

**PROPOSED REGULATIONS FROM MASSACHUSETTS  
BOARD OF REGISTRATION IN MEDICINE**

243 C.M.R. 1.00: GENERAL PROVISIONS

Section

- 1.01: Definitions
- 1.02: Operation of the Board
- 1.03: Communication
- 1.04: Board Records
- 1.05: Public Nature of Board Meetings
- 1.06: Requirement to Respond to the Board
- 1.07: Failure to Respond to the Board
- 1.08: Statutory Reports
- 1.09: Reporting by Health Care Facilities and Health Care Providers
- 1.10: Exception for Reports to the Board under M.G.L. c. 112 § 5F
- 1.11: Prescribing Practices
- 1.12: Medical Records
- 1.13: Provision of Medical Services in Emergencies
- 1.14: Mandatory Professional Liability Insurance
- 1.15: Discrimination Against Recipients of Public Assistance Prohibited
- 1.16: Medicare Payments
- 1.17: Advertising and Professional Notices
- 1.18: Organization of Practice
- 1.19: Breast Cancer and Mammography
- 1.20: Ownership Interest in Facilities Providing Physical Therapy Services
- 1.21: Responsibility for Medical Students and Others
- 1.22: Supervision of Nurses Engaged in Prescriptive Practice
- 1.23: Physician Assistants

1.01: Definitions

As used in 243 C.M.R. 1.00 - 4.00, the following words shall have the following meanings unless the context requires otherwise:

Adjudicatory hearing means a formal administrative hearing conducted pursuant to M.G.L. c. 30A.

Administrative Magistrate means a hearing officer from the Division of Administrative Law Appeals, conducting an adjudicatory hearing on behalf of the Board, pursuant to M.G.L. c. 30A and 801 C.M.R. 1.00 *et seq.*

Board means the Board of Registration in Medicine, as established by M.G.L. c. 13 § 10, and its committees.

Complaint means a communication filed with the Board, which reasonably alleges that a licensee has violated a Board regulation or policy or has violated the regulations or statutes of the Commonwealth of Massachusetts.

Disciplinary Action means an action adversely affecting a licensee, which simultaneously meets the descriptions in sections (a), (b) and (c) of this definition, and which is limited as described in sections (d), (e) and (f) of this definition:

(a) An action of an entity, including, but not limited to, a governmental authority, a health care facility, an employer, or a professional medical association (international, national, or local).

(b) An action that is:

(1) formal or informal; and

(2) oral or written.

(An oral reprimand is not a "disciplinary action." However, the fact that conduct resulted in an oral reprimand does not relieve an individual's reporting obligation under M.G.L. c. 112 § 5F.)

(c) Any of the following actions or their substantial equivalents, whether voluntary or involuntary:

(1) Revocation of a right or privilege.

(2) Suspension of a right or privilege.

(3) Censure.

(4) Written reprimand or admonition.

(5) Restriction of a right or privilege.

(6) Non-renewal of a right or privilege.

(7) Fine.

(8) Required performance of public service.

(9) A course of education, training, counseling, or monitoring, only if such course arose out of the filing of a complaint or the filing of any other formal charges reflecting upon the licensee's competence to practice medicine.

- (10) Denial of a right or privilege.
- (11) Resignation.
- (12) Leave of absence.
- (13) Withdrawal of an application.
- (14) Termination or non-renewal of a contract with a licensee.

(d) Divisions (5), (6), (10), (11), (12), (13), and (14) above are "disciplinary actions" only if they relate, directly or indirectly, to:

- (1) the licensee's competence to practice medicine, or
- (2) a complaint or allegation regarding any violation of law or regulation (including, but not limited to, the regulations of the Board) or by-laws of a health care facility, medical staff, group practice, or professional medical association, whether or not the complaint or allegation specifically cites violation of a specific law or regulation.

(e) If based only upon a failure to complete medical records in a timely fashion or failure to perform minor administrative functions, the action adversely affecting the licensee is not a "disciplinary action" for the purposes of mandatory reporting to the Board, provided that the adverse action does not relate directly or indirectly to:

- (1) the licensee's competence to practice medicine, or
- (2) a complaint or allegation regarding any violation of law or a Board regulation, whether or not the complaint or allegation specifically cites violation of a specific law or regulation.

(f) This definition does not include actions taken by the Board.

Electronic medium means any device used to transmit information electronically, including but not limited to facsimile and e-mail, but not including the telephone.

Good Moral Character means those aspects of morality, attention to duty, forthrightness and self-restraint which are usually associated with the accepted definition of good moral character, as determined by the Board. Any conduct, whether or not arising in the context of medical practice, which calls into question an applicant's or licensee's fitness or ability to practice medicine, or which is antithetical to the promotion of the public health, safety and welfare, as determined by the Board, constitutes a lack of good moral character.

Hand delivery means delivery in hand or to the last known address, or by any method other than pre-paid U.S. mail or electronic medium, including but not limited to, private mail services. Hand delivery to a licensee shall be made to the licensee's last reported address.

Health care facility means any facility licensed pursuant to M.G.L. c. 111 § 51 or M.G.L. c. 19 § 19; any nursing home, within the meaning of M.G.L. c. 111 § 203(d); any state, county or municipal hospital or clinic; any entity maintaining more than one primary or episodic walk-in center; and any health maintenance organization within the meaning of M.G.L. c. 176G § 1.

Health care provider means any provider as defined in M.G.L. c. 111 § 1.

License means the certificate of registration issued by the Board pursuant to M.G.L. c. 112 §§ 2 through 9B authorizing the licensee to engage in the practice of medicine.

Licensee means a person holding or having held any type of certificate of registration issued pursuant to M.G.L. c. 112 §§ 2 through 9B.

Medical emergency means a set of circumstances that immediately threatens a person's life or is likely to cause serious injury absent the provision of immediate professional assistance.

Party means a respondent, a complaint counsel representing the Enforcement Division, or an intervener in an adjudicatory proceeding.

The "Practice of medicine" includes the following:

- (a) (1) advertising, holding out to the public, or representing in any manner that one is authorized to practice medicine in Massachusetts;
- (2) offering or undertaking to prescribe, order, give, or administer any drug, medicine, or medical device for the use of any other person;
- (3) offering or undertaking to prevent or to diagnose, correct and/or treat in any manner or by any means, methods, or devices any disease, illness, pain, wound, fracture, infirmity, defect or abnormal physical or mental condition of any person, including the management of pregnancy and parturition;
- (4) offering or undertaking to perform any surgical operation upon any person;
- (5) performing an act that is part of patient care initiated in this state, including but not limited to the performance or interpretation of a

radiological examination, or the preparation or interpretation of pathological material, that would affect the diagnosis or treatment of the patient, through any medium, including but not limited to an electronic medium;

- (6) rendering treatment to a patient located within this state by a physician located outside this state as a result of transmission of individual patient data by electronic or other means from this state to such physician or his agent;
- (7) providing an independent medical examination or a disability evaluation;
- (8) deciding that a treatment or procedure ordered or carried out by a licensee is not medically necessary and, on those grounds, refusing, or causing others to refuse, to reimburse for or make a health care facility available for such procedure;
- (9) using the designation Doctor, Doctor of Medicine, Doctor of Osteopathy, Physician, Surgeon, Physician and Surgeon, Dr., M.D., D.O. or any combination thereof in the conduct of any occupation or profession pertaining to the prevention, diagnosis, or treatment of human disease or condition, unless such a designation additionally contains the description of another branch of the healing arts for which one holds a valid license in Massachusetts; or
- (10) conducting any dermatologic procedure at any location including, but not limited to, medical or beauty clinics, walk-in clinics, spas, salons, health clubs, retail locations or other environments. Dermatologic procedure includes, but is not limited to, laser/light and radiofrequency devices, chemical peels, soft tissue fillers/augmentation, microdermabrasion techniques, laser hair removal, botulinum toxin, and sclerotherapy.

(b) The practice of medicine does not include conduct of the type described above when engaged in by persons authorized by statute or regulation to engage in such conduct and licensed by other boards of registration authorized to regulate such conduct, nor does it mean assistance rendered in medical emergencies by persons other than licensees.

(c) Acupuncture may be performed only by a full licensee or by an acupuncturist duly licensed and registered in the Commonwealth.

Respondent means the licensee named in a Statement of Allegations.

Stale matter means any complaint arising out of conduct by a licensee that occurred more than seven years prior to the date the complaint is filed with the Board.

Statement of Allegations means an order to show cause why the respondent should not be disciplined; a Statement of Allegations is an order to show cause within the meaning of 801 C.M.R. 1.01 *et seq.*

Statutory Report means any report required by statute to be made to the Board.

For convenience, the pronouns “he,” “him,” and “his,” as used throughout these regulations, include both genders.

#### 1.02: Operation of the Board

- (1) Membership of Committees. The Board may establish committees of its members to assist in accomplishing its responsibilities. The Board may designate former members for assignment to these committees; however, at least one member of each committee shall be a current member of the Board.
- (2) Conference. The Board, or any of its committees, may require any applicant, licensee or health care facility to attend a conference at any time. If the Board or Committee requires attendance, the Board or Committee shall give notice of the conference, including a reference to the complaint, the statutory report or a statement of the nature of the issues to be discussed.
- (3) Decisions by the Board: Quorum. Each Board meeting must be attended by a quorum of its members. A quorum is a majority of the Board, excluding vacancies. Every Final Decision and Order of the Board requires the concurrence of at least four members, or of a majority of the Board if it has more than one vacancy. In all other situations, a majority of members present and voting at a Board meeting shall make all decisions.
- (4) Adjudicatory Proceedings. After the Board issues a Statement of Allegations, the Board or its designee shall conduct all hearings in accordance with M.G.L. c. 30A and 801 C.M.R. 1.00 *et seq.*, the Standard Adjudicatory Rules.
- (5) Standing Orders. From time to time, the Board may issue standing orders consistent with these regulations and 801 C.M.R. 1.00 *et seq.*
- (6) Change of Address. Whenever a licensee changes his mailing, home or principal business address, he shall notify the Board of his new address within 30 days of such change.

#### 1.03: Communication

- (1) Correspondence. All written correspondence should be addressed to and filed with the Board of Registration in Medicine at its official mailing address.
- (2) Filing Format. Papers and written correspondence, including documents and correspondence relating to adjudicatory matters, may be filed with the Board by hand delivery, prepaid U.S. mail or electronic medium, unless the Board orders otherwise. Where these regulations require that applications, notices, evidence, and other documents be in writing or require a signature, the Board may approve of and provide for the electronic submission and sending of those documents and the use of an electronic signature.
- (3) Identification and Signature. All papers filed with the Board in the course of an adjudicatory proceeding must contain the name, address, and telephone number of the party making the filing and must be signed by either the party or an authorized representative.
- (4) Paper Size. Paper size shall be 8½” by 11”.
- (5) Dates of Receipt, Computation of Time, and Extensions of Time.

(a) Date of Receipt for Papers filed with the Board.

- (i) All papers filed with the Board by U.S. mail, other than those using a postal meter stamp, shall be deemed filed on the date contained in the U.S. postal cancellation stamp or U.S. postmark.
- (ii) Papers filed by electronic medium shall be deemed filed with the Board on the date received by the Board during usual business hours.
- (iii) Papers filed with the Board by all other means, including those using a postal meter stamp, shall be considered hand delivered and shall be deemed filed on the date received by the Board during usual business hours. The Board shall provide, upon request, dated receipts to persons filing papers by hand delivery during business hours.
- (iv) Papers received after usual business hours shall be deemed filed on the following business day.

(b) Date of Receipt for Communications from the Board.

Notice of actions and other communications from the Board shall be presumed to be received upon the day of hand delivery or, if mailed, three days after deposit in the U.S. mail. The postmark shall be evidence of the date of mailing.

(c) Computation of Time Periods.

Unless otherwise specifically provided by these regulations, 801 C.M.R. 1.00 *et seq.*, or by other applicable law, computation of any time period referred to in the Board's regulations shall begin with the first day following the act that initiates the running of the time period. The last day of the time period is included unless it is a Saturday, Sunday, legal holiday, or any other day on which the Board is closed, when the period shall run until the end of the following business day. Intervening days when the Board is closed are included in that time period, unless the time period is seven (7) days or less, in which case such intervening days shall be excluded.

(d) Extension of Time.

Except when an Administrative Magistrate has jurisdiction over an adjudicatory proceeding, the Board may, for good cause shown, extend any time limit contained in these regulations or in 801 C.M.R. 1.00 *et seq.* Nothing herein shall require the Board to extend any time limit required in 243 C.M.R. 1.06 and 1.07. All requests for extensions of time shall be filed in writing before the expiration of the original time period. The filing of such request shall toll the time period sought to be extended until the Board acts on the request. This section shall not apply to any limitations of time prescribed by statute, unless the applicable statute permits extensions.

(6) Service by the Board.

- (a) When the Board issues a Statement of Allegations, it shall provide notice of such action by prepaid U.S. and certified U.S. mail, return receipt requested, or by reasonable attempts at hand delivery, to the last known address filed with the Board.
- (b) Except when an Administrative Magistrate has jurisdiction over an adjudicatory proceeding, and except as specified in subsection (a), when the Board is required to notify parties pursuant to 243 C.M.R. 1.00 *et seq.*, service may be made by prepaid U.S. mail, by electronic medium, or by hand delivery.

(7) Service Upon the Board in Adjudicatory Proceedings.

- (a) When an Administrative Magistrate has jurisdiction over an adjudicatory proceeding, proper service by the parties includes the filing of the original of all papers and exhibits with the Administrative Magistrate assigned to the adjudicatory proceeding, and the filing of copies of all papers and exhibits with:
  - (i) the Board, in care of its General Counsel;
  - (ii) all other parties; and
  - (iii) the Director of Enforcement.



(b) When the Board has jurisdiction over an adjudicatory proceeding, proper service by the parties includes the filing of an original and 13 copies of all papers and exhibits with the Board. One of these 13 copies shall be filed with the other party, and the remaining 12 shall be filed with the General Counsel. All copies shall be filed at the time of the filing of the original.

- (8) Notice of Appearance. A notice of appearance on behalf of a Respondent shall be deemed an agreement between the Respondent and the person appearing on the Respondent's behalf that such person shall accept service of any document on behalf of the Respondent.
- (9) Service. All papers served in an adjudicatory proceeding shall be accompanied by a statement certifying the date copies have been served, specifying the mode of service, the name of the party served, and the address of service. Papers served by electronic medium shall indicate the date transmitted and the facsimile number or electronic address used for transmittal. Failure to comply with this rule shall be grounds for the Board or the Administrative Magistrate to refuse to accept papers for filing.
- (10) Ex Parte Communication with Board members. Neither a party nor the representative of a party shall make or knowingly cause to be made an ex parte communication with any Board member regarding an adjudicatory proceeding.

