat. § 14.115, subd. 2 requires that when an agency proposes new or amended rules, it must consider "methods for reducing the impact of the rule on small business", "document how it has considered these methods" and "provide an opportunity for small businesses to participate in the rulemaking process." The Board does not believe that the requirements of section 14.115 apply to the proposed rules, because that section does not apply to "agency rules that do not affect small business directly." The Board's authority relates only to the qualifications of its licensees and registrants to provide services — the Board has no authority over the industry in which they practice. Therefore the rules do not affect small businesses as such, and the Board is exempt from the requirements of section 14.115.

However, should these proposed rules be construed as being subject to Minn. Stat. § 14.115, the Board notes below how the five suggested methods listed in section 14.155, subdivision 2, for reducing the impact of the rules on small businesses should be applied to the proposed amendments. The five suggested methods enumerated in subdivision 2 are as follows:

- a) the establishment of less stringent compliance or reporting requirements for small business;
- b) the establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
- c) the consolidation or simplification for compliance or reporting requirements for small businesses;
- d) the establishment of performance standards for small business to replace design or operational standards required in the rule;
- e) the exemption of small businesses from any or all requirements of the rule.

The feasibility of implementing each of the five suggested methods and whether implementing any of the five methods would be consistent with the statutory objectives that are the basis for this rulemaking are considered below.

1. It would not be feasible to incorporate any of the five suggested methods into these proposed rules.

Methods (a) to (c) of subdivision 2 related to lessening compliance or reporting requirements for small businesses either by (a) establishing less stringent requirements (b) establishing less stringent schedules or deadlines for compliance with the requirements, or (c) consolidating or simplifying the requirement. Since the Board is not proposing any compliance or reporting requirements for either small or large businesses, it follows that there are no such requirements for the Board to lessen with respect to businesses. If, however, these proposed rules and amendments are viewed as compliance or reporting requirements for businesses, then the Board finds that it should be unworkable to lessen the requirements for those physicians and physical therapists who practice in the solo or clinic setting of fewer than 50 employees, since that would include the vast majority of licensees and registrants. Method (d) suggests replacing design or operational standards with performance standards for small businesses. The Board's rules do not propose design or operational standards for small businesses as a replacement for design or operation standards that do not exist. Finally, method (e) suggests exempting small businesses from any or all requirements of the rules. The application of this provision would exempt most licensees and registrants from the purview of the rules, a result which would be absurd.

2. Reducing the impact of the proposed rules on small businesses would undermine the objectives of the Minnesota Licensing law for physicians and physical therapists.

Pursuant to Minn. Stat. §§147.01 et seq., the Board was designated as the agency for establishing requirements for licensure and for disciplinary action to govern the practices or behavior of all physicians. Pursuant to Minn. Stat. §147.01, subd. 3., the Board is specifically mandated to promulgate rules as may be necessary to carry out the purposes of the Minn. Stat. §§147.01 to 147.33. The Board is also the agency pursuant to Minn. Stat. §148.65 et seq., for establishing requirements for registration of physical therapists and is authorized under Minn. Stat. §148.74 to promulgate rules to carry out the purpose of §§148.65 to 148.78. Given the statutory mandates, it is the Board's duty to establish licensure and registration qualifications and disciplinary standards which apply to and govern all applicants, licensees and registrants regardless of their practice.

As it has been stated above, it is the Board's position that the proposed rules will not affect small businesses and certainly do not have the potential for imposing a greater impact on physicians and physical therapists in solo or small practice than those practices large enough to remove themselves from the definition of small business. It has also been explained above that the Board considers it infeasible to implement any of the five suggested methods enumerated in subdivision 2 of the small business statute. Nonetheless, to the extent that the proposed rules may affect the business operation of a physician/physical therapist group and to the extent it may be feasible to implement any of the suggested methods for lessening the impact on small businesses, the Board believes it would be unwise and contrary to the purposes to be served by these rules for the board to exempt one group of physicians or physical therapists indeed possibly the vast majority of physicians/physical therapists, from the requirement of these rules. Similarly, the Board believes it would be unwise and contrary to its statutory mandate for the Board to adopt one set of standards for those physicians/physical therapists (which may consist of a non-existent class) who work in a large business setting and adopt another, less stringent set of standards to be applied to those physicians/physical therapists who practice in a solo or small clinic type of setting. It is the Board's view that these rules must apply equally to all physicians and physical therapists or the licensing system will be chaotic.

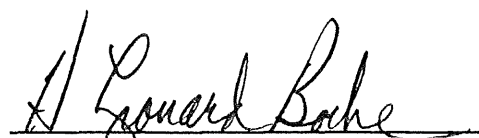
Licensees, or registrants, regardless of whether they are considered as individuals or small businesses, have had and will continue to have an opportunity to participate in the rulemaking process for the proposed rules and amendments. The Board has used a very open process to draft these rules. The Board has kept the various associations well informed of the proposed rules as they were developed and has also provided notices and articles about the proposed rules in its newsletter issued to all licensees and registrants.