#### 1.04: Board Records

##### (1) Availability of Board Records to the Public.

- (a) The availability of the Board's records to the public is governed by the provisions of the Public Records Law, M.G.L. c. 66 § 10, and M.G.L. c. 4 § 7, clause 26, as limited by the confidentiality provisions of M.G.L. c. 112 §§ 5 through 5I, these regulations and other relevant provisions of federal and state law.
- (b) All information collected by the Board shall be public except that the following information shall be confidential:
1. During the pendency of an investigation or an adjudicatory proceeding, all Board files except materials docketed or introduced into evidence in an adjudicatory proceeding, unless impounded or placed under seal by the Administrative Magistrate or the Board;
  2. Statutory Reports and related materials that do not result in a final Board adjudicatory action, except those that are required by statute to be public and those reports filed pursuant to M.G.L. c. 231 § 60b, c. 221 § 26, and M.G.L. c. 112 § 12AA;

3. Peer review information and records and other materials protected by statute or recognized common law privilege, and any materials related to review and investigation of such information, records, or materials unless introduced into evidence at an adjudicatory proceeding;
4. Identities of professional reviewers and the contents of their reports, unless such information is introduced into evidence at an adjudicatory proceeding. However, reports by professional reviewers and the identities of reviewers shall be available to the Respondent in an adjudicatory proceeding. The contents of such reports, with the exception of the reviewers' names, may be made available to a licensee under investigation prior to the issuance of a Statement of Allegations at the discretion of Complaint Counsel;
5. Correspondence received by the Board prior to July 1, 2006, which contains allegations against a licensee and which was not docketed as a complaint due to lack of jurisdiction or staleness;
6. Letters of Agreement and related materials; except that, if the Board suspends the license of a physician for violation of the terms of a Letter of Agreement, the fact that the physician had entered a Letter of Agreement shall become public, and a general description of Letters of Agreement will be provided, but the Letter of Agreement itself and the related materials shall remain confidential.
7. Memoranda from Board attorneys and staff to Board members regarding matters considered in adjudicatory, executive, or otherwise confidential session, including matters considered in confidential session by a committee of the Board;
8. Policy development memoranda addressed to Board staff or Board members; however, after a determination has been made with regard to the policy addressed in the memoranda, such memoranda shall thereafter be public;
9. Identities of patients or complainants, unless authorized to be made public by the patient, the patient's authorized representative or the complainant, or otherwise ordered by the Board;
10. Home addresses of licensees, provided, however, that the Board may release a home address for good cause;

11. Responses to questions on license application forms, the release of which would constitute an unwarranted invasion of privacy;
  12. Social security numbers and prescribing numbers issued by the Drug Enforcement Agency or the Department of Public Health; and
  13. Any other information required to be held as confidential by federal or state statute, regulation or common law.
- (c) The databases from which the individual physician profiles are drawn are not public documents.
- (d) National Provider Identifier (NPI) numbers are not public documents.
- (e) Pursuant to M.G.L. c. 112 § 5, information from open investigatory files may be made available, at the discretion of the Board, to the following:
- (1) the complainant;
  - (2) a patient whose care is being investigated, only as to information about the investigation into his care.
- (f) Information in the Board's files shall be made available to the data subject or his designee consistent with the Fair Information Practices Act, M.G.L. c. 66A and these regulations except that, pursuant to M.G.L. c. 112 § 5, the Board restricts the disclosure of open investigatory files or other information to the licensee under investigation for a period of one year from the docketing of the complaint or receipt of the statutory report, unless Complaint Counsel decides otherwise or a Statement of Allegations issues.

(2) Investigative Records or Confidential Information.

Pursuant to M.G.L. c. 112 § 5, the Board may, in its discretion, share information from open investigative records or other confidential information, as it believes is in the public interest and consistent with the Fair Information Practices Act (FIPA), and any other federal or state statutes or regulations that govern the release of said confidential information with the following:

- (1) Federal, state, or municipal law enforcement agencies;
- (2) Federal, state, or municipal health care oversight and regulatory agencies, boards or institutions; and

(3) any other federal, state, or municipal agencies, boards or institutions as approved by the Board.

All recipients of confidential information designated by this section shall preserve the confidentiality of such information and make it available to the data subject, to the extent such access is required by FIPA and not otherwise precluded by statute or regulation.

#### 1.05: Public Nature of Board Meetings

- (a) All meetings of the Board are open to the public to the extent required by M.G.L. c. 30A § 11A½.
- (b) As provided by M.G.L. c. 30A, a Board meeting held for the purpose of making a decision required in an adjudicatory proceeding is not open to the public.
- (c) Evidentiary hearings on behalf of or before the Board are generally open to the public, but the Board or its designee may carry out its functions under 243 C.M.R. 1.00 and 801 C.M.R. 1.00 in closed session if the Board or its designee decides that functioning in closed session would be in the public interest or would prevent an unwarranted invasion of personal privacy.
- (d) In all cases, hearings and other proceedings shall be conducted in a manner that preserves patient confidentiality.

#### 1.06: Requirement to Respond to Board

A licensee shall respond within 30 days to a written communication from the Board or its designee and shall make available to the Board any relevant records with respect to an inquiry or complaint about the licensee. The 30-day period commences on the date the Board sends the communication by certified mail with return receipt requested to the licensee's mailing address of record with the Board. A licensee may request an extension of the above time period, provided that such request is made within the 30-day period and upon a demonstration of good cause.

#### 1.07: Failure to Respond to the Board

If a licensee fails to respond within the 30-day period, the Board will initiate disciplinary action in accordance with the following provisions.

- (1) Following the 30-day period referenced in 243 C.M.R. 1.06, a seven-day Order to Respond will issue and a complaint alleging failure to respond will be

docketed against the licensee. In that Order, the licensee will be notified that failure to respond within the seven-day period will result in the issuance of a Statement of Allegations.

- (2) If the licensee fails to respond to the Order within the seven-day time period, the Board will, at its next scheduled meeting, issue a Statement of Allegations.
- (3) The Chairman of the Complaint Committee or his designee may approve a written request for an extension of the above time period, provided that such request is made within the seven-day period and that the basis for such request demonstrates good cause.

#### 1.08: Statutory Reports

- (1) Initiation of Statutory Reports. A statutory report shall be in writing on a form designated or approved by the Board.
- (2) Compilation of Statutory Reports. The Board shall maintain a Data Repository to compile all data required under M.G.L. c. 112 §§ 5A through 5J inclusive, and under any other law or regulation which requires that information be reported to the Board. Statutory reports include, but are not limited to, health care facility disciplinary action reports (M.G.L. c. 111 §§ 53B and 203); medical association disciplinary action reports (M.G.L. c. 112 § 5B); responses on license applications (M.G.L. c. 112 § 2); court reports of criminal matters (M.G.L. c. 221 § 26); court reports of medical malpractice matters (M.G.L. c. 231 § 60B); reports by government agencies (M.G.L. c. 112 § 5D); peer reports (M.G.L. c. 112 § 5F); reports by an insurer of a secondary remedial action (M.G.L. c. 175A § 5C); and reports of financial interest in physical therapy services (M.G.L. c. 112 § 12AA).
- (3) Disposition of Statutory Reports.
  - (a) Referrals pursuant to Data Repository policy. The Data Repository may designate certain types of statutory reports as requiring immediate or direct referral to another division of the Board for appropriate disposition. Such referrals may be made at any point in the consideration of a statutory report.
  - (b) Review by Data Repository. The Data Repository may review any statutory reports that are not referred to another division of the Board. Such review may include, but is not limited to, a request for response from the licensee. Review of a statutory report by the Data Repository does not preclude review and investigation by any other committee or division of the Board.
- (4) Dissolution or Disassociation from a Practice Group

A licensee shall report to the Board the detailed circumstances regarding a dissolution of or disassociation from a professional corporation, partnership or professional practice group, if such dissolution or disassociation is related, directly or indirectly, to:

- (a) a licensee's competence to practice medicine, or
- (b) a complaint or allegation regarding any violation of law or regulation (including but not limited to the Board's regulations), or by-laws of a health care facility, medical staff, group practice, or professional medical association, whether or not the complaint or allegation specifically cites violation of a specific law, regulation or bylaw.

This report shall be filed within 10 days of the dissolution or disassociation from a practice group.

#### 1.09: Reporting by Health Care Facilities and Health Care Providers

The following reporting requirements apply to hospitals, health maintenance organizations and nursing homes, and to licensees with responsibility for reporting on behalf of such entities, and are pursuant to M.G.L. c. 111 §§ 53B and 203, M.G.L. c. 112 §§ 2 through 9B, and M.G.L. c. 13 § 10:

(1) Reporters. M.G.L. c. 111 § 53B and 203 require that a reporting entity report any disciplinary action relating to employment practice or association for the purpose of providing patient care or privileges. For the purposes of reporting pursuant to M.G.L. c. 111 §§ 53B and 203 or this section, a "physician registered with the Board as qualified to practice medicine in the commonwealth" includes any person holding any type of license issued pursuant to M.G.L. c. 112 §§ 2 through 9B. A health maintenance organization (HMO) that is not a clinic and reports to the Board pursuant to M.G.L. c. 111 § 53B shall report to the Board any disciplinary action it takes against a licensee. A nursing home shall report to the Board any disciplinary action it takes against a licensee including, but not limited to, a revocation of or limitation on the licensee's privileges to examine or treat nursing home residents, or a resignation directly or indirectly resulting from the threat of disciplinary action.

(2) Urgent Notice of Termination and Suspension. If the disciplinary action taken is a suspension or termination of all privileges, a report must be filed with the Board within 48 hours of the action taken by the facility, unless otherwise required by law. A health care facility, HMO or nursing home making a 48-hour report of suspension or termination to the Board may do so initially by telephone or by facsimile transmission, to be followed by a written report within 10 days unless otherwise required by law.

- (3) Requirement of Substantiation. Whenever a report is required pursuant to M.G.L. c. 111 §§ 53B and 203, or these regulations, the person or entity reporting shall use the form provided by the Board. A report filed pursuant to M.G.L. c. 111 §§ 53B and 203 shall be substantiated by the person or entity reporting. A report that is incomplete is not a substantiated report. The report shall include a statement detailing the nature and circumstances of the action, its date, and the reasons for it.
- (4) Filing Initial Report. The initial report of disciplinary action shall be filed within 10 days of the actual imposition of the action, unless otherwise required by law, regardless of whether further appellate remedies are available to the licensee. If the disciplinary action is later reversed, the reporting entity shall file a supplementary report with the Board.
- (5) Subsequent Reporting Required. Whenever a disciplinary action is ongoing, the reporting entity has a continuing reporting requirement. The reporting requirement is satisfied only when the disciplinary action taken against the licensee is completed. The reporting entity shall submit to the Board a subsequent report every 60 days from the date of the initial disciplinary action, indicating the licensee's progress or compliance with the disciplinary action. The reporting entity shall make a final report to the Board within 10 days of the completion of a disciplinary action unless otherwise required by law.
- (6) Annual Summary of Disciplinary Actions. All health care facilities, including health maintenance organizations and nursing homes, shall file an annual summary of disciplinary actions, no later than January 31 for the previous calendar year, on a form provided by the Board. The annual disciplinary action summary report shall summarize the reports made by the facility to the Board in the previous calendar year.
- (a) All health care facilities, including health maintenance organizations and nursing homes, shall submit the names of all full licensees who have terminated their relationship with the entity in the past calendar year. Such submission shall be made on the annual disciplinary summary form.
  - (b) The annual disciplinary summary shall be sent by certified or registered mail, and it shall be signed under pains and penalties of perjury. If the entity submitted no reports for the previous calendar year, then the annual disciplinary summary shall state that no disciplinary actions were taken.
  - (c) The annual disciplinary summary report is a public document.
- (7) Violation of Reporting Obligation. The Board shall enforce the reporting obligations set forth in M.G.L. c. 111 §§ 53B and may, upon finding a violation of this section, assess a fine not in excess of ten thousand dollars. However,

before taking formal enforcement action, the Board shall provide 30 days written notice to the reporting entity so that it may implement corrective measures, unless the Board, by majority vote, determines that the public health, safety or welfare necessitates earlier action.

1.10: Exception for Reports to the Board under M.G.L. c. 112 § 5F

A health care provider (reporter) who is required to report a licensee to the Board pursuant to M.G.L. c. 112 § 5F, is exempt from filing such a report if all of the following conditions are present:

- (1) The reporter has a reasonable basis to believe that the licensee is or has been impaired by, dependent upon or misusing alcohol or drugs such that a report could be required under M.G.L. c. 112 § 5F, and is not otherwise in violation of M G.L. c. 112 § 5 or 243 C.M.R. 1.00 through 6.00.
- (2) The licensee is currently in compliance with a drug or alcohol program, or the reporter obtains direct confirmation from such drug or alcohol program, within 30 days of acquiring the "reasonable basis to believe," that the licensee is in compliance with such program.
- (3) The drug or alcohol program is approved by a majority vote of the Board. Approval may be withdrawn, at any time, for cause, by majority vote of the Board and with reasonable advance notice to the program of the reasons for the proposed withdrawal of approval and an opportunity to dispute such reasons. However, nothing herein shall be construed to provide a right to an adjudicatory hearing pursuant to M.G.L. c. 30A.
- (4) The drug or alcohol program requires as a condition of the licensee's participation that the licensee consent, pursuant to 42 CFR Chapter 1, Subpart A, Part 2, Subsection C, to disclosure of relevant information to the Board, under any of the following conditions:
  - (a) If the licensee fails to correct, within a reasonable period of time, a failure to provide documentation of his continuing freedom from unauthorized substance use.
  - (b) If the licensee is known by the program to be in a state of unauthorized substance use, or if the subject physician is in a state of unauthorized substance use after signing his contract with the program.
  - (c) If the program has a reasonable basis to believe that the licensee, for any reason, cannot render professional services without undue risk to the public.



- (d) If the licensee revokes consent to disclose information to the Board during the course of the licensee's contract with the program.
  - (e) If the licensee terminates his contract with the program for any reason other than his successful recovery, in which the program concurs.
- (5) The drug or alcohol program requires that the licensee consent to confirmation to the reporter, pursuant to federal regulations, that the licensee is participating in the program, to the extent that the reporter needs such confirmation pursuant to this section.
- (6) The licensee's involvement with alcohol or drugs has not involved an allegation of patient harm.

#### 1.11: Prescribing Practices

- (1) Self-Prescribing and Prescribing for Family Members. A licensee is prohibited from prescribing controlled substances in Schedules II, III, and IV for his own use. Except in a medical emergency, a licensee is prohibited from prescribing Schedule II controlled substances to a member of his immediate family, or to any person permanently residing in the same residence as the licensee.
- (2) Prescribing Anabolic Steroids. A licensee is prohibited from prescribing anabolic steroids for the purpose of enhancing a patient's athletic ability or performance.
- (3) Prescribing Anorectics. A licensee is prohibited from prescribing any controlled substance in Schedule II for its anorectic effect.
- (4) Emergency Contraceptives. In accordance with M.G.L. c. 94C § 19A, a licensee may sign written, standardized procedures or protocols authorizing licensed pharmacists to dispense emergency contraceptives, as defined in §19A.

#### 1.12: Medical Records

- (1) Patient Records. A licensee shall maintain a medical record for each patient that is complete, timely, legible, and adequate to enable the licensee and any other health care provider to provide proper diagnosis and treatment. Any records received from another health care provider involved in the care and treatment of the patient shall be maintained as part of the patient's medical record.

(2) Requirement to Maintain Patient Records. With respect to patient records existing on or after January 1, 1990, a licensee must maintain a patient's medical records for a minimum of seven (7) years from the date of the last patient encounter, or until the patient reaches the age of nine (9), if longer than seven (7) years, and in a manner that permits the patient or a successor physician access to them within the terms of these regulations. This regulation applies to all licensees, including but not limited to those with active, inactive, lapsed, suspended, revoked, resigned or retired status.

(3) Providing Medical Records. Upon a patient's request, a licensee shall provide in a timely manner, to a patient, other licensee or other specifically authorized person:

- (a) the opportunity to inspect that patient's medical record;
- (b) a copy of such record, except in the circumstances described in 243 C.M.R. 1.12(6); and
- (c) a copy of any previously completed report required for third party reimbursement.