Fees

Minn. Stat. § 16A.128, subd. 1a requires that "fees for accounts for which appropriations are made may not be established or adjusted without the approval of the commissioner of finance." Subdivision 2a requires that "before an agency submits notice to the State Register of intent to adopt rules that establish or adjust fees, the agency must send a copy of the notice and the proposed rules to the chairs of the house ways and means committee and senate finance committee." The Board has determined that the proposed amendment will have no effect on fees.

Expert Witnesses

Minnesota rules, part 1400.0500, subpart 1 requires that if rules are adopted with a public hearing, the statement of need and reasonableness must include "a list of any witnesses to be called by the agency to testify on its behalf." The Board does not anticipate that it will be necessary to have a public hearing on the proposed amendments.



H. Leonard Boche
Executive Director

June 28, 1994

APPENDIX

- A. Notice of Intent to Solicit Outside Information and Opinions (12-8-93)
- B. Board Authorizing Resolution of May 14, 1994
- C. Notice of Intent to Adopt Rules Without a Public Hearing
- D. Copy of Proposed Rules
- E. American Medical Association Requirements for Approval of CME Courses

BOARD OF MEDICAL PRACTICE

**Notice of Solicitation of Outside Information or Opinions
Regarding Minnesota Rules, part 5605 (CONTINUING EDUCATION)**

Notice is hereby given that the Minnesota Board of Medical Practice is seeking information or opinions from sources outside the Board in preparing to propose non-controversial amendments to Minnesota Rules, part 5605, relating to continuing education for physicians in Minnesota. The amendment of the rule is authorized by Minnesota Statutes, section 214.12, which permits the Board to promulgate rules as are necessary to promote the continuing professional competence of licensees.

All interested persons or groups are requested to participate. Statements of information and comment may be made orally or in writing. Written statements should be addressed to:

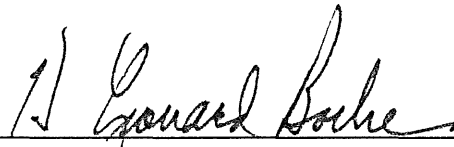
H. Leonard Boche, Executive Director
Minnesota Board of Medical Practice
2700 University Avenue West, Suite 106
St. Paul, Minnesota 55114

Oral statements will be received during regular business hours over the telephone at (612)642-0538 (Minnesota Relay Operator (612)297-5353 or (800)627-3529) and in person at the above address.

APPENDIX A

All statements of information and comment will be accepted until further notice is given or the Notice of Hearing or Notice of Intent to Adopt Without a Hearing are published in the State Register. Any written material received by the Minnesota Board of Medical Practice shall become part of the rulemaking record to be submitted to the Attorney General in the event that the rule is adopted.

Dated: 12/8/93

A handwritten signature in cursive script, reading "H. Leonard Boche", is written over a horizontal line.

H. Leonard Boche

Executive Director

**CERTIFICATE OF BOARD OF MEDICAL PRACTICE
AUTHORIZING RESOLUTION**


Continuing Medical Education Rules

I, David Kidder, do hereby certify that I am a member and the President of the Minnesota Board of Medical Practice, a board duly authorized under the laws of the State of Minnesota, and that the following is a true, complete, and correct copy of a resolution adopted at a meeting of the Board, duly and properly called and held on the 14th day of May 1994, that a quorum was present, and that a majority of those present voted for the resolution which has not been rescinded or modified.

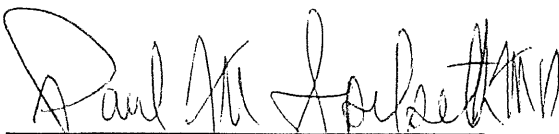
RESOLVED, that H. Leonard Boche, the Executive Director of the Board of Medical Practice is hereby granted the authority and directed to sign the statement of need and reasonableness and sign and give the Notice of the Board's Intent to Adopt a rule governing continuing medical education to all persons who have registered their names with the Board for that purpose and publish the Notice and rule in the State Register, and to perform any necessary acts to initiate the rulemaking comment period.

IN WITNESS WHEREOF, I have hereunto subscribed my name this 14th day of May, 1994.