(4) Fees. A licensee may charge a reasonable fee for the expense of providing copies of medical records. However, a licensee may not require prior payment of the charges for the medical services to which such material relates as a condition for making the records available. Charges for providing copies of medical records must be in compliance with M.G.L. c. 111 § 70 and M.G.L. c. 112 § 12CC. Licensees may also charge the actual cost of providing copies of x-rays and similar documents not reproducible by ordinary photocopying.

(5) When Medical Record Required in Relation to a Needs-Based Benefit Program. A licensee shall not charge a fee of any applicant, beneficiary or individual representing said applicant or beneficiary if the record is requested for the purpose of supporting a claim or appeal under any provision of the Social Security Act or any federal or state financial needs-based benefit program. Any person for whom no fee shall be charged shall present reasonable documentation at the time of such record request that the purpose of such request is to support a claim or appeal under any provision of the Social Security Act or any federal or state financial needs-based benefit program.

(6) Psychiatric Records. Pursuant to M.G.L. c. 112 § 12CC, if a licensee, who devotes a substantial portion of his time to the practice of psychiatry, determines, in the reasonable exercise of his professional judgment, that providing the entire medical record would adversely affect the patient's well being, the licensee shall make a summary of the record available to the patient. If a patient continues to request the entire record, notwithstanding the licensee's determination, the licensee shall make the entire record available to either the patient's attorney, with the patient's consent, or to such other psychotherapist as designated by the patient.

### 1.13: Provision of Medical Services in an Emergency

- (1) General Rule. A licensee shall render medical services to a person experiencing a medical emergency. A licensee shall assume that a person who is referred to him by another licensee for the purpose of securing medical services of an emergency nature is experiencing a medical emergency.
- (2) Limitations on General Rule.
  - (a) A licensee whose professional training or experience is insufficient to enable him to provide medical services of adequate quality to a person experiencing a medical emergency is exempt from complying with the requirements of this section. However, he must provide reasonable assistance to the person and make a reasonable attempt to secure competent medical services for the person.
  - (b) A licensee whose professional training or experience, while sufficient to enable him to provide medical services of adequate quality, is not as appropriate as that of another licensee or other competent source of assistance known to him, may refer a person experiencing a medical emergency to such an alternative source of services if, in the exercise of reasonable professional judgment, doing so would be in the person's best interest, delay would not create additional harm, and the licensee talks directly with the source of medical services to ensure that the person will be seen promptly.
  - (c) A licensee may not refuse to provide medical services in the ordinary course of his practice to a person experiencing a medical emergency because the person is unable to pay for the services.

### 1.14: Mandatory Professional Liability Insurance

- (1) As a Condition of Practice. As a condition of engaging in the practice of medicine in Massachusetts, a licensee must obtain professional malpractice liability insurance as follows:
  - (a) "Professional Malpractice Liability Insurance" shall include only insurance or self-insurance coverage provided by an entity which provides certification to the Board, upon request, or to the Division of Insurance, that funding of the entity is adequate to provide the coverage required under this section.

- (b) The coverage amount shall be at least \$100,000.00 per claim, with a minimum annual aggregate of not less than \$300,000.00, unless otherwise established by law. Coverage may be provided on an individual or shared limit basis.
  - (c) Nothing in this chapter shall preclude any hospital or other health care facility from requiring greater coverage amounts as a condition of appointment or granting privileges.
  - (d) These requirements shall not apply to the following categories of licensees:
    - (i) Licensees not engaged in the practice of medicine in Massachusetts.
    - (ii) Licensees whose patient care in Massachusetts is limited to professional services rendered at or on behalf of federal, state, county or municipal health care facilities.
    - (iii) Limited Licensees who are insured through the programs designated on their certificates of limited registration.
- (2) Request to Substitute Bond or Indemnity. In lieu of obtaining such professional malpractice liability insurance, the licensee may petition the Board for permission to obtain a suitable bond or other indemnity against liability for professional malpractice, in the amounts specified above.
- (3) Extent of Coverage. Coverage required by this regulation shall be continued until the expiration of any statute of limitations relevant to the events or occurrences covered. Compliance may be through occurrence coverage or claims-made with appropriate tail coverage.

#### 1.15: Discrimination Against Recipients of Public Assistance Prohibited

- (1) General Rule. A licensee may not discriminate against a person seeking medical services solely because the person is a recipient of public assistance. This section prohibits a licensee from acting differently toward a recipient of public assistance in any material manner and requires a licensee to provide medical services of the same quality and in the same manner to a recipient of public assistance as he would to any other person in similar circumstances who is not a recipient of public assistance.
- (2) Limitations on General Rule. A licensee may act in any of the following ways without violating this section:

- (a) Impose limits upon the availability of his services in other than medical emergencies, which are based upon non-discriminatory criteria, *e.g.*, professional training and experience;
- (b) Impose a limit upon the availability of his services in other than medical emergencies, which requires a person seeking his services to present reasonable evidence of the person's ability to pay for services rendered prior to their rendition;
- (c) Withdraw from or decline to participate in the Commonwealth's medical care and assistance program established by M.G.L. c. 118E; or
- (d) Require personal payment of his usual charge for services by a person who is a beneficiary of the Commonwealth's medical care and assistance program, only if the licensee is not a "provider" as defined in M.G.L. c. 118E § 8. Any licensee acting pursuant to this provision shall inform the person of the following:
  - (1) the licensee is not a provider within the meaning of the laws regulating the Commonwealth's medical care and assistance program;
  - (2) if the person requests the licensee's services despite the fact that he is not a provider, the licensee will require the person to pay directly his usual charge for services;
  - (3) other physicians who are providers and would not charge the person directly are available; and
  - (4) upon request, the licensee will attempt to refer the person to a licensee who is a provider.

#### 1.16: Medicare Payments

Pursuant to M.G.L. c. 112 § 2, if a licensee accepts for treatment a beneficiary of health insurance under Title XVIII of the Social Security Act (Medicare), the licensee shall not charge to or collect from such beneficiary any amount in excess of the amount allowed to be charged for that service as determined by the Centers for Medicare and Medicaid Services and published in its fee schedules.

#### 1.17: Advertising and Professional Notices

- (1) Public Interest. A full licensee may advertise for patients by means that are in the public interest. Advertising that is not in the public interest includes the following:
  - (a) advertising that is false, deceptive, or misleading;

- (b) advertising that has the effect of intimidating or exerting undue pressure;
- (c) advertising that guarantees a cure; or
- (d) advertising that makes claims of professional superiority that a licensee cannot substantiate.

(2) Contents of Advertising. A full licensee may advertise fixed prices, or a stated range of prices, for specified routine professional services, provided such advertisement clearly states whether additional charges may be incurred for related services that may be required in individual cases. A full licensee shall include in an advertisement or professional notice his name, business address and degree (M.D. or D.O.).

(3) Advertising Records. A full licensee shall maintain a complete, accurate, and reproducible version of the audio and visual contents of any advertising for a period of three years. The licensee shall furnish the complete copy of this advertising to the Board upon request. The cost of maintaining and providing this advertising copy shall be borne by the licensee.

#### 1.18: Organization of Practice

A licensee may conduct the practice of medicine in Massachusetts as an individual, or through, or on behalf of, an organization, including:

- (1) a not-for-profit organization;
- (2) a business corporation organized under G.L. c. 156B;
- (3) a professional corporation organized under G.L. c. 156A;
- (4) a limited liability company organized under G.L. c. 156C;
- (5) a partnership (including a registered limited liability partnership) organized under G.L. c. 108A; or
- (6) an organization similar to those organizations described above and organized under a comparable law of any other United States jurisdiction

only if licensees have effective control over all practice of medicine decisions made by or on behalf of such organization.

#### 1.19: Breast Cancer and Mammography

##### (1) Patient Rights

- (a) A licensee is required to provide the following information in an understandable manner to a patient whom the licensee accepts for treatment with known or suspected cancer of the breast, unless the patient waives compliance with this section. This information shall include a description of treatment options, including but not limited to surgical procedures, radiation therapy, chemotherapy and combinations of these methods; a discussion of the currently known risks and benefits of each method; and answers to the patient's questions concerning the treatment options. If the patient desires information about treatment options, a licensee shall provide the name or names of qualified licensees.
- (b) A licensee is excused from compliance with the above requirements if the licensee informs the patient of the licensee's willingness to provide information concerning treatment and said patient does not wish to discuss the matter further.
- (c) A licensee shall document compliance with the requirements of this section in the patient's office and hospital record, together with said patient's informed consent.

(2) Standards for Reading and Interpreting Mammography

(a) Pursuant to M.G.L. c. 112 § 5L, a licensee may read and interpret mammography only if the licensee meets the following criteria:

- (1) has American Board of Radiology (ABR) or American Osteopathy Board of Radiology (AOBR) certification, or has successfully completed and graduated from an accredited radiology residency within the past 24 months;
  - (2) has read and interpreted an average of no less than 480 mammograms in the prior year, and continues to perform mammograms at this frequency;
  - (3) has successfully completed or taught a minimum of 40 hours post-graduate instruction in mammography interpretation prior to beginning this activity; and
  - (4) completes or teaches a minimum of 15 hours of post-graduate work in mammography interpretation every 36 months while performing the duties of an interpreting physician.
- (b) A licensee who does not meet the criteria in paragraph (a)(1) but who meets the criteria in paragraphs (a)(2), (a)(3) and (a)(4) of this regulation may submit a written request and supporting documentation to the Board for authorization to

read and interpret mammography for a time-limited period, pending ABR or AOBR certification.

(1) The request must include at least three (3) months of documented formal training in the interpretation of mammograms and in topics relating to mammography. The training shall include instructions in radiation physics, including radiation physics specific to mammography, radiation effects and radiation protection. The mammographic interpretation component shall be under the direct supervision of a physician who meets the requirements of paragraphs (a) (1) – (4) of this regulation.

(2) A licensee who satisfies the Board's alternative qualification under paragraph (b)(1) shall maintain a copy of the Board's authorization readily available for inspection by the Department of Public Health at each mammography facility licensed under 105 C.M.R. 127.00 *et seq.* where the licensee reads and interprets mammography.

#### 1.20: Ownership Interest in Facilities Providing Physical Therapy Services

- (1) Disclosure to the Board. In accordance with c.112 § 12AA, any licensee who has an ownership interest in any partnership, corporation, firm or other legal entity that provides physical therapy services shall bi-annually disclose this ownership interest to the Board on a form to be provided by the Board. This disclosure shall include a description of the ownership structure of the facility and the nature of the licensee's interest in the facility, including the percentage of total ownership interest represented by his share. This disclosure shall include the names of all other parties who have ownership interests in the facility and the nature and amount of their shares of ownership interests.
- (2) Disclosure to Patients. Any licensee who refers a patient for physical therapy services to any partnership, corporation, firm or other legal entity in which he has a ownership interest shall disclose such ownership interest to the patient and shall inform the patient that such services may be available from other physical therapists in the patient's community. Each patient who is referred by a licensee shall be furnished by the licensee with a written referral that states conspicuously on its face the following: "The referring licensee maintains an ownership interest in the facility to which you are being referred for physical therapy service. Physical therapy services may be available elsewhere in the community."
- (3) List of Referrals. Any licensee who refers a patient for physical therapy services to any partnership, corporation, firm or other legal entity in which he has an ownership interest shall maintain a list of any such referrals. A licensee shall make said list available to the Board for inspection at the Board's request.
- (4) Ownership Interest. Ownership interest shall mean any and all ownership interest including, but not limited to, any membership, proprietary interest, stock interest,



partnership interest, co-ownership in any form or any profit-sharing arrangement. Ownership interest shall not apply to health maintenance organizations' financial arrangements or to preferred provider organizations' financial arrangements with participating providers, or to financial arrangements among participating providers of health maintenance organizations or preferred provider organizations.

#### 1.21: Responsibility for Medical Students and Others

- (1) Supervising Medical Students. A full licensee may permit a medical student to practice medicine subject to the provisions of M.G.L. c. 112 § 9A. The full licensee must:
  - (a) ensure that the medical student is identified to a patient as a medical student and informs each patient that the patient has a right to refuse examination or treatment by the medical student.
  - (b) ensure that the medical student practices medicine in accordance with accepted medical standards.
- (2) Delegation of Medical Services to Unlicensed Assistants. A full licensee may permit a skilled, unlicensed assistant to perform services in a manner consistent with accepted medical standards and appropriate to the assistant's skill. The full licensee must:
  - (a) ensure that the assistant is identified to the patient as a non-licensee; and
  - (b) ensure that the assistant performs services in accordance with accepted medical standards.
- (3) Delegation of Medical Services to Licensed Health Care Professionals. Consistent with 243 C.M.R. 1.22 and 1.23, a full licensee may permit a licensed health care professional to perform services in a manner consistent with accepted medical standards.

#### 1.22: Supervision of Nurses Engaged in Prescriptive Practice

##### (1) Purpose.

The purpose of 243 C.M.R. 1.22 is to establish, pursuant to M.G.L. c. 112 §§ 80E and 80G, substantive standards governing the practice of medicine with respect to the supervision of nurses engaged in prescriptive practice.

Such prescriptive practice is defined and regulated in 244 C.M.R. 4.00 *et seq.* (regulations of the Board of Registration in Nursing).

(2) Definition of a Supervising Physician. Supervising physician means a licensee holding an unrestricted full license in the Commonwealth, who:

(a) has completed training in the United States approved by the Accreditation Council for Graduate Medical Education (ACGME) or in Canada approved by the Royal College of Physicians and Surgeons in Canada (RCPSC) in a specialty area appropriately related to the nurse's area of practice, is Board-certified in a specialty area appropriately related to the nurse's area of practice, or has hospital admitting privileges in a specialty area appropriately related to the nurse's area of practice. Notwithstanding the above, a physician who supervises a psychiatric nurse mental health clinical specialist shall have completed training in psychiatry approved by the ACGME or the RCPSC, or be Board certified in psychiatry;

(b) holds valid registration(s) to issue written or oral prescriptions or medication orders for controlled substances from the Massachusetts Department of Public Health and the U.S. Drug Enforcement Administration;

(c) signs mutually developed and agreed upon guidelines with the nurse engaged in prescriptive practice; and

(d) reviews the nurse's prescriptive practice at least every three months and provides ongoing direction to the nurse regarding prescriptive practice, or delegates such review and direction to another licensee holding an unrestricted full license in the Commonwealth who meets the requirements of 243 C.M.R. 1.22(2)(a) and (b).

(3) Physician Supervision of a Nurse Engaged in Prescriptive Practice.

A supervising physician shall review and provide ongoing direction for the nurse's prescriptive practice in accordance with written guidelines mutually developed and agreed upon with the nurse pursuant to M.G.L. c. 112 §§ 80E or 80G, 244 C.M.R. 4.00 *et seq.* and 243 C.M.R. 1.22. This supervision shall be provided as is necessary, taking into account the education, training and experience of the nurse, the nature of the nurse's practice, and the availability to the nurse of clinical back-up by physicians, to ensure that the nurse is providing patient care services in accordance with accepted standards of practice.

(a) A supervising physician shall sign prescriptive practice guidelines only with those nurses for whom he/she is able to provide supervision consistent with 243 C.M.R. 1.22(2) and (3), taking into account factors including, but not limited to geographical proximity, practice setting, volume and complexity of the patient population, and the experience, training and availability of the supervising physician and the nurse(s).