STATE OF MINNESOTA
BOARD OF MEDICAL PRACTICE



David Kidder, President



Attesting Board Member

STATE OF MINNESOTA
BOARD OF MEDICAL PRACTICE

APPENDIX C

In the Matter of Proposed Rule
Amendments of Rules of the
Minnesota Board of Medical Practice
Relating to Continuing Medical Education

NOTICE OF INTENT
TO ADOPT A RULE
WITHOUT A
PUBLIC HEARING

The Minnesota Board of Medical Practice (hereinafter "Board") intends to adopt permanent rules without a public hearing following the procedures set forth in the Administrative Procedure Act, Minnesota Statutes, sections 14.22 to 14.28. You have 30 days to submit written comments on the proposed rules.

Comments or questions on the rule and written requests for a public hearing on the rule must be submitted to:

H. Leonard Boche, Executive Director
Minnesota Board of Medical Practice
2700 University Avenue West, Suite 106
St. Paul, MN 55114
(612) 642-0538
FAX (612) 642-0393

The proposed rule is about continuing medical education. The statutory authority to adopt this rule is Minnesota Statutes 147.01, 214.06, and 214.12 (1993). A copy of the proposed rule is published in the State Register and attached to this notice as mailed.

You have until 4:30 p.m., on August 12, 1994 to submit written comment in support of or in opposition to the proposed rule and any part or subpart of the rule. Your comment must be in writing and received by the agency contact person by the due date. Comment is encouraged. Your comment should identify the portion of the proposed rule addressed, the reason for the comment, and any change proposed.

In addition to submitting comments, you may also request that a hearing be held on the rule. Your request for a public hearing must be in writing and must be received by the agency contact person by 4:30 PM, on August 12, 1994. Your written request for a public hearing must include your name and address. You are encouraged to identify the portion of

the proposed rule which caused your request, the reason for the request, and any changes you want made to the proposed rule. If 25 or more persons submit a written request for a hearing, a public hearing will be held unless a sufficient number withdraw their requests in writing. If a public hearing is required, the agency will follow the procedures in *Minnesota Statutes*, sections 14.131 to 14.20. The proposed rule may be modified as a result of public comment. The modifications must be supported by data and views submitted to the agency and may not result in a substantial change in the proposed rule as attached and printed in the State Register. If the proposed rule affects you in any way, you are encouraged to participate in the rule making process.

A statement of need and reasonableness is now available from the agency contact person identified above. This statement describes the need for and reasonableness of each provision of the proposed rule and identifies the data and information relied upon to support the proposed rule.

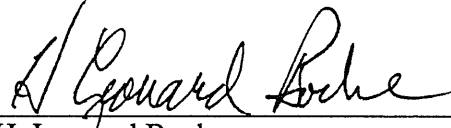
It is the position of the Board that it is not subject to Minnesota Statute 14.115 regarding small business considerations in rule making. The basis for this position is addressed in the statement of need and reasonableness.

The Minnesota Board of Medical Practice has reviewed the proposed rules, and finds no evidence that the rules would cause the expenditure of public money by any local public body.

The Minnesota Board of Medical Practice has reviewed the proposed rules, and finds that the subject matter of the rules is not related to agriculture land.

After the end of the comment period, the agency may adopt the rule. The rule and supporting documents will then be submitted to the attorney general for review as to legality and form to the extent form relates to legality. You may request to be notified of the date the rule is submitted to the attorney general or be notified of the attorney general's

decision on the rule. If you wish to be so notified, or wish to receive a copy of the adopted rule, submit your request to the agency contact person listed above.

A handwritten signature in cursive script that reads "H. Leonard Boche". The signature is written in black ink and is positioned above a horizontal line.

H. Leonard Boche
Executive Director

June 23, 1994

Office of the Revisor of Statutes

Administrative Rules



TITLE: Proposed Permanent Rules Relating to Continuing Education

AGENCY: Board of Medical Practice

MINNESOTA RULES: Chapter 5605

The attached rules are approved for publication in the State Register

A handwritten signature in cursive script, appearing to read "Carla Riehle".

Carla M. Riehle
Senior Assistant Revisor

1 Board of Medical Practice

2

3 Proposed Permanent Rules Relating to Continuing Education

4

5 Rules as Proposed

6 5605.0100 CONTINUING EDUCATION CYCLES.

7 During three-year cycles, each physician licensed to
8 practice by this board shall obtain 75 hours of continuing
9 medical education credit as required by this chapter, with at
10 least three hours in the subject of infection control, including
11 blood borne diseases. "Infection control" means programs,
12 procedures, and methods to reduce the transmission of agents of
13 infection for the purpose of preventing or decreasing the
14 incidence of infectious diseases. "Blood borne diseases" means
15 diseases that are spread through exposure to, inoculation of, or
16 injection of blood, or through exposure to blood contained in
17 body fluids, tissues, or organs. Blood borne diseases include
18 infection caused by such agents as the human immunodeficiency
19 virus (HIV) and hepatitis B virus (HBV). Infection control
20 continuing education credits must be obtained from the Category
21 1 activities in part 5605.03007-item-A. Continuing education in
22 infection control is required for renewal periods beginning on
23 or after October 1, 1993. For initial continuing education
24 periods of less than three years, one continuing education hour
25 in infection control is required for each remaining full year.

26 5605.0300 ~~CATEGORIES-OF-CREDITED-ACTIVITIES~~ CONTINUING MEDICAL
27 EDUCATION CREDIT.

28 ~~Continuing-medical-education-credit-may-be-obtained-from~~
29 ~~the-following-activities:~~

30 ~~A7--Category-1--No-less-than-45~~ At least 75 hours of
31 continuing medical education credit must be obtained in any
32 cycle by attendance at ~~educational-activities-approved-by-the~~
33 ~~board-pursuant-to-part-5605-0500~~ continuing medical education
34 activities designated by an accredited sponsor as Category 1 of
35 the Physician's Recognition Award of the American Medical

1 Association. Continuing medical education sponsors must be
 2 accredited by the Accreditation Council for Continuing Medical
 3 Education (ACCME) or by a state medical society recognized by
 4 the ACCME as an intra-state accreditor of continuing medical
 5 education sponsors.

6 B--Category-2--No-more-than-20-hours-of-credit-may
 7 be-obtained-in-any-cycle-through-educational-activities
 8 sponsored-by-a-hospital, clinic, or medical or osteopathic
 9 society-and-not-meeting-the-standards-contained-in-category-1-

10 E--Category-3--No-more-than-20-hours-of-credit-may
 11 be-obtained-in-any-cycle-through-medical-teaching-of-medical
 12 students, residents, practicing physicians, and allied health
 13 professionals-

14 B--Category-4--No-more-than-20-hours-of-credit-may
 15 be-obtained-in-any-cycle-for-papers, publications, books,
 16 lectures, and exhibits-

17 (1)-Papers, publications, and books--Ten-hours
 18 of-credit-shall-be-granted-for-a-scientific-paper-or-book
 19 chapter-published-in-a-scholarly-medical-journal-or-book-

20 (2)-Lectures--An-hour-of-credit-shall-be-granted
 21 for-each-hour-spent-lecturing-at-a-course-which-would-qualify
 22 for-approval-under-these-rules-

23 (3)-Exhibits-and-nonpublished-papers--Ten-hours
 24 of-credit-shall-be-granted-for-a-paper-or-exhibit-presented
 25 before-a-professional-medical-or-allied-health-audience--Credit
 26 may-be-claimed-only-once-for-each-scientific-material-presented-

27 E--Category-5--No-more-than-20-hours-of-credit-may
 28 be-obtained-by-engaging-in-professional-reading, peer-patient
 29 care-review-activities, self-assessment-examinations-sponsored
 30 by-a-professional-organization-recognized-by-the-board-as
 31 maintaining-a-significant-level-of-quality-control, and
 32 preparation-for-certification-or-recertification-examinations
 33 administered-by-a-national-specialty-board-

34 For purposes of relicensure, the board shall accept the
 35 equivalent of Category 1 credit hours as defined by the American
 36 Osteopathic Association Bureau of Professional Education, the

1 Royal College of Physicians and Surgeons of Canada, or by
2 organizations that have reciprocal arrangements with the
3 physician recognition award program of the American Medical
4 Association.

5 5605.0700 ALTERNATIVE COMPLIANCE.

6 The board may accept certification or recertification by an
7 a member of the American specialty Board of Medical Specialties,
8 the American Osteopathic Association Bureau of Professional
9 Education, or the Royal College of Physicians and Surgeons of
10 Canada in lieu of compliance with the continuing education
11 requirements during the cycle in which certification or
12 recertification is granted.

13 5605.0900 VERIFICATION OF COMPLIANCE.

14 Licensees shall, at the relicensure period coinciding with
15 the end of their cycle, provide a signed statement to the board
16 on a form provided by the board indicating compliance with this
17 chapter. The board may, in its discretion, require such
18 additional evidence as is necessary to verify compliance with
19 this chapter. ~~The board may also accept certification of other~~
20 ~~state or national medical groups whose continuing medical~~
21 ~~education requirements are the equivalent of or greater than~~
22 ~~those of this board in lieu of compliance with these standards.~~

23 A licensee failing to submit a statement or who submits a
24 statement which, on its face, indicates noncompliance with this
25 chapter may be subject to the disciplinary provisions contained
26 in part 5605.1100.

27 REPEALER. Minnesota Rules, parts 5605.0400; 5605.0500; and
28 5605.0600, are repealed.

29

30 EFFECTIVE DATE. Minnesota Rules, parts 5605.0700 and 5605.0900
31 and the repeal of parts 5605.0400, 5605.0500, and 5605.0600 are
32 effective January 1, 1995. Parts 5605.0100 and 5605.0300 are
33 effective for three-year cycles beginning on or after January 1,
34 1995.