(b) A supervising physician shall not enter into guidelines, pursuant to M.G.L. c. 112 §§ 80E or 80G and 243 C.M.R. 1.22, unless the nurse has professional malpractice liability insurance with coverage of at least \$100,000.00 per claim, with a minimum annual aggregate of not less than \$300,000.00. This requirement shall not apply in circumstances where guidelines limit the nurse to engage in prescriptive practice in or on behalf of federal, state, county or municipal health care facilities.

(4) Development, Approval, and Review of Guidelines for a Nurse Engaged in Prescriptive Practice.

A physician who supervises a nurse engaged in prescriptive practice shall do so in accordance with written guidelines mutually developed and agreed upon with the nurse.

(a) In all cases, the written guidelines shall:

- (1) identify the supervising physician;
- (2) include a defined mechanism for the delegation of supervision to another physician including, but not limited to duration and scope of the delegation;
- (3) specifically describe the nature and scope of the nurse's practice;
- (4) identify the types of medication(s) to be prescribed, specify any limitations on medications to be prescribed, and describe the circumstances in which physician consultation or referral is required;
- (5) describe the use of established procedures for the treatment of common medical conditions which the nurse may encounter;
- (6) include provisions for managing emergencies;
- (7) include a defined mechanism to monitor prescribing practices, including documentation of review by the supervising physician at least every three months;
- (8) include protocols for the initiation of intravenous therapies and Schedule II drugs;
- (9) specify the frequency of review of initial prescription of controlled substances; the initial prescription of Schedule II drugs must be reviewed within 96 hours; and
- (10) conform to M.G.L. c. 94C, the regulations of the Department of Public Health at 105 C.M.R. 700.000 *et seq.*, M.G.L. c. 112, §§ 80E or 80G, and 244 C.M.R. 4.00 *et seq.*, as applicable.

(b) Written guidelines governing the practice of a nurse midwife engaged in prescriptive practice shall also comply with the requirements of M.G.L. c. 112, §§ 80C and 244 C.M.R. 4.25(1).

(5) The Board may request at any time an opportunity to review the guidelines under which a physician is supervising a nurse or nurses engaged in prescriptive practice. Failure to provide guidelines to the Board is a basis for and may result in disciplinary action. The Board may require changes in the guidelines if it determines that they do not

comply with 243 C.M.R. 1.22 and accepted standards of medical practice. The Board may also disapprove guidelines in their entirety if it determines that the supervising physician is incapable of providing adequate supervision to the nurse(s) engaged in prescriptive practice.

(6) The Board may request at any time documentation of review by the supervising physician of the nurse engaged in prescriptive practice. Failure to provide documentation to the Board is a basis for and may result in disciplinary action.

#### 1.23: Physician Assistants

(1) Definition of a Supervising Physician. Supervising physician means a full licensee who supervises a physician assistant. A physician assistant's supervising physician may use a physician assistant to assist him in the process of gathering data necessary to make decisions and institute patient care plans. A physician assistant may not supplant a licensee as the principal medical decision maker.

(2) Physician Supervision of a Physician Assistant. A full licensee must supervise the activities of a physician assistant. A supervising physician may supervise no more than two physician assistants at a time. A supervising physician shall afford supervision adequate to ensure that:

(a) The physician assistant provides medical services in accordance with accepted medical standards. 243 C.M.R. 1.23 does not require the physical presence of the supervising physician whenever a physician assistant renders medical services.

(b) The physician assistant, except in life-threatening emergencies and when no licensee is available, informs each patient that she is not a physician and that a physician assistant renders medical services only under the supervision of a full licensee.

(c) The physician assistant wears a name tag which identifies him as a physician assistant.

(d) The supervising physician reviews diagnostic and treatment information, as agreed upon by the supervising physician and the physician assistant, in a timely manner consistent with the patient's medical condition.

(e) On follow-up care, hospital visits, nursing home visits, attending the chronically ill at home, and in similar circumstances in which the supervising physician has established a therapeutic regimen or other written protocol, the physician assistant checks and records a patient's progress and reports the patients' progress to the supervising physician. Supervision is adequate under this subsection if it permits a physician assistant who encounters a new problem not

covered by a written protocol or which exceeds established perimeters to initiate a new patient care plan and consult with the supervising physician.

(f) In an emergency, the physician assistant renders emergency medical services necessary to avoid disability or death of an injured person until a licensee arrives.

(g) When a supervising physician is unable or unavailable to be the principal medical decision maker, another licensed physician must be designated to assume temporary supervisory responsibilities of a physician assistant. The name and scope of responsibility for the physician providing the temporary supervision must be readily ascertainable from the records kept in the ordinary course of business which are available to patients. The supervising physician(s) of record is ultimately responsible for ensuring that each task performed by a physician assistant is properly supervised.

### (3) Delegation of Medical Services to a Physician Assistant.

A supervising physician may permit physician assistants to perform those services which are within the competence of the physician assistant as determined by the supervising physician's assessment of his or her training or experience and within the scope of services for which the supervising physician can provide adequate supervision to ensure that accepted medical standards are followed.

Physician assistants may approach patients of all ages and with all types of conditions, elicit histories, perform examinations, perform and interpret diagnostic studies, perform therapeutic procedures, instruct and counsel patients regarding physical and mental health issues, respond to life-threatening situations, and facilitate the appropriate referral of patients, consistent with his or her supervising physician's scope of expertise and responsibility and delegated to him or her by the supervising physician. Nothing contained herein shall be construed to allow a physician assistant to: (1) give general anesthesia; (2) perform procedures involving ionizing radiation; or (3) render a formal medical opinion on procedures involving ionizing radiation.

Where major invasive procedures are involved, such procedures shall be identified and shall be undertaken under specific written protocols, available to the Board upon request, developed between the supervising physician and the physician assistant, which, *inter alia*, must specify the level of supervision the service requires, *e.g.*, direct (physician in room), personal (physician in building), or general (physician available by telephone).

### (4) Billing For Services of a Physician Assistant.

A physician assistant may not bill separately for services rendered. The services of a physician assistant are the services of the supervising physician.

### (5) Prescription Practices of a Physician Assistant.

(a) Definition of a Supervising Physician. Supervising physician means a licensee holding an unrestricted full license in the Commonwealth who:

- (1) has completed ACGME-accredited or accredited Canadian post-graduate medical training in a specialty area appropriately related to the physician assistant's area of practice, is board-certified in a specialty area appropriately related to the physician assistant's area of practice, or has hospital admitting privileges in a specialty area appropriately related to the physician assistant's area of practice; provided, however, that any physician supervising physician assistants in prescriptive practice prior to January 1, 1996, who does not meet the requirements of 243 C.M.R. 1.23(5)(a)1 shall be permitted to remain a supervising physician until January 1, 1999; and
- (2) holds valid registration(s) from the Massachusetts Department of Public Health and the U.S. Drug Enforcement Administration to issue written or oral prescriptions or medication orders for controlled substances; and
- (3) signs mutually developed and agreed upon guidelines with the physician assistant engaged in prescriptive practice; and
- (4) reviews the physician assistant's prescriptive practice at least every three months and provides ongoing direction to the physician assistant regarding prescriptive practice, or, pursuant to 263 C.M.R. 5.05(4)(g), temporarily delegates such review and direction to another licensee holding an unrestricted full license in the Commonwealth who meets the requirements of 243 C.M.R. 1.23(5)(a)1 and 243 C.M.R. 1.23(5)(a)2.

(b) Physician Supervision of a Physician Assistant Engaged in Prescriptive Practice.

A supervising physician shall review and provide ongoing direction for the physician assistant's prescriptive practice in accordance with written guidelines mutually developed and agreed upon with the physician assistant pursuant to M.G.L. c. 112, § 9E, 263 C.M.R. 5.00 *et seq.* and 243 C.M.R. 1.23, and signed by both parties. This supervision shall be provided as necessary, taking into account the education, training and experience of the physician assistant, the nature of the physician assistant's practice, and the availability to the physician assistant of clinical back-up by physicians, to ensure that the physician assistant is providing patient care services in accordance with accepted standards of practice.

A supervising physician shall sign prescriptive practice guidelines only with those physician assistants for whom he is able to provide supervision consistent with 243 C.M.R. 1.23(5)(a) and 243 C.M.R. 1.23(5)(b), taking into account factors including, but not limited to, geographical proximity, practice setting, volume and complexity of the patient population, and the experience, training and availability of the supervising physician and the physician assistant(s).

(c) Development, Approval and Review of Guidelines for a Physician Assistant Engaged in Prescriptive Practice. A physician who supervises a physician assistant engaged in prescriptive practice shall do so in accordance with written guidelines mutually developed and agreed upon with the physician assistant, and signed by both parties. Such guidelines shall be reviewed annually, and dated and initialed by both the supervising physician and the physician assistant at the time of each review. The guidelines may be altered at any time upon agreement by the supervising physician and physician assistant; any such changes shall be initialed and dated by both parties. In all cases, the written guidelines shall:

- (1) identify the supervising physician;
- (2) include a defined mechanism for the delegation of supervision to another physician including, but not limited to, duration and scope of the delegation;
- (3) specifically describe the nature and scope of the physician assistant's practice;
- (4) identify the types and classes of medication(s) to be prescribed, specify any limitations on medications to be prescribed, indicate the quantity of any medications including initial dosage limits and refills, and describe the circumstances in which physician consultation or referral is required;
- (5) include a defined mechanism to monitor prescribing practices, including documentation of review by the supervising physician at least every three months;
- (6) include protocols for the initiation of intravenous therapies and Schedule II drugs;
- (7) specify the frequency of review of initial prescriptions or changes in medication of controlled substances; any prescription or medication order issued by a physician assistant for a Schedule II controlled substance, as defined in 105 C.M.R. 700.002, shall be reviewed by his supervising physician, or by a temporary supervising physician designated pursuant to 263 C.M.R. 5.05(4)(g), within 96 hours after its issuance;
- (8) specify the types and quantities of Schedule VI medications which may be ordered by the physician assistant from a drug wholesaler, manufacturer, laboratory or distributor for use in the practice setting in question;
- (9) identify and specify any limitations on the initiation and/or renewal of prescriptions which are not within the ordinary scope of practice for the specific work setting in question, but which may be needed to provide appropriate medical care; and

(10) conform to M.G.L. c. 94C, the regulations of the Department of Public Health at 105 C.M.R. 700.000 *et seq.*, M.G.L. c. 112 § 9E, 263 C.M.R. 1.00 *et seq.* and 243 C.M.R. 1.23.

(d) The use of pre-signed prescription blanks or forms is prohibited.

(e) The Board may request at any time an opportunity to review the guidelines under which a physician is supervising a physician assistant or physician assistants engaged in prescriptive practice. Failure to provide guidelines to the Board is a basis for and may result in disciplinary action. The Board may require changes in such prescriptive practice guidelines if it determines that they do not comply with 243 C.M.R. 1.23 and accepted standards of medical practice. The Board may also disapprove guidelines in their entirety if it determines that the supervising physician is incapable of providing adequate supervision to the physician assistant(s) engaged in prescriptive practice.

(f) The Board may request at any time documentation of review by the supervising physician of the physician assistant engaged in prescriptive practice. Failure to provide documentation to the Board is a basis for and may result in disciplinary action.

## 243 C.M.R. 2.00: LICENSING

### Section

- 2.01: General Provisions
- 2.02: Full License
- 2.03: Limited License
- 2.04: Volunteer License
- 2.05: Administrative License
- 2.06: Temporary License
- 2.07: Short-term Faculty License
- 2.08: Short-term License for Clinical Assessment
- 2.09: Preliminary Denial of Licensure
- 2.10: Conditions of Holding a License
- 2.11: Renewal Provisions
- 2.12: Health Care Facility Affiliation Agreements

### 2.01: General Provisions

(1) Definitions. For the purposes of 243 C.M.R. 2.00, the following terms have the following meanings:

ABMS means American Board of Medical Specialties.

ACGME means Accreditation Council for Graduate Medical Education.



Accredited Canadian Medical School means a medical school accredited by the Liaison Committee on Medical Education (LCME) in cooperation with the Committee on Accreditation of Canadian Medical Schools (CACMS).

Accredited Canadian Post-graduate Medical Training means training accredited by the Royal College of Physicians and Surgeons of Canada (RCPSC), the College of Family Physicians of Canada (CFPC), or the Federation of Medical Regulatory Authorities of Canada (FMRAC).

AMA means American Medical Association.

AOA means American Osteopathic Association.

Canadian Medical Graduate means a person who attained an M.D. or D.O. degree from an accredited Canadian medical school.

COMLEX means Comprehensive Osteopathic Medical Licensing Examination – USA.

CORI means Criminal Offender Record Information report.

ECFMG means Educational Commission for Foreign Medical Graduates.

FSMB means Federation of State Medical Boards.

Fifth Pathway means a program of medical education that meets the following requirements:

- (a) Completion of two years of pre-medical education in a U.S. college or university acceptable to the Board;
- (b) Completion of all the formal requirements for the degree corresponding to doctor of medicine or doctor of osteopathy at a medical school outside the United States which is recognized by the World Health Organization;
- (c) Completion of one academic year of supervised clinical training sponsored by an approved medical school in the United States, Puerto Rico or Canada; and
- (d) Completion of one year of graduate medical education in a program approved by the Liaison Committee on Medical Education.

FLEX means Federation Licensing Examination.

International Medical School means a medical or osteopathic school in a country other than the United States, Puerto Rico or Canada.

International Medical Graduate means a graduate of an international medical school.

Lapsed License means the automatic expiration of a certificate of registration of any full licensee upon the licensee's failure to file a completed renewal application together with the required fee within the time period required.

LCME means Liaison Committee on Medical Education.

LMCC means Licentiate of the Medical Council of Canada.

MCCQE means Medical Council of Canada Qualifying Examination.

Medical Student means a person enrolled in a United States or international medical school.

NBME means National Board of Medical Examiners.

NBOME means National Board of Osteopathic Medical Examiners.

NPI means the National Provider Identifier, a unique national identification number issued to each provider of Medicare services by the Centers for Medicare and Medicaid Services (CMS) through the National Plan and Provider Enumeration System (NPPES).

Person means an individual, but not an association of individuals or a legal entity.

Renewal date means the last day on which the license is in effect.

Risk Management Study means instruction in medical malpractice prevention, such as risk identification, patient safety, and medical error prevention, and may include instruction in any of the following areas: medical ethics, quality assurance, medical-legal issues, patient relations, utilization review that directly relates to quality assurance, and non-economic aspects of practice management. Risk management includes study of the Board's Patient Care Assessment Regulations (243 C.M.R. 4.01 *et seq.*) but does not include study of the Board's other regulations or procedures or operations.

Specialty Board means a specialty board recognized by the ABMS or the AOA.

United States Medical Graduate means a person who attained a M.D. or D.O. degree from a United States medical school.

United States Medical School means a LCME accredited school of medicine, or an AOA accredited school of osteopathy, located in the United States.

USMLE means United States Medical Licensing Examination, a multi-part examination.

(2) Original Documents. All documents submitted to the Board in support of a license application shall be original documents, unless otherwise provided by the Board. If the applicant wants any original document returned, he must include an identical photocopy of the document and a self-addressed stamped envelope. Once the original document is compared to the copy, the original will be returned.

(3) Foreign Language Documents. A person who wishes to submit a document written in a foreign language must also submit a notarized English translation of the documents or a copy prepared by a translation service approved by the Board.