APPENDIX E

Part I

Information For Physicians Applying For The
AMA PRA

Brief Summary of Requirements for the PRA

Physicians may apply for either a standard PRA certificate or a PRA certificate with Special Commendation for Self Directed Learning, and can apply for one, two, or three-year certificates. The hours required are outlined in the tables below. Education must be in a single consecutive period. Credit hours are based on hour for hour participation in a continuing medical education activity (except for reports of residency training, fellowships, and similar activities, and the publication of journal articles). Except for viewing television, CME should be reported in one hour blocks. Televised CME can be reported in 1/2 hour blocks. Other credit should be rounded to the nearest hour.

A. The Standard PRA Certificate

- 3 year certificate = 150 hours of continuing medical education minimum of 60 hours AMA PRA Category 1 education remaining 90 hours of either AMA PRA Category 1 or Category 2
Reading reportable as Category 2
- 2 year certificate = 100 hours of continuing medical education minimum of 40 hours AMA PRA Category 1 education remaining 60 hours of either AMA PRA Category 1 or Category 2
Reading reportable as Category 2
- 1 year certificate = 50 hours of continuing medical education minimum of 20 hours of AMA PRA Category 1 education remaining 30 hours of either AMA PRA Category 1 or Category 2
Reading reportable as Category 2

All applicants are expected to read authoritative medical literature on the average of 2 hours per week.

B. The PRA Certificate with "Special Commendation for Self Directed Learning"

- 3 year certificate = 150 hours of continuing medical

education minimum of 60 hours AMA PRA Category 1 education minimum of 60 hours of Category 2 education remaining 30 hours in either Category 1 or Category 2

Reading cannot be reported.

- 2 year certificate = 100 hours of continuing medical education minimum of 40 hours AMA PRA Category 1 education minimum of 40 hours of Category 2 education remaining 20 hours in either Category 1 or Category 2

Reading cannot be reported.

- 1 year certificate = 50 hours of continuing medical education minimum of 20 hours of AMA PRA Category 1 education minimum of 20 hours of Category 2 education remaining 10 hours in either Category 1 or Category 2

Reading cannot be reported.

All applicants are expected to read authoritative medical literature on the average of 2 hours per week. These hours cannot be reported for the Certificate with Special Commendation for Self Directed Learning.

Detailed Description of AMA PRA Requirements

AMA PRA Category 1:

CME Activities Designated AMA PRA Category 1 by an Accredited Sponsor and International Conferences approved by the AMA for Category 1 credit.
(Documentable and Sponsor-verifiable Education)

AMA PRA Category 1 CME designated by an accredited sponsor must meet the following requirements:

- be sponsored by an organization accredited for continuing medical education by one of the state medical associations or by the Accreditation Council for Continuing Medical Education (ACCME), and
- be designated as AMA PRA Category 1 education by that organization.

Brochures and descriptive materials for AMA PRA Category 1 activities will include a designation statement providing the name of the accredited sponsor, the amount of credit provided, and the category of credit. The texts of designation statements are provided on page 26.

AMA PRA Category 1 activities can take the form of lectures, seminars, use of self-study materials, self-assessment programs, mini-residencies, and use of audio-visual or computer based materials, so long as they are designated as AMA PRA Category 1. Criteria for AMA PRA Category 1 education are provided in Part II of this booklet.

International Continuing Medical Education

International CME activities, for instance World Congresses, can be reported for AMA PRA Category 1 credit if their quality has been endorsed by a specialty society participating in the AMA House of Delegates, and approved by the AMA. The procedures must be completed prior to the occurrence of the activity. The Office of Physician Credentials and Qualifications will maintain a list of approved international activities.

IA PRA Category 2: All Other CME Activities

Education reported under Category 2 must meet the definition of continuing medical education and fit one of the descriptions of education provided below. Category 2 activities must also comply with the AMA "Ethical Opinion on Gifts to Physicians." All lectures and seminars reported for PRA credit must be designated AMA PRA Category 2 by an accredited sponsor of CME.

Non-Supervised Personal Learning Activities

- Clinical consultations that contribute to a physician's education

Informal educational consultations about a patient can be reported; these hours should be estimated and reported in hour blocks.

- Participation in patient care review activities
- Teaching of medical and other health care professionals
- Patient centered discussions with colleagues
- Journal club activities
- Use of self-assessment examinations and reviews

Some self-assessment activities are designated as AMA PRA Category 1 and should be reported as such; undesigned self-assessment activities should be reported as AMA PRA Category 2.

- Use of databases and other computer based materials in connection with patient care activities
- Use of self instructional materials, such as audiovisual materials, teleconferences, programmed medical education materials and computer assisted instruction
- Publication of medical or medically related articles and books, and preparation of exhibits

Ten hours of credit may be claimed for publication of a medical or medically related article, for each chapter of a medical or medically related book, or other medical education materials. Articles must be published in a recognized medical journal, that is a journal that is read primarily by physicians or members of other health professions.

Credit may be claimed only once for the medical or educational content of a publication or exhibit regardless of its being reissued in a changed format.

Ten hours of credit also can be claimed for preparation of an exhibit that is displayed at a scientific medical meeting or at another continuing medical education activity.

- Attendance at conferences, lectures, and seminars designated as AMA PRA Category 2 by accredited organizations.

Activities that Earn both AMA PRA Category 1 and Category 2 Credit

Recertification

Passing examinations, such as license examinations or specialty board certification examinations, is not accepted toward qualification for the PRA. The study a physician does in preparation for these types of examinations is accepted toward qualifying for the PRA.

As of January 1, 1991, recertification by a specialty board recognized by the AMA will be endorsed for a 3 year PRA certificate. The object is to recognize the extensive educational effort involved in meeting recertification requirements, including examination when that is one of the requirements. A PRA certificate will be issued that is valid for three years after the issue date of the certificate of recertification. Specialty board certification (as opposed to recertification) is not accepted for PRA credit.

Part 2

Information for Organizations Sponsoring Continuing Medical Education Programs

Please be sure to read the sections: Category 2, Ethics, and the Definition of Continuing Medical Education. These sections contain important information which is not repeated here.

Institutional Accreditation for Continuing Medical Education

Only an institution or organization accredited for continuing medical education can designate a CME activity as earning AMA PRA Category 1 credit or AMA PRA Category 2 credit.

The Accreditation Council for Continuing Medical Education (ACCME) is responsible for CME accreditation of medical schools, state medical societies, and other institutions and organizations which provide CME activities for a national or regional audience of physicians.

State medical societies accredit institutions and organizations which provide CME activities primarily for physicians within the state or bordering states. All institutions and organizations accredited by state medical societies are recognized by the ACCME and placed on one national list of CME accredited institutions and organizations. Only institutions and organizations are accredited.

The ACCME and state medical societies do not accredit or approve individual CME activities nor does the AMA review and evaluate individual CME activities for purposes of granting credit except in the case of international conferences. The responsibility for designating AMA PRA Category 1 credit rests solely with the accredited institutions and organizations, following the criteria established by the AMA PRA Program.

Institutions and organizations interested in obtaining CME accreditation should contact the ACCME or a state

medical society. The address of the ACCME is:
Accreditation Council for Continuing Medical Education
51-B Sherwood Terrace
Lake Bluff, Illinois 60044
Telephone: 708 295-1490

Withdrawal of Right to Designate Credit

The American Medical Association will withdraw the right to designate AMA PRA Category 1 and/or Category 2 credit if the accredited sponsor is judged to have designated for credit CME activities which:

- do not meet the definition of CME
- are not in accord with the AMA "Ethical Opinion on Gifts to Physicians" and the Accreditation Council for Continuing Medical Education "Standards for Commercial Support of CME";
- solely advocate modalities for diagnosis or treatment which are not subjects for instruction in most U.S. medical schools;
- promote CME activities primarily for non-educational purposes.

Organizations with questions about whether a CME activity meets the above conditions should consult the AMA Division of Continuing Medical Education prior to designating credit for a CME activity.

Criteria for Designation of AMA PRA Category 1

An activity can be designated AMA PRA Category 1 if it is sponsored or jointly sponsored by an institution or organization accredited for continuing medical education by ACCME, or by a state medical society and if the activity meets the following criteria:

- it conforms to the AMA definition of continuing medical education,
- it conforms to the AMA "Ethical Opinion on Gifts to Physicians", and the ACCME, Standards for Commercial Support of CME,
- it is based on perceived or demonstrated educational need,
- it is intended to meet the continuing medical education needs of an individual physician or a specific group of physicians,

- the educational objectives for the activity are stated,
- the content is appropriate for the specified objectives,
- the teaching/learning methodologies and techniques are suitable for the objectives and format of the activity,
- evaluation mechanisms are defined to assess the quality of the activity and its relevance to the stated needs and objectives, and
- there is documentation of physicians' participation by the sponsoring institution/organization.

Continuing medical education activities should cover a subject area in the depth that is appropriate for the intended audience and appropriate for the stated educational objectives. The objectives define a level of knowledge or a specific performance skill to be attained.

Continuing medical education activities cannot be retroactively designated AMA PRA Category 1. Institutional continuing medical education committees must designate all programs before they are provided to participants.