(4) Payment of Fees. Fees payable to the Board in the amount of \$5.00 or more may be paid by personal check or money order drawn on a U.S. bank in U.S. funds. Fees payable in the amount of \$5.00 or less, may be paid by personal check. The Board may require any fee to be paid by certified check, money order, credit card or electronic fund transfer.

(5) General Licensure Requirements.

(a) Application Form and Fee. Each applicant for licensure or renewal shall submit to the Board a completed application form, any additional information requested by the Board, and the applicable fee as determined by the Secretary of Administration and Finance pursuant to M.G.L. c.7 § 3B.

(b) Completed Application. An application for licensure or renewal shall be considered complete when: (a) it is legible; (b) all required information, documentation and signatures have been supplied; (c) the fee has been paid in full; and (d) all supplemental information required by the Board has been supplied to the Board's satisfaction.

(c) Good Moral Character. At all times an applicant for licensure or renewal has the burden to demonstrate his good moral character. Each applicant for licensure or renewal shall submit to the Board satisfactory proof of good moral character.

(d) Examination Requirements. Each applicant for licensure shall fulfill the examination and other requirements for a license as set forth herein or as required by the Board.

(e) NPI. Each applicant for licensure or renewal shall provide the Board with his NPI number or certify that he has applied for an NPI number and that he will provide it to the Board upon receipt, or shall authorize the Board to apply for an NPI on his behalf.

(f) CORI. Each applicant for licensure or renewal shall authorize the Board to access any and all criminal case information concerning the applicant held by the Massachusetts Criminal History Systems Board and other law enforcement agencies.

- (g) Pre-medical Education. Each applicant for licensure shall have completed a minimum of two years in a college or university program acceptable to the Board.
- (h) Post-graduate Medical Training. Each applicant for licensure shall satisfy the post-graduate training requirements as set forth herein.
- (i) Applicants For Licensure or Renewal Who Have Changed Their Names. Each applicant for licensure or renewal who has been known by a name other than that used on his application shall complete the name change forms used by the Board to verify name changes, and shall submit the completed forms along with the documentation required therein.
- (j) Continuous Duty to Update Information. Each applicant for licensure or renewal has a continuing duty to report to the Board any change in the information supplied to the Board in support of his application for licensure or renewal, as soon as he becomes aware of the change, but in any event no later than 72 hours from that date. Failure to do so may result in disciplinary action.
- (k) Withdrawal of Application. An applicant for licensure may withdraw his application at any time unless such application has been reviewed by the Licensing Committee. After review by the Licensing Committee, an applicant may only withdraw his application if he requests and receives written permission to do so from the Licensing Committee or the Board. This section does not apply to applicants who cannot comply with the Board's medical education requirements for graduates of international medical schools and graduates of fifth pathway programs, and who have submitted a request for waiver of those requirements, pursuant to 243 C.M.R. 2.02(2)(d).
- (l) Duty to Report. Each applicant for licensure or renewal, and each licensee, has a continuing duty to apprise the Board of any change in his contact information, information related to hospital affiliations, or any other information related to his application or license.

## 2.02: Full License

In order to qualify for a full medical license, an applicant shall meet the following requirements in addition to other applicable requirements for licensure as set forth in these regulations and M.G.L. c. 112:

### (1) United States and Canadian Medical Graduates

- (a) Medical Education. Each applicant for a full license must have received the degree of doctor of medicine from a medical school accredited by the LCME, or the doctor of osteopathy from an osteopathic school accredited by the AOA.

(b) Post-Graduate Medical Training. Each applicant for a full license who submits his application on or after July 1, 2006, must have completed two years of post-graduate medical training in an ACGME approved, or accredited Canadian program. In the case of sub-specialty clinical fellowship programs, however, the Board may accept post-graduate training in a hospital that has an ACGME approved, or accredited Canadian, post-graduate medical training program in the parent specialty.

(i) In its sole discretion, the Board may consider for licensure an applicant who has completed one year of ACGME approved, or accredited Canadian, post-graduate training and who:

(A) holds a current, active, unrestricted medical license in another state; and

(B) demonstrates continuous clinical activity; and

(C) is board certified by either ABMS or AOA.

(2) International Medical Graduates

(a) Medical Education. Each applicant for a full license must have received the degree of doctor of medicine or its equivalent from a program determined by the Board to be substantially equivalent to the medical school programs accredited by the LCME, or the degree of doctor of osteopathy or its equivalent from a program determined by the Board to be substantially equivalent to the osteopathic school programs accredited by the AOA.

(b) Substantial Equivalency of Medical Education.

In order to be considered substantially equivalent, such medical education shall include:

(i) Two academic years of basic science study, including:

- (a) gross anatomy,
- (b) biochemistry,
- (c) pathology,
- (d) physiology,
- (e) microbiology,
- (f) immunology, and
- (g) pharmacology.

(ii) Two academic years of clinical study, including:

- (a) internal medicine,
- (b) surgery,

- (c) pediatrics,
- (d) obstetrics and gynecology,
- (e) public health and preventive medicine, and
- (f) psychiatry.

(iii) The Board must also be satisfied that all clinical training is substantially equivalent to the standards required of United States medical school graduates. The applicant shall submit documentation satisfactory to the Board that all clinical study was done:

(A) Under the direct control and approval of the medical school and under on-site supervision and evaluation by the faculty of the medical school in which the applicant was enrolled at the time of study, and in hospitals which have, in the Board's opinion, programs equivalent to ACGME approved programs in the area of clinical study; or

(B) If done in the United States, clinical study shall be in hospitals which have ACGME approved programs in the area of clinical study. If done in Canada, the clinical study shall be in hospitals which have accredited Canadian post-graduate medical training programs. Supervising clinical faculty shall be physicians who are fully licensed by the jurisdiction where such study is done.

(iv) Board staff may, at any time, request additional documentation which may include but is not limited to:

(A) a formal evaluation by the faculty of the clinical clerkship;

(B) a formal written agreement between the medical school and the place of clinical study; or

(C) a course catalog.

(v) The Board may, in its discretion, determine that any college of medicine which had its accreditation withdrawn by a national or regional accreditation organization; or had its authorization, certification or licensure revoked or withdrawn by a national governmental supervisory agency; or issued a medical degree based on coursework via the Internet or an on-line program, is inconsistent with quality medical education. Such a program of education will not be an approved college of medicine for the

purpose of fulfilling the medical education requirement of 243 C.M.R. 2.02(2).

- (c) Post-Graduate Medical Training. Each applicant for a full license who submits his application on or after July 1, 2006, must have completed three years of post-graduate medical training in an ACGME approved, or accredited Canadian, program. In the case of sub-specialty clinical fellowship programs, however, the Board may accept post-graduate training in a hospital that has an ACGME approved, or accredited Canadian, post-graduate medical training program in the parent specialty.

(i) The Board may, in its sole discretion, accept as post-graduate training, teaching experience consisting of a faculty appointment at or above the assistant professor level at a medical school accredited by the LCME if the majority of the teaching experience documented is clinical teaching with supporting evidence of the following: special honors or awards which the applicant has achieved, or articles the applicant has published in reputable medical journals or medical textbooks. With the same supporting evidence, the Board may accept teaching experience at the instructor level with the following consideration: There is a presumption against accepting instructor level teaching experience when combined with a waiver request for any section of 243 C.M.R. 2.02(2)(a). The Board may, in its discretion, overcome this presumption only in extraordinary circumstances.

(ii) In its sole discretion, the Board may consider for licensure an applicant who has completed two years of ACGME approved, or accredited Canadian, post-graduate training and who:

(A) holds a current, active, unrestricted medical license in another state; and

(B) demonstrates continuous clinical activity; and

(C) is board certified by either ABMS or AOA.

- (d) ECFMG. An applicant for a full license pursuant to this section shall submit ECFMG certification valid on its face as of the date of issuance. Pursuant to M.G.L. c. 112, §2, an ECFMG certificate is not required for graduates of Fifth Pathway programs.

- (e) Waiver. An applicant for a full license pursuant to 243 C.M.R. 2.02(2) may make a written request to the Board for a waiver of any requirement in 243 C.M.R. 2.02(2). The Board, in its sole discretion, may grant the waiver as requested, or with modifications thereof, upon finding:

- (i) the applicant meets the standards of M.G.L. c. 112, §§ 2-9; and
- (ii) such a waiver would promote the public health, safety or welfare.

(3) Examination Requirements.

(a) USMLE and COMLEX. Each applicant for a full license, except those who satisfy the requirements of section 2.02(3)(b), must submit evidence, including certification by the examining body, of having achieved a score of 75 or more on each of Steps 1, 2, and 3 of the USMLE, or each of the three levels of NBOME's COMLEX exam, within a seven-year time period, beginning with the examination date when the examinee first passes a step of either exam. An applicant who fails to pass Step 3 of the USMLE, or level 3 of the COMLEX, within three (3) attempts, shall be required to take one (1) additional year of ACGME approved post-graduate training before the Board will authorize the applicant to attempt the step a fourth time. If the fourth attempt at Step 3 or level 3 is failed, the applicant is not eligible for Massachusetts licensure. If the applicant did not complete an additional year of ACGME approved post-graduate training between the third and fourth attempt at Step 3 or level 3, the applicant is not eligible for Massachusetts licensure.

(i) Joint Degree Exception to Seven-year Rule. The Board may grant an exception to the seven-year exam completion requirement in the case of an applicant who is actively pursuing a joint M.D./Ph.D., provided:

- (A) The applicant requesting an exception to the seven-year rule must be enrolled in a LCME accredited program and be a student in good standing;
- (B) The Ph.D. studies must be in a field of biological sciences tested in the Step 1 content of the USMLE, including but not limited to: anatomy, biochemistry, physiology, microbiology, pharmacology, genetics, pathology, neuroscience, and molecular biology. Fields explicitly not included are business, economics, ethics, history, or other fields not directly related to biological science; and
- (C) The Board shall consider the length of time the applicant is beyond the seven years; a candidate requesting an exception to the seven-year rule will be required to present a verifiable and rational explanation for his



inability to meet the seven-year requirement. In no case will an extension be granted beyond a total period of ten (10) years for completion of all three steps of the USMLE.

(ii) Exception to the Seven-year Rule. In very limited and extraordinary circumstances the Board, in its sole discretion, may grant a case-by-case exception to the seven-year period upon petition by an applicant for licensure and demonstration of:

(A) A verifiable and rational explanation for his failure to satisfy the regulation;

(B) Strong academic and post-graduate record; and

(C) A compelling totality of circumstances.

(b) Examinations Completed Before January 1, 2000. Applicants may submit evidence, including certification by the examining body, of having achieved scores acceptable to the Board on the following combinations of exams, if satisfactorily completed before January 1, 2000, in lieu of passing scores on the USMLE or COMLEX:

(i) Part I of the examination of the NBME or Step 1 of the USMLE, or Part II of examination of the NBME or Step 2 of the USMLE, or Part III of the examination of the NBME or Step 3 of the USMLE; or

(ii) Both Component 1 and Component 2 of the FLEX; or

(iii) All parts of the MCCQE; or

(iv) Individual state examinations given prior to June 19, 1970, which are satisfactory to the Board; or

(v) Component 1 of the FLEX and Step 3 of the USMLE; or

(vi) Component 2 of the FLEX and:

(A) Part I and Part II of the examination of the NBME;

(B) Step 1 and Step 2 of the USMLE;

(C) Part I of the examination of the NBME and Step 2 of the USMLE; or

(D) Step 1 of the USMLE and Part II of the examination of the NBME.

(c) FLEX Requirements:

- (i) (i) Beginning with the June 1985 examination, an applicant who received the passing score of 75 or higher on Component 1 and 2 has passed the licensing examination. Prior to the June 1985 examination, an applicant who completed the FLEX in one sitting and received a passing grade of a FLEX weighted average of 75% or higher has passed the licensing examination.
- (ii) An applicant who applies on the basis of an examination taken in June 1985 or later must have received a passing score of 75 or higher on each of the two components and be otherwise qualified. An applicant who applies on the basis of an examination taken prior to June 1985 must have taken the FLEX in one sitting, must have received a grade of a FLEX weighted average of 75% or higher and be otherwise qualified.

#### (4) Issuance of License.

Upon the determination by the Board that it is in the public interest to do so, an applicant who meets all of the requirements of 243 C.M.R. 2.02(1) and (3) or 2.02(2) and (3), to the satisfaction of the Board will be granted a full license and is entitled to a certificate of registration signed by the chairman and the secretary of the Board.

### 2.03 Limited License

In order to qualify for a limited medical license, an applicant shall meet the following requirements, in addition to other applicable requirements for licensure as set forth in these regulations and M.G.L. c. 112:

- (1) Medical Education. Each applicant for a limited license must satisfy the degree requirements of 243 C.M.R. 2.02 (1)(a), or 243 C.M.R. 2.02(2)(a), or be a graduate of a Fifth Pathway program.
- (2) Examination Requirements. Each applicant for a limited license must submit evidence, including certification by the examining body, of having achieved a score of 75 or more on Steps 1 and 2 of the USMLE, or the first two levels of the COMLEX exam.
- (3) ECFMG Certification. International medical graduates, other than graduates of a Fifth Pathway program, shall submit ECFMG certification valid as of the date of issuance.
- (4) ACGME approved Position. Each applicant for a limited license must submit proof of an appointment to an ACGME approved post-graduate training program in Massachusetts, or a fellowship in a Massachusetts health care facility which conducts on its premises ACGME approved programs.

- (5) Issuance of License. Upon the determination by the Board that it is in the public interest to do so, an applicant who meets all of the requirements of 243 C.M.R. 2.03 to the satisfaction of the Board will be granted a limited license and is entitled to a certificate of registration signed by the chairman and the secretary of the Board.

(a) A limited license permits the licensee to practice medicine only in the specified training program. The licensee may only practice at the facility designated on the license or any of that facility's approved affiliates. Limited licensees may, however, practice for up to eight weeks in any single year of residency at a non-designated facility, if that facility is a teaching hospital with three or more ACGME accredited programs. A limited licensee may practice only under the supervision of a full licensee affiliated with the designated health care facility. The Board will not issue more than one limited license to a person at a time.

(b) A health care facility that takes a disciplinary action against a limited licensee in a training program must report this action to the Board pursuant to 243 C.M.R. 1.09. If, for any reason, a limited licensee terminates his appointment at a health care facility or his participation in a training program prior to the limited license's expiration date, or has his appointment or participation terminated, the health care facility designated on the license shall submit to the Board, pursuant to M.G.L. c.111, § 53B, a written notice of termination which sets forth the reasons for the termination and which is signed by the director or the administrator of the health care facility or training program.

- (6) Duration of a Limited License.

(a) The duration of a limited license shall be one year. The Board may, in its sole discretion, issue a limited license for the duration of a trainee's enrollment in an ACGME training program when a specific and trainee-focused program of quality and safety exists as an integrated element of the sponsoring institution's Patient Care Assessment program, and said program provides documentation that it is in compliance with all the provisions of 243 C.M.R. 4.00 *et seq.* The issuance of a limited license beyond a total of six years of practice pursuant to a limited license, may be granted only by a vote of the Board.

(b) Nothing herein shall limit the Board's authority to revoke a limited license at any time in accordance with M.G.L. c. 112 § 9 and M.G.L. c. 30A. Nothing herein shall limit the Board, in its discretion, from deciding that a limited license

may be initially issued or renewed with appropriate restrictions on the scope of practice or subject to probationary conditions.

(7) Restrictions on Billing by Limited Licensees. In a training program, a full licensee may bill for the services of a limited licensee, but only if such services are rendered as part of the training program under the direct personal supervision of the full licensee. Except as provided in the preceding sentence, no one may bill for the services of a limited licensee, but the salary of a limited licensee may constitute part of a health care facility's service charges.

#### 2.04: Volunteer License

In order to qualify for a volunteer medical license, an applicant shall satisfy the requirements for a full license as set forth herein at 243 C.M.R. 2.02, and the following requirements, in addition to other applicable requirements for licensure as set forth in these regulations and M.G.L. c. 112:

(1) General. Each applicant for a volunteer license shall submit the following information:

(a) a written statement from the applicant outlining the scope and duration of services to be provided by him;

(b) a written statement from the director of the applicant's proposed work site outlining the scope and duration of the applicant's responsibilities; and

(c) evidence satisfactory to the Board that the volunteer physician's proposed work will serve the public interest.

(2) Issuance of License. Upon the determination by the Board that it is in the public interest to do so, an applicant who meets all of the requirements of 243 C.M.R. 2.04 to the satisfaction of the Board will be granted a volunteer license and is entitled to a certificate of registration signed by the chairman and the secretary of the Board.

(3) Scope of Practice. A licensee engaged in volunteer practice may practice medicine only at work sites approved by the Board in conjunction with his license application, shall be subject to the same conditions and responsibilities as a full licensee, and may not accept compensation for his practice of medicine.

#### 2.05 Administrative License

In order to qualify for an administrative license, an applicant shall satisfy the educational and postgraduate training requirements for a full license as set forth herein at 243 C.M.R.

2.02, and the following requirements, in addition to other applicable requirements for licensure as set forth in these regulations and M.G.L. c. 112:

- (1) General. The Board may issue an administrative license to an applicant whose primary responsibilities are those of an administrative or academic nature; such as professional managerial, administrative, or supervisory activities related to the practice of medicine or the delivery of health care services and medical research, the practice of investigative medicine or the administration of health insurance organizations. It does not include the authority to diagnose or treat patients, issue prescriptions for drugs or controlled substances, delegate medical acts or prescriptive authority, or issue opinions regarding medical necessity.
- (2) Issuance of License. Upon the determination by the Board that it is in the public interest to do so, an applicant who meets all of the requirements of 243 C.M.R. 2.05 to the satisfaction of the Board will be granted an administrative license and is entitled to a certificate of registration signed by the chairman and the secretary of the Board.

## 2.06 Temporary License

(1) General. Pursuant to M.G.L. c.112 § 9B, the Board may issue temporary licenses of the following types:

- (a) Academic Appointment License. The Board may issue a temporary license to a visiting physician who is licensed to practice in another jurisdiction, and who has:
  - (i) a temporary faculty appointment certified by the dean of a medical school in Massachusetts for purposes of medical education in an accredited hospital associated with the medical school; and
  - (ii) a scope of practice plan certified by the Chair of the Department, approved by the Board and subject to audit thereof.

A temporary license issued in accordance with this subsection shall be valid for a period not exceeding 12 months and shall terminate automatically upon termination of the faculty appointment, and shall not, in the aggregate, exceed three years. All practice of medicine by a licensee under this section must be essential to his teaching and shall be restricted to the specified institution or any of that facility's approved affiliates. A temporary licensee may not practice outside

the scope of practice that is directly related to his educational and training responsibilities.

- (b) Substitute Physician. The Board may issue a temporary license to a physician who is licensed to practice medicine in another U.S. jurisdiction to permit him to act as a substitute physician for a physician licensed in Massachusetts. A temporary license issued in accordance with this subsection may be granted only upon written request of the physician licensed in Massachusetts and shall be limited to a period of three months or less.
- (c) Continuing Medical Education. The Board may issue a temporary license to a physician who is licensed to practice in another jurisdiction, and who is enrolled in a course of continuing medical education in Massachusetts. A temporary license issued in accordance with this subsection is limited to continuing medical education activities conducted under the supervision of a physician licensed in Massachusetts and shall terminate automatically upon termination of the course, and, in any event, at the end of three months.

(2) Issuance of License.

Upon the determination by the Board that it is in the public interest to do so, an applicant who meets all of the requirements of 243 C.M.R. 2.06 to the satisfaction of the Board will be granted a temporary license and is entitled to a certificate of registration signed by the chairman and the secretary of the Board.

2.07 Short Term Faculty License

(1) General. Pursuant to M.G.L. c. 112 § 9B, the Board may issue a temporary license to a physician who is licensed to practice in another jurisdiction and who has a temporary faculty appointment certified by the dean of a medical school in Massachusetts for purposes of medical education in an accredited hospital associated with the medical school. A short term faculty license issued in accordance with this subsection shall be for a period not exceeding thirty (30) days, and shall terminate automatically upon termination of the faculty appointment. All practice of medicine by a licensee under this section must be essential to his teaching and shall be restricted to the specified institution or any of that facility's approved affiliates. A temporary licensee may not practice outside the scope of practice that is directly related to his educational and training responsibilities.

(2) An applicant for licensure under this section must demonstrate eligibility for a temporary license pursuant to M.G.L. c. 112 § 9B.

(3) Issuance of License. Upon the determination by the Board that it is in the public interest to do so, an applicant who meets all of the requirements of 243 C.M.R. 2.07 to the satisfaction of the Board will be granted a short term faculty license and is entitled to a certificate of registration signed by the chairman and the secretary of the Board.

#### 2.08 Short Term Clinical Assessment License [reserved]

#### 2.09 Preliminary Denial of Licensure

- (1) The Board may preliminarily deny a license application if it determines that the applicant does not meet the requirements for a license as set forth in the Board's regulations and M.G.L. c. 112, or because of acts which, were they engaged in by a licensee, would violate M.G.L. c.112 § 5 or 243 C.M.R. 3.01.
- (2) If the Board preliminarily denies a license application, it will notify the applicant in writing of the following:
  - (a) the facts relied upon as the basis for the preliminary denial;
  - (b) the statutes and/or regulations which are the basis of the Board's decision to preliminarily deny the license application; and
  - (c) the applicant's right to request a hearing, in writing, within 21 days of such notification.
- (3) Upon receipt of an applicant's request for a hearing within such 21-day period, the Board may grant such request if:
  - (a) the applicant has adequately specified a factual and/or legal basis for overturning the preliminary denial; and
  - (b) the Board determines that specific factual issues, if further developed at a hearing, would be sufficient to overturn the preliminary denial.
- (4) If, after the expiration of the time in which to request a hearing, or after the Board's decision not to grant a hearing, or after a hearing, the Board decides that the applicant should not be licensed, the Board may vote to deny the license application. If, after a hearing, the applicant has demonstrated to the Board's satisfaction that a license should be issued, the Board shall vote to issue a license.

#### 2.10 Conditions of Holding a License

If the Board, in its sole discretion, decides that an applicant's experience, qualifications, or professional training indicate that the Board should place conditions upon his practice consistent with M.G.L. c.112 §5A, the Board may, after providing the applicant the opportunity to respond to the Board's decision, issue a license with conditions, including but not limited to restricting the scope of the licensee's practice and/or requiring participation by the licensee in appropriate treatment or monitoring.

## 2.11 Renewal Provisions

(1) Renewal of a Full, Administrative or Volunteer License. A licensee must renew his full, administrative or volunteer license, pursuant to M.G.L. c.112 § 2, every two years or any other period as required by law. The following are the requirements for renewal of a full, administrative or volunteer license:

- (a) A licensee must submit to the Board a completed renewal application form and the required fee according to the schedule established by the Board. A license that has not been renewed expires on 11:59 PM on the renewal date.
- (b) A licensee must fulfill his continuing education requirements as defined in 243 C.M.R. 2.11(3) or obtain a waiver from the Board pursuant to 243 C.M.R. 2.11(3)(g).
- (c) The Board, in its sole discretion, may permit a licensee to obtain an extension of time to file a completed renewal application, and extend the validity of his current license, when the Board fails to provide the licensee with his renewal application 60 days prior to the renewal date due to an administrative error by the Board. Such extension shall not exceed 60 days.

## (2) Inactive Status

- (a) A licensee may request inactive status in writing to the Board certifying that he will not practice medicine in Massachusetts. A licensee who is inactive is exempt from the continuing medical education requirements set forth in 243 C.M.R. 2.11(3) and malpractice insurance requirements as set forth in 243 C.M.R. 1.14, but is subject to all applicable provisions of 243 C.M.R. 2.00, including renewal provisions.
- (b) A licensee may request at any time that the Board permit him to return to active status. In granting such a request, the Board may require him to satisfy such continuing medical education requirements over such a period of time as it deems appropriate, and the Board shall require him to reinstate appropriate malpractice insurance requirements.



(3) Continuing Medical Education

(a) Basic Biennial Requirement. Subject to the exemptions set forth below, each licensee shall obtain no fewer than 100 continuing medical education (CME) credits during each two-year period that begins on the date that his license is issued or renewed by the Board and ends on the following renewal date. Credits shall be earned as follows:

(i) not less than 40 credit hours of Category 1 programs sponsored by an organization accredited for CME by the Accreditation Counsel for Continuing Medical Education, the Post-graduate Medical Institute, or a state medical society; and

(ii) not more than 60 credit hours of Category 2 activities, as defined and adopted by the AMA or AOA.

(iii) ten credit hours studying risk management, as defined in 243 C.M.R. 2.01(1), at least four of which shall be in Category 1.

(iv) two credit hours in either Category 1 or 2 studying the Board's regulations (243 C.M.R. 1.00 through 6.00).

(b) A temporary licensee with an academic appointment, as defined in 243 C.M.R. 2.06(1)(a), shall have fulfilled 50% of the CME requirement upon renewal of the temporary license.

(c) The Board may require a licensee to participate in a clinical skills/competency assessment as a condition for renewal or revival of licensure.

(d) Exemptions. The following categories of licensees are not required to fulfill any CME requirement:

(i) Limited licensees.

(ii) Licensees on inactive status, except as specified in 243 C.M.R. 2.11(2)(b).

(iii) Licensees enrolled in any of the following programs:

(A) a post-graduate medical education program (*e.g.*, a residency or fellowship) approved by the ACGME;

(B) the first or second year of a fellowship, including consecutive fellowships, not approved by the ACGME (*e.g.*, a pure research fellowship).

(iv) Licensees serving in active military duty as members of the National Guard or of a uniformed service who are called into service during a national emergency or crisis. An exemption of the CME requirement may be granted on a pro-rated basis. The exemption shall constitute a permanent waiver, and the licensee shall not be required to complete the excused credits at a future time. A licensee may apply to the Board for a waiver of the CME requirements pursuant to this exemption by submitting the waiver request in writing to the Board, together with proof of service, no later than 30 days prior to the license renewal date.

(e) Calculating Credits

(i) A newly-licensed physician, not otherwise subject to the exemptions set forth herein, shall fulfill the basic biennial CME requirement during the two-year period that begins on the date his license is issued by the Board. If that license will be renewed in less than two years, the licensee shall obtain credits as follows:

(A) If the license renewal period is one year or shorter, the licensee need not obtain any CME credits during that renewal period.

(B) If the license renewal period is longer than one year but shorter than two years, the licensee shall fulfill one-half (1/2) of the basic biennial CME requirement during that renewal period.

(ii) A licensee seeking to return to active status from lapsed license status shall first have fulfilled the basic biennial CME requirement of the two-year period ending on the date preceding his return to active status.

(iii) A licensee completing or leaving a program described in 243 C.M.R. 2.11(3)(d)(iii) shall fulfill the basic biennial CME requirement during the two-year period that begins on the first license renewal date after the program or the second fellowship year has ended, or if earlier, that begins

on the first license renewal date after the licensee leaves the program or fellowship.

(f) Miscellaneous Provisions

(i) A majority of the total CME credits required for each renewal cycle shall be directly related to the licensee's primary area(s) of practice.

(ii) Licensees shall document Category 1 CME credits by maintaining a written record that lists the date and type of activity, the program sponsor (if applicable) and the number of credits earned, and shall retain each certificate of attendance or letter of attestation issued by a program sponsor. Licensees shall document Category 2 CME credits and credits certified pursuant to 243 C.M.R. 2.11(3)(a)(iii) and (iv) by maintaining a written record that lists the approximate number of hours spent on each type of CME activity. Such records shall be maintained for no less than one full license renewal cycle after the credits have been earned and must be available for Board inspection upon request.

(iii) The Board may certify that any activity, course, or training not described in 243 C.M.R. 2.11(3) is eligible for the equivalent of Category 1 or Category 2 credit for purposes of license renewal in Massachusetts.

(g) Waivers

(i) A licensee may apply to the Board for a waiver of the portion of the CME requirements that he cannot meet. The licensee must submit the waiver request to the Board no later than 30 days prior to the license renewal date.

(ii) A waiver request must include the following written information:

(A) an explanation of the licensee's failure to complete the CME requirements;

(B) a listing of the CME credit hours that the licensee believes that he has earned; and

(C) the licensee's plan for completing the CME requirement.

(iii) The Board, in its sole discretion, may grant a waiver of the CME requirement. The grounds for waiver may include:

(A) prolonged illness of the licensee; or

(B) inaccessibility or unavailability of CME programs.

(iv) Licensees granted a waiver by the Board will be given additional time to complete the Board's CME requirement. Licensees required to make up a deficiency in CME credits, by the terms of a waiver or otherwise, may apply those credits only to the period in which the deficiency arose.

(4) Lapsed License

(a) A license not renewed shall lapse at 11:59 PM on the license renewal date. Continued practice of medicine following lapse shall be considered the unauthorized practice of medicine, shall be referred to law enforcement, and shall be subject to discipline as set forth in 243 C.M.R. 3.00 *et seq.*

(b) A licensee whose license has lapsed may petition the Board, upon submission of a lapsed license application and payment of the required fee to revive his license. The Enforcement Division or any other unit may review the matter and, if it deems necessary, docket and investigate the matter. The Board may defer action on the lapsed license application pending completion of the investigation or 180 days after the Board's receipt of a complete lapsed license application, whichever is shorter, or should the Board bring charges against the physician, pending completion of the adjudicatory process by the Board. The 180-day period allowed for investigation shall be extended by any period of time during which the physician is unavailable or fails to cooperate with the Board.

(5) Retirement

A licensee who no longer wishes to practice medicine may request, in writing, that the Board change his license status to retirement status. In any such request, a licensee must acknowledge that, if the Board changes his license status to retirement status, the licensee relinquishes his inchoate right to renew his license. A physician is not eligible to retire if he has been named in an open complaint, is otherwise subject to an investigation by the Board, or is the respondent in an ongoing disciplinary case. The physician's retirement status becomes effective when he receives written Board notification that the Board has changed his license status. If the Board finds that a physician has misled the Board in a material matter

in the application for retirement, the Board may rescind its approval of such retirement. A physician with retirement status who wishes to apply for reinstatement of his license must complete application forms approved by the Board. Allowance of such reinstatement is within the sole discretion of the Board. An applicant for reinstatement shall undergo an assessment of his competency as determined by the Board.

## 2.12: Health Care Facility Affiliations

- (1) Approval of Health Care Facility Affiliations. The Board must approve, by a majority vote, affiliations between health care facilities and training programs, if one of the affiliations is not an ACGME accredited program. In order to approve an affiliation, the Board must determine, among other things, that the supervision available for training purposes is adequate. Limited licensees may rotate between teaching hospitals with three or more ACGME accredited programs without prior approval of the Board, for up to eight weeks in any single year of residency.