Institutional Continuing Medical Education Committees
Institutional continuing medical education committees should develop their own procedures and forms. The committees must assure that all activities designated for AMA PRA Category 1 credit meet the criteria stated in this booklet. Materials documenting committee procedures should be on hand before the credit designation is made. Committee files should document committee procedures in reviewing activities and the awarding of credit.

While all the criteria necessary for Category 1 activities do not need to be met for Category 2 activities, CME committees should assure that all activities designated for AMA PRA Category 2 credit meet an educational need and are effective educational experiences. Sufficient information must be provided to the committee for this judgment to be made.

An institution's status as an approved provider is not

transferrable. CME committees should not provide either AMA PRA Category 1 credit or AMA PRA Category 2 credit designations to activities developed by other organizations.

Institutions may not indicate in a brochure or program announcement that credit has been applied for. Credit must be clearly indicated in all promotional materials.

Responsibilities of an Accredited Organization for Joint Sponsorship of CME Activities Designated AMA PRA Category 1 or AMA PRA Category 2

An accredited organization or institution may jointly sponsor a CME activity with an institution or organization which is not accredited and designate this CME activity AMA PRA Category 1 or AMA PRA Category 2. In joint sponsorship, the accredited sponsor must meet the requirements of Essential 7 of the ACOME Essentials which provide that the accredited sponsor must participate integrally in the planning, implementation, and evaluation of the activity. In other words, the accredited sponsor must exercise the same responsibility for the CME activity that it jointly sponsors as for a CME activity which is completely its own. An accredited sponsor cannot enter into joint sponsorship retroactively, that is, after a program is being provided or evaluated.

The name of the accredited sponsor should appear on all promotional materials and on the printed program of the jointly sponsored activity. If more than one accredited sponsor jointly sponsors a CME activity, one should assume responsibility for the activity and designate the credit.

Activities Appropriate for AMA PRA Designation of Category 1 or Category 2 Credit

Many formats are appropriate for continuing medical education activities. They include:

- Lecture Series
- Grand Rounds
- Teaching Rounds
- Departmental Scientific Meetings
- Seminars

- Workshops
- Clinical Traineeships
- Mini-Residencies
- Multimedia Self
- Instruction Programs

Periodic activities, such as a lecture series or grand or teaching rounds, can be planned and presented systematically so that over a designated period of time, all significant areas of a specialty or subspecialty are covered.

Educational objectives should be based on clearly identified needs and should identify the target group. Frequently group or individual needs can be determined from a practice profile, peer review, self-assessment, case audit, or individually identified needs. New medical knowledge can also serve as a basis for developing the educational objectives that are specific for a particular knowledge level or performance capability.

Brochures and announcements for continuing medical education activities must state educational objectives and the intended audience as a means of helping physicians decide whether to participate.

CME Learning Assessment Form (CLAF)

In June 1992, the AMA House of Delegates adopted as policy a report of the Council on Medical Education which recommended that "the AMA urge CME sponsors, hospital credentials committees, and physicians to use the 'CME Learning Assessment Form (CLAF)' when CME is intended to support a request for initial or expanded hospital privileges for a newly developed procedure."

Consistent with actions of the AMA House of Delegates the Executive Committee of the American Hospital Association Board of Trustees reviewed the CME Learning Assessment Form in July 1992 and took action to approve the form and to encourage its use by CME course directors.

In general, the CLAF provides the following information:

- The name of the accredited sponsor, date, length of

time, and location of activity.

- The explicit objective(s) of the activity.
- A description of the education methodology used in the activity.
- A description of the methodology used to evaluate the satisfactory completion of the activity.
- A statement that the physician has satisfactorily completed the learning objectives.

Criteria for AMA PRA Category 1 Enduring Materials (Educational Materials)

When audiovisual materials are used as an integral part of an activity which is designated as meeting the criteria for AMA PRA Category 1 or 2, the time spent in using these materials is included in the total instruction time reported.

For the purposes of the PRA, the term "enduring materials" includes printed educational material, audiotapes, videocassettes, films, filmstrips, slides and computer-assisted instruction. It also includes education disseminated by open- and closed-circuit networks, broadcasts by satellite or radio with or without two-way communication, and electronic teaching aids and devices.

When any of the above "enduring materials" are to be designated AMA PRA Category 1, they must meet all of the following criteria:

- Be sponsored or jointly sponsored by an organization accredited for CME by the ACCME or a state medical society.
- Comply with the ACCME Guidelines for Enduring Materials.
- Provide a clear, concise statement of educational objectives and indicate the intended audience.
- Provide clearly stated instructions to the learner.
- Provide supplemental materials to amplify, clarify and reinforce specific information, as well as to give the activity breadth and balance.