- (2) Procedure For Approval of Health Care Facility Affiliations.

The directors of the health care facilities or the health care facility and the training program seeking to affiliate must submit a written request to the Board, on a form provided by the Board.

## 243 C.M.R. 3.00: ENFORCEMENT PROVISIONS

3.01: Grounds for Discipline

3.02: Complaints

3.03: Miscellaneous Provisions

3.04: Final Decisions and Orders of the Board

### 3.01: Grounds for Discipline

(1) The Board may impose disciplinary action against a licensee on one or more of the grounds for discipline listed in M.G.L. c. 112 §5 or § 61 and/or on one or more of the following grounds:

- (a) Violating any of the duties and standards set out in these regulations, or any Board policy or rule;
- (b) Engaging in misconduct in the practice of medicine;

- (c) Being unable to practice medicine with reasonable skill and with safety to patients by reason of illness, use of alcohol, drugs, chemicals, or any other type of substance, or as a result of any mental or physical condition;
- (d) Engaging in abuse or illegal use of prescription drugs or controlled substances;
- (e) Continuing to practice medicine after a registration is lapsed or suspended;
- (f) Violating the terms of a Consent Order, Final Decision and Order, Probation Agreement, Voluntary Agreement, Assurance of Discontinuance, Letter of Agreement, or any other order of or agreement with the Board;
- (g) Engaging in conduct that has the capacity or potential to place the public health, safety, or welfare at risk;
- (h) Being convicted of any crime, entering a plea of guilty to any crime, entering a plea of *nolo contendere* to any crime, or admitting to sufficient facts to warrant a finding of guilty of any crime;
- (i) Engaging in conduct that has the capacity to deceive or defraud;
- (j) Fraudulently procuring a certificate of registration or its renewal;
- (k) Providing false information on an application for registration or renewal;
- (l) Cheating or attempting to compromise the integrity of any medical licensing or certification examination;
- (m) Failing to respond to a Board subpoena or failing to furnish the Board, its investigators, or representatives with records, documents, information, or testimony to which the Board is legally entitled;
- (n) Failing to respond to a written communication from the Board, in violation of 243 CMR 1.06 and 1.07;
- (o) Engaging in conduct that undermines public confidence in the integrity of the medical profession;
- (p) Engaging in conduct that demonstrates a lack of good moral character;
- (q) Committing an act that violates recognized standards of medical care;
- (r) Operating on or conducting a medical or surgical procedure at the wrong site or on the wrong side;
- (s) Misrepresenting credentials pertaining to the practice of medicine;

- (t) Failing to report a licensee to the Board, pursuant to the peer reporting law, M.G.L. c. 112, § 5F, or any other regulation or statute requiring a licensee to file a report;
- (u) Failing to maintain recognized professional physician-patient boundaries;
- (v) Engaging in conduct with a patient, that is sexual or engaging in behavior, gestures, or expressions, verbal or nonverbal, that are seductive, suggestive, or sexually demeaning to a patient;
- (w) Failing to comply with recognized ethical standards of the profession, specialty, or subspecialty;
- (x) Engaging in disruptive behavior that affects or has the potential to affect the delivery of professional medical services;
- (y) Altering medical records in a manner that is inconsistent with good and accepted medical practice;
- (z) Failing to comply with accepted research standards, ethics, principles, or procedures, or with governmental statutes, regulations, or policies regarding research;
- (aa) Violating M.G.L. c. 94C or any rules or regulations promulgated thereunder;
- (bb) Issuing a prescription by means of the Internet or other electronic process without taking an adequate medical history, without conducting an appropriate physical and/or mental status examination, or without recording the results of said examination;
- (cc) Having been disciplined in another jurisdiction for reasons substantially the same as those set forth in this section.

(2) Nothing contained in these regulations shall limit the Board's adoption of policies and grounds for discipline through adjudication as well as through rule making.

### 3.02: Complaints

(1) Filing of Complaint. A complaint against a licensee may be filed with the Board orally, electronically, or in writing.

(2) Docket. The Board shall assign a docket number to all complaints, except stale matters. Stale matters may be docketed if the Board or the Complaint Committee decides good cause exists to docket a complaint.

(3) Complaint Committee. The Board may establish a committee known as the Complaint Committee.

(4) Investigation: After the receipt of a complaint or statutory report, the Board may conduct or cause to be conducted an investigation.

(5) Access to Information. The Board shall have access to any and all information that it deems necessary to assist in the furtherance of its investigation, including seeking a written response from the licensee under investigation and interviewing said licensee. A written response from the licensee under investigation shall address the substantive allegations set forth in the complaint or statutory report and must be signed by said licensee.

(6) Subpoenas. Consistent with M.G.L. c. 112, §5, during the course of any investigation, the Chair of the Board or his designee may authorize the issuance of a subpoena to compel witnesses to testify under oath, including the licensee under investigation, and/or to produce medical records and other documents in accordance with the following provisions:

- (a) For Attendance of Witnesses. A subpoena may issue to any person, private organization, or public body, including any officer, partner, proprietor, employee, or custodian of records of any private organization or public body.
- (b) For Production of Documents. A subpoena may require the production of any records, reports, papers, documents, correspondence, photographs, films, computer data files, or other material relevant to any matter under investigation. The original of these items must be produced, unless such production is waived by Complaint Counsel.
- (c) Motion to Modify or Vacate. Any person or entity to whom a subpoena is directed may, within seven days after receipt, file a motion with the Board to vacate or modify the subpoena. Such motion shall state with particularity the extent of the requested action and the reasons therefore. Complaint Counsel may file a response to this motion within seven days. A hearing on the motion may be held at the discretion of the Chair of the Board or another Board member designated by the Chair of the Board. Such motion shall be decided by the Chair of the Board or the designee.

(7) Access to medical records.

- (a) Access to medical records under control of the licensee. The Board may require the licensee under investigation to immediately provide the Board with complete certified copies of medical records concerning any patient



treatment related to any complaint or statutory report being investigated by the Board.

- (b) Access to institutional and hospital records. Pursuant to subsection (6), a subpoena may be issued to any health care facility for the production of medical records concerning any patient treatment related to any complaint or statutory report being investigated by the Board. Any subpoena requiring the production of medical records shall have the full force of the law and shall be effective without court order.

- (8) Assurance of Discontinuance. In cases of minor violations of 243 C.M.R. 3.01, and if there has been no patient harm, the Complaint Committee may decide that an Assurance of Discontinuance is an appropriate resolution of the complaint or statutory report and may invite the licensee to enter into an Assurance of Discontinuance.

- (a) An Assurance of Discontinuance shall include, but not be limited to:
  - 1. Recitation of circumstances giving rise to the Assurance of Discontinuance;
  - 2. The licensee's assurance of discontinuance;
  - 3. The licensee's agreement that violation of the Assurance of Discontinuance shall be prima facie evidence of violation of the applicable law, regulations, or standards of good and accepted medical practice referenced in the Assurance of Discontinuance; and
  - 4. If appropriate, may include a sanction.

- (b) An Assurance of Discontinuance may, at the discretion of the Board, include reimbursement of costs related to the investigation and resolution of the complaint or statutory report resulting in the Assurance of Discontinuance.

- (c) Any negotiated Assurance of Discontinuance must be forwarded to the Board for its approval. Pursuant to M.G.L. c.112, §2, the Board must report an Assurance of Discontinuance to any national data reporting system, which provides information on individual physicians.

- (9) Letter of Agreement. A Letter of Agreement is a non-disciplinary monitoring agreement between the Complaint Committee and a licensee. Letters of Agreement are limited to impaired licensees who meet the following criteria:
  - a. There has been a voluntary disclosure of an impairment problem to the Board by the licensee;
  - b. There has been no patient harm or risk of patient harm as a result of the impairment;

- c. The physician has not been the subject of disciplinary action as defined in 243 CMR 1.01.
- d. There is not sufficient evidence to warrant disciplinary proceedings against the licensee.

(10) Complaint Committee Action. The Complaint Committee may take the following action:

- (a) Refer the matter to the Board with a recommendation that it issue a Statement of Allegations;
- (b) Refer the matter to the Board with the recommendation that it issue a Statement of Allegations and approve a Consent Order;
- (c) Refer the matter to the Board with a recommendation that it approve an Assurance of Discontinuance.
- (d) Resolve matters with non-disciplinary action as follows:

(1) Close complaints or statutory reports under the terms and conditions it deems appropriate;

(2) Approve Letters of Agreement.

(3) Defer consideration of complaints or statutory reports against a physician whose license has lapsed pursuant to 243 C.M.R. 2.11(4)(a), whose license has been voluntarily not renewed, or whose license has been revoked by the disciplinary process. In regard to a physician whose license has lapsed or whose license has been voluntarily not renewed, such deferral may be until such time as the physician takes action to complete the renewal process. Nothing herein shall be construed to bar the Board from commencing disciplinary proceedings at any time, including any proceedings that may or may not have previously been deferred.

(4) Offer remediation on a voluntary basis, pursuant to M.G.L. c. 112, §5, as an alternative to disciplinary action. The Board may select providers of remediation and assessment services for physicians and make referrals of physicians to these providers. The Board shall monitor the progress of each physician undertaking a remediation program and based on the results of the assessment and remediation, the Complaint Committee:

- 1. may close the matter; or
- 2. refer the matter to the Board as set forth in subsections (a) through (c) above.

The Complaint Committee may take any other action as directed by the Board that is not inconsistent with these regulations, Massachusetts law or federal law.

### 3.03: Miscellaneous Provisions

- (1) Disposition by the Board.  
The Board shall take action on the Complaint Committee's recommendations.
- (2) Referral to the Division of Administrative Law Appeals.  
If the Board issues a Statement of Allegations, it may refer the matter to the Division of Administrative Law Appeals for an adjudicatory hearing conducted pursuant to M.G.L. c. 30A in regard to Findings of Fact and Conclusions of Law only.
- (3) Redaction or Impoundment of Evidence.  
The Board or the Administrative Magistrate may order that evidence be redacted, impounded, or otherwise protected when required by law or when such evidence is of a personal nature or when the public interest so requires.
- (4) Suspension Prior to Hearing.
  - (a) The Board may temporarily suspend a license or place restrictions on a license pending a hearing on the merits of the Statement of Allegations if, based upon affidavits and/or other competent evidence, the Board decides that a licensee poses a serious threat to the public health, safety, or welfare.
  - (b) The Board may temporarily suspend or refuse to renew a license when the licensee has violated any agreement he has entered into with the Board or has failed to comply with any terms or conditions of a Board order, when said agreement or order contains a provision for summary suspension.
  - (c) In the event the Board decides to summarily suspend a license and issues an order of reference to the Division of Administrative Law Appeals, it shall identify the affidavits and/or other competent evidence it considered during its deliberation of the summary suspension.
  - (d) If the Respondent requests a hearing on the necessity of the summary action within seven (7) days after the suspension, the Board will provide such a hearing.

#### 3.04 Final Decisions and Orders of the Board

- (1) Sanctions. In disposition of disciplinary charges brought by the Board, the Board may impose one or more of the following:
  - (a) revocation, suspension, probation, reprimand, censure, admonishment, imposition of a fine not to exceed \$10,000 for each classification of violation, the performance of up to 100 hours of public service in a manner and at a time and place to be decided by the Board; and/or a course of education or training.

(b) In addition to or instead of the sanctions listed in 3.04(1)(a), the Board may restrict the practice of a physician in any manner to prohibit a licensee from performing certain medical procedures, or from performing certain medical procedures except under certain conditions, if the Board determines that:

- (1) The licensee has engaged in a pattern or practice which calls into question competency to perform such medical procedures, or
- (2) The restrictions are otherwise warranted by the public health, safety and welfare.

(c) In addition to or instead of the sanctions listed in 3.04(1)(a) and (b), the Board may require a Respondent to enter into a Probation Agreement under terms and conditions the Board deems appropriate at that time. A Probation Agreement may also be required by the Board as a condition of the stay of an indefinite suspension. Failure to comply with the terms of a Probation Agreement may result in the immediate suspension of the licensee's license to practice medicine.

(d) The Board may require reimbursement of costs related to the investigation and prosecution of the case.

(e) The Board may otherwise discipline the physician.

(2) Nature and Effect, Generally. Any order of the Board that imposes a sanction as a result of a disciplinary action is effective immediately, unless the Board orders otherwise.

(3) Revocation. A person whose license has been revoked by the Board may apply for a stay of the revocation no sooner than five years after revocation, unless the Board orders otherwise. An application for a stay will be granted only if the Board, in its discretion, decides that doing so would advance the public interest and the applicant has demonstrated his competence to practice medicine. If the Board denies a petition for a stay of revocation, the Petitioner shall not re-petition for a stay until at least two years after the date of denial, unless the Board orders otherwise.

(4) Resignation.

(a) Subject to subsection (c), a licensee who is subject to an investigation by the Board may resign his license by delivering to the Board a written statement asserting the following: the licensee desires to resign his license; the resignation is tendered voluntarily; the licensee realizes that resignation is a public disciplinary action reportable to national data reporting systems; the resignation is an irrevocable act which permanently deprives the licensee of all privileges of registration and is not subject to reconsideration or judicial review; and that the licensee is not currently licensed to practice in any other

state or jurisdiction, or will resign any other licenses contemporaneously with the resignation in the Commonwealth, and will make no attempt to gain registration elsewhere.

(b) If a complaint, statutory report, investigation, or Statement of Allegations arises solely out of a disciplinary action in another jurisdiction, as described in 243 C.M.R. 3.01(1)(cc) then, subject to 3.04(4)(c), the licensee may submit a resignation pursuant to 243 C.M.R. 3.04(4)(a), but need not make any representation regarding registration status in other jurisdictions, is permitted to gain registration elsewhere, and need not resign any other licenses contemporaneously with the resignation.

(c) The acceptance of a resignation is within the discretion of the Board.

## 243 CMR 4.00: QUALIFIED PATIENT CARE ASSESSMENT PROGRAMS

### Section

- 4.01: Scope and Purpose
- 4.02: Definitions
- 4.03: Establishment of and Participation in Qualified Patient Care Assessment Programs (QPCAP)
- 4.04: Confidentiality of Records and Information
- 4.05: QPCAP - Credentialing
- 4.06: QPCAP - Structure
- 4.07: QPCAP - Internal Occurrence Reporting and Occurrence Screening
- 4.08: QPCAP - Reporting to the Patient Care Assessment Division at the Board of Medicine
- 4.09: QPCAP - Impaired Health Care Providers
- 4.10: QPCAP - Specified Requirements in the Practice of Medicine
- 4.11: Qualified Care Assessment Safety Program - Licensee's Office Setting
- 4.12: Miscellaneous Provisions
- 4.13: QPCAP - Health Maintenance Organizations
- 4.14: Medical Care Quality Reporting to the Board - Nursing Homes

#### 4.01: Scope and Purpose

The Board of Registration in Medicine, in promulgating 243 CMR 4.00, has as its primary goal to ensure that patients in both health care facilities and office settings receive optimal care. Accordingly, 243 CMR 4.00 is intended to assist the physicians and health care facilities of the Commonwealth in their efforts to identify problems in practice before they occur, and to put in place preventive measures designed to improve systems and minimize or eliminate substandard practice. This enhancement of patient care assessment will be accomplished through establishment of the Patient Care Oversight Committee (PCOC) and the Quality Improvement Committee (QIC).

The duties of the PCOC and the QIC shall include, but not be limited to, the strengthening and formalizing of programs of quality assurance, quality improvement, performance improvement, credentialing, utilization review, peer review and risk management in health care facilities and office settings and by assuring that these functions are thoroughly integrated and overseen by the health care facilities' corporate and physician leadership. The PCOC, the QIC and 243 CMR 4.00 contemplate active self-scrutiny and reporting of unexpected occurrences in both in-patient and out-patient settings, so that individual physicians, health care facilities, the PCOC and the QIC can recognize patterns requiring corrective action or other actions aimed at improving both institutional and practitioner performance.

Further, 243 CMR 4.00 encourages the creation and adoption of minimum standards of practice in areas in which expert consensus is reached in order to permit physicians to establish and utilize touchstones of practice, to allow the Board, other tribunals, the PCOC and the QIC to determine with a high degree of predictability when a practice pattern falls within consensus standards, and to guarantee that all patients will be treated in accordance with generally accepted principles of care. Achieving these goals will decrease avoidable unexpected occurrences and will contribute to the maintenance of an atmosphere of mutual trust between physicians and their patients. In so doing, 243 CMR 4.00 will concomitantly achieve the reduction or stabilization of the frequency, amount and cost of claims against physicians and health care facilities that was the goal of the legislature in M.G.L. c. 111, § 203, and M.G.L. c. 112, §§ 5 through 5L.

To assure free self-examination by physicians and institutions, the legislature provided extensive safeguards of confidentiality, immunity and privilege for both internal reviews and reports to the Board of Registration in Medicine. It is the explicit intent of 243 CMR 4.00, that such safeguards be strengthened and extended to the extent permitted by law.

In establishing these patient care assessment requirements, the Board of Registration in Medicine formalizes and enhances those committees that, in the aggregate, they henceforth provide, at a minimum, for all of the functions enumerated by the Board of Registration in Medicine, herein as the functions of the Patient Care Assessment Program. Such committees include, for example, those groups responsible for quality assurance, quality improvement, performance improvement, credentialing, peer review, utilization review, and risk management.

A further purpose of 243 CMR 4.00 is to assist health care providers in the fulfillment of their reporting obligations under M.G.L. c. 112, § 5F. Finally, 243 CMR 4.00 is in further fulfillment of the Board's obligation to "adopt rules and regulations governing the practice of medicine in order to promote the public health, welfare and safety," pursuant to M.G.L. c. 112, § 5.

#### 4.02: Definitions

As used in 243 C.M.R. 4.00, the following words shall have the following meanings unless the context requires otherwise:

Clinic means any entity, however organized, which, in whole or in part, is advertised, announced, established, or maintained for the purpose of providing: ambulatory; medical; surgical; physical rehabilitation; and dermatologic procedures considered the practice of medicine pursuant to 243 CMR 1.01. In addition, "clinic" shall include any entity, however organized, which, in whole or in part, is advertised, announced, established, or maintained under a name which includes, but is not limited to, the word "clinic," "dispensary," or "institute," and which suggests that ambulatory; medical; surgical; physical rehabilitation; and dermatologic procedures considered the practice of medicine pursuant to 243 CMR 1.01, are rendered therein. With respect to any entity which is not advertised, announced, established, or maintained under one of

the names in the preceding sentence, “clinic” shall include two or more licensees engaged in a group practice, however organized, so long as such practice is wholly owned and controlled by one or more of the licensees so associated, or, in the case of a not for profit organization, so long as its only members are one or more of the licensees so associated.

Governing Body means the trustees, governing board or other persons responsible for establishing policy, maintaining quality patient care and providing for institutional management and planning at a health care facility.

Health Care Facility means, for purposes of 243 CMR 4.00 only, any entity licensed pursuant to M.G.L. c. 111 § 51 and defined in M.G.L. c. 111 § 52; clinics also defined in 243 CMR 4.02; any nursing home, within the meaning of M.G.L. c. 111 § 203(d); any state, county or municipal hospital; and any health maintenance organization within the meaning of M.G.L. c. 176G §1. The application of 243 CMR 4.00 to nursing homes and health maintenance organizations is limited by 243 CMR 4.13 and 4.14.

Licensee Office Setting means any medical office building affiliated with a health care facility where the practice of medicine occurs, or any other location, structure, building, office, spa, salon, health club, retail location or other environment not defined as a health care facility, where the practice of medicine occurs.

Medical Peer Review Committee consistent with M.G.L. c. 111, §§ 1 and 204, means a committee of a state or local professional society of health care providers or of a medical staff of a licensed hospital, nursing home, or other health care facility, provided the medical staff operates pursuant to written by-laws that have been approved by the governing board of the hospital, nursing home, or other health care facility, which committee has as its function the evaluation or improvement of the quality of health care rendered by providers of health care services, the determination whether health care services were performed in compliance with the applicable standards of care, the determination whether the cost of health care services rendered was considered reasonable by the providers of health services in the area, the determination of whether a health care provider's actions call into question such health care provider's fitness to provide health care services, or the evaluation and assistance of health care providers impaired or allegedly impaired by reason of alcohol, drugs, physical disability, mental instability or otherwise.

Patient Care Assessment Committee means a medical peer review committee, as defined by 243 CMR 4.02, that is created by the by-laws at the governing body level of a health care facility and which includes among its members not fewer than one governing body member; department heads, and other senior personnel responsible for the provision of quality patient care. In a health care facility where graduate medical education is given or received, the Director of Graduate Medical Education or equivalent, shall also be a member.

Patient Care Assessment Coordinator means a qualified physician or non-physician designated by a health care facility to implement and coordinate the facility's



Qualified Patient Care Assessment Program established pursuant to these regulations. To be qualified, the Patient Care Assessment Coordinator shall evidence by education, training or experience the ability to carry out the functions and activities of the Patient Care Assessment Program, including completing certification training by the Board of Registration in Medicine after July 1, 2007. In lieu of appointing a single Patient Care Assessment Coordinator, the governing body of a health care facility may designate a committee to carry out the Patient Care Assessment Coordinator's functions as enumerated in 243 CMR 4.00. Thus, upon election of the health care facility's governing body, all references herein to "Patient Care Assessment Coordinator" may include "Patient Care Assessment Committee."

Patient Care Oversight Committee (PCOC) means a non-confidential, multidisciplinary committee at the Board of Registration in Medicine, comprised of non-Board and Board members, established by the Board, and charged with overseeing Qualified Patient Care Assessment Plans and aggregate de-identified reports.

Quality Improvement Committee (QIC) means a confidential, peer review protected multidisciplinary committee at the Board of Registration in Medicine, comprised of non-Board members, established by the Board, and charged with overseeing Qualified Patient Care Assessment Programs.

Qualified Patient Care Assessment Program (QPCAP) means a health care facility's rules, standards and procedures, adopted pursuant to the facility's by-laws (unless otherwise required by statute), designed to establish effective programs in quality assurance, quality improvement, performance improvement, credentialing, utilization review, peer review, risk management, identification and prevention of substandard practice, and maximization of patient care assessment and thus minimization of loss, and which meet or exceed the rules, procedures, and standards set forth in 243 CMR 4.00. A "Qualified Patient Care Assessment Program" is a "risk management program" established by the Board of Registration in Medicine pursuant to M.G.L. c. 111, § 203(d) and recognized as a "risk management program" within the meaning of M.G.L. c. 112, § 5.

Unexpected Occurrence means an unanticipated event involving a patient regardless of whether or not there was patient harm; such as, but not limited to, medical errors; medication errors; patient injuries; equipment malfunctions or user error; and any variances requiring a patient to undergo significant additional diagnostic or treatment measures.

#### 4.03: Establishment of and Participation in Qualified Patient Care Assessment Programs

(1) Every health care facility shall establish a Qualified Patient Care Assessment Program that requires all health care providers to participate in said Qualified Patient Care Assessment Program.

(2) A Qualified Patient Care Assessment Program shall be described in a written plan, hereinafter called the Patient Care Assessment Plan. The Patient Care Assessment Plan shall be reviewed and updated at least annually by the governing body of the health care facility. The Patient Care Assessment Plan shall also be submitted every three years to the Board's Patient Care Oversight Committee, and approved by the Patient Care Oversight Committee to be a Qualified Patient Care Assessment Plan. The three-year schedule for each health care facility shall be determined by the Patient Care Oversight Committee.

(3) Written instructions for the Patient Care Assessment Plan, pursuant to 243 CMR 4.06(5); any amendments to the Patient Care Assessment Plan and any proposed amendments thereto, pursuant to 243 CMR 4.03(1), shall be filed annually with the Patient Care Oversight Committee, concurrently with the annual report to the Quality Improvement Committee required under 243 CMR 4.07(7).

(4) Pursuant to 243 CMR 4.12(7), the Patient Care Oversight Committee may assess a fine for failure to submit a Patient Care Assessment Plan; failure to have a Patient Care Assessment Plan approved by the Patient Care Oversight Committee; or failure to submit a Patient Care Assessment Plan by the due date set by the Committee.

(5) After January 1, 2009, the Patient Care Oversight Committee shall annually issue a list of health care facilities that failed to submit or failed to have a plan approved by the Patient Care Oversight Committee.

(6) The Patient Care Assessment Plan shall include, at a minimum, procedures for compliance with 243 CMR 4.00, including:

- (a) governing body responsibility for the program including, but not limited to, patient care assessment related committees established pursuant to governing body authorization;
- (b) risk identification and analysis including, but not limited to, internal occurrence reporting and screening, and the process for reporting to the Quality Improvement Committee;
- (c) loss prevention and risk reduction activities including, but not limited to, policies and procedures regarding medication errors, credentialing, identification of and counseling for impaired health care providers, and the establishment of guidelines and standards for clinical specialties;
- (d) patient communications and documentation activities including, but not limited to, informed consent policies, maintenance of medical records, and the processing of patient complaints;

- (e) policies governing the responsibilities of the Patient Care Assessment Coordinator and Committee;
- (f) emergency management or preparedness plans pursuant to 243 CMR 4.05(3);
- (g) quality and patient safety trainee-focused training and education programs for medical residents, if applicable;
- (h) education and training provided pursuant to 243 CMR 4.07(3)(a); and
- (i) other criteria as established by the Patient Care Oversight Committee and Quality Improvement Committee.

(7) Pursuant to M.G.L. c. 112, § 5, every licensee must participate in the Qualified Patient Care Assessment Program established by a health care facility where the licensee has employment, practice, association for the purpose of providing patient care, or privileges, and a licensee may not accept employment, practice, association for the purpose of providing patient care, or privileges at a health care facility unless it has a Qualified Patient Care Assessment Program.

(8) Whether or not a licensee is employed by, associated with for the purpose of providing patient care, or has practice or privileges at a health care facility with a Qualified Patient Care Assessment Program, the licensee must, as a condition of licensure, adhere to the rules, standards and procedures in 243 CMR 4.10 and 4.11.

#### 4.04: Confidentiality of Records and Information

(1) To promote free and full compliance with the reporting requirements set forth below, which will enhance the protection of the public, information and records both generated pursuant to 243 CMR 4.00, and which relate to the functions of a Medical Peer Review Committee, with the exception of Patient Care Assessment Plans and other information pursuant to 243 CMR 4.03, are hereby deemed confidential and, to the extent allowable under M.G.L. c. 111, § 204, not subject to subpoena, discovery or introduction into evidence.

(2) To protect the confidentiality of information and records both generated pursuant to these regulations and which also relate to the functions of a Medical Peer Review Committee, and to assure that this information and these records are not subject to subpoena, discovery or introduction into evidence, the Patient Care Assessment Coordinator may designate such information and records as "proceedings, reports and records of a medical peer review committee," within the meaning of M.G.L. c. 111, § 204(a). However, such designation shall not preclude full compliance with 243 CMR 4.00.

(3) The provisions in this section shall not apply to "proceedings, reports and records of a medical peer review committee," within the meaning of M.G.L. c. 111, § 204(a), if such proceedings, reports or records are obtained from a source independent of a Medical Peer Review Committee.

(4) Information and records required to be submitted by health care facilities solely to the Quality Improvement Committee, shall remain solely with the Quality Improvement Committee and shall not be shared with or disclosed to other Divisions and Committees of the Board, unless de-identified or aggregated.

#### 4.05: QPCAP - Credentialing

(1) No health care facility in the Commonwealth shall appoint, hire, associate with for the purpose of providing patient care, or grant privileges to a licensee, unless the health care facility first completes the credentialing requirements set forth below. For the purposes of 243 CMR 4.05, "health care facility" includes a substantially equivalent facility outside of the Commonwealth. The health care facility must repeat these credentialing requirements at least every three years. These credentialing requirements are modified as follows:

(a) The credentialing requirements may be performed during the time period in which the health care facility grants temporary appointment or privileges, for up to 120 days in any one year period, to a licensee seeking initial staff membership, provided the health care facility maintains on file a completed application for staff membership and written and timely evidence of a valid Massachusetts license, malpractice insurance, a current DEA certificate of registration for licensees who will be prescribing controlled substances, and appropriate references; and provided further that the health care facility pursues in good faith the credentialing of each licensee holding such temporary appointment or privileges. The aforementioned temporary appointment or privileges shall not be granted by a facility to a licensee in more than two consecutive years.

(b) The credentialing requirements do not apply when the health care facility grants temporary appointment or privileges for up to 30 days in any one year period to a licensee who is not seeking staff membership, provided the health care facility maintains on file written and timely evidence of a valid Massachusetts license, malpractice insurance, a current DEA certificate of registration for licensees who will be prescribing controlled substances, and letters of recommendation or references as deemed appropriate by the health care facility. The aforementioned temporary appointment or privileges shall not be granted by a facility to a licensee in more than two consecutive years.

(c) The credentialing requirements do not apply, during an emergency declared by the federal government or the Governor, or when the Chairman of the Board or

his designee, after consulting with the Governor or his designee, has determined that an emergency exists that exceeds a health care facility's ability to respond through its emergency management or emergency preparedness plan.

(d) For the credentialing of telemedicine providers, health care facilities may follow the Joint Commission for Accreditation of Health Care Organizations (JCAHO) standard MS 4.120; provided however that the originating site, distant site and the telemedicine provider are located in the United States of America or its territories, and said telemedicine provider is licensed in Massachusetts.

(i) The categories of licensees that shall be considered telemedicine providers for purposes of this section shall be determined or reviewed, at least annually, by a sub-committee of the Board.

(ii) Telemedicine providers, pursuant to this section, shall use a credentialing form approved by the Board, and health care facilities shall solely accept said forms from said providers.

(2) No health care facility in the Commonwealth shall appoint, hire, associate with for the purpose of providing patient care, or grant to or renew privileges of any licensee unless:

(a) The health care facility verifies that the licensee holds a current license to practice medicine.

(b) The licensee provides to the health care facility consent allowing the health care facility to conduct a criminal background check and a copy of his most recent application for initial or renewal registration to practice medicine in the Commonwealth, including all attachments and other explanatory materials submitted with the application, whether required or voluntarily submitted. Only to the extent allowed by M.G.L. c. 151B, § 4, the licensee may delete from such application information disclosing:

(i) an arrest, detention, or disposition, regarding any alleged violation of law from which no conviction resulted;

(ii) a first conviction for any of the following misdemeanors: drunkenness, simple assault, speeding, minor traffic violations, affray, or disturbance of the peace; and

(iii) any conviction of a misdemeanor where the date of such conviction