These supplemental materials should form an integral part of the activity and contain all of the following, unless inappropriate or duplicative:

- an outline or study guide,
- references for both the body of knowledge presented and for later individual extended study beyond the content covered in the educational material,
- graphic or demonstration materials, -audio materials, and
- systems that require student interaction to reinforce the education, such as answering questions or considering a patient-management problem.
- Be evaluated in terms of the educational objectives of the activity and their ability to convey information correctly.

Deficiencies found through evaluation should be corrected and the material re-evaluated prior to distribution. Information about the methods of evaluation and the findings and action taken should be available upon request.

For materials periodically produced, each subject area, series, or educational unit should be evaluated prior to release.

Although an examination is not required in order for enduring materials to meet the criteria for AMA PRA Category 1, it is often used as a means of evaluating and of verifying physician participation.

If an examination is used as a method of evaluating the materials after distribution, it should measure whether the physician has acquired basic information, and whether the physician can integrate, analyze, and apply it in a simulated problem.

Examinations should be scored confidentially. Individual scores, including relative performance on individual questions, should be returned to individual physicians on a confidential basis, so they can use this information in planning their personal programs of continuing medical education. Composite scores should be made available to the accredited sponsoring organization so that the scores

can be used to evaluate and improve the activity. Tests should be sent to the accredited sponsoring organization or to a bonded organization for scoring.

- Have a means of verifying physician participation.
- Provide a local instructor when audiovisual materials designated AMA PRA Category 1 for Educational Materials are used by groups of physicians.

The instructor may be selected by the medical organizations having the local responsibility for the program. When a local instructor is required, a suitable instructor's kit must be provided far enough in advance of the program to allow the instructor to be well prepared. The kit should include additional materials, such as

- an instructor's guide,
- questions for discussion,
- additional patient-management problems,
- materials for display or demonstration,
- copies of the photographs, charts, graphs, slides, audio materials used in the audiovisual program,
- materials designed for a review of the basic points of presentation,
- additional or supplemental materials for distribution.

The local instructor is expected to participate actively in the activity by leading the discussion. Physicians who serve as local instructors may claim credit in Category 2.

Criteria for Designation of AMA PRA Category 2 Credit by an Accredited Sponsor

Sponsors accredited by the ACCME or a state medical society may designate CME activities such as lectures, conferences, and workshops for AMA PRA Category 2 if they meet the following:

- The activity complies with the AMA definition of CME.
- The activity complies with the AMA Ethical Opinion on Gifts to Physicians.
- The activity for some reason does not meet all the criteria for Category 1. For instance, attempting to meet all the criteria for Category 1 would make the activity less effective (e.g. a small group discussion, an

innovative learning activity), or would result in missing an opportunity (e.g. inviting a visiting professor to give a lecture and answer questions), or would mean delay by the quality assurance committee).

- The activity is judged to be an effective learning experience.

The same unit in an accredited organization must have responsibility for designating both AMA PRA Category 1 and 2 credit. Please be sure to read the section on Category 2, page 5. The section contains important information not repeated here.

Certificates for AMA PRA Credit

Sponsors should be careful that attendance certificates are provided only to those who participated in the activity and completed its requirements. Attendance certificates can be provided to all health professionals. Certificates providing AMA PRA credit should be issued only to physicians.

Category and Credit Hour Designation Statements for the PRA

Organizations and institutions are responsible for the designation of the category and hours of credit provided for activities they sponsor or jointly sponsor. The following designation statements should be used on brochures, printed programs, and educational materials that are designated AMA PRA Category 1.

Designation Statement for AMA PRA Category 1 Activities and Materials

The (name of accredited sponsor) designates this continuing medical education activity for () credit hours in Category 1 of the Physician's Recognition Award of the American Medical Association.

Designation Statement for AMA PRA Category 1 Meetings with Concurrent Sessions

The (name of the accredited sponsor) designates this continuing medical education activity as Category 1 of the

Physician's Recognition Award of the American Medical Association. One credit hour may be claimed for each hour of participation.

Designation Statement for AMA PRA Category 2 Education

The (name of accredited sponsor) designates this continuing medical education activity for () credit hours in Category 2 of the Physician's Recognition Award of the American Medical Association.

If a program includes activities that do not meet the definition of continuing medical education, then only the portions that do meet the definition should be designated for credit.

Consultation or Appeals

Brochures and announcements are monitored by the staff of the PRA program. When circumstances indicate, followup inquiries are made to determine whether or not the designated criteria for the category and hours are met. In most circumstances, incorrect designations are based on misunderstandings which can be resolved easily by consultation. The PRA staff offers consultation to individuals and organizations regarding questions about the correct AMA PRA category and number of hours for a specific activity. Unfavorable interpretations made by the PRA staff may be appealed to the Continuing Medical Education Advisory Committee and, if necessary, to the Council on Medical Education of the AMA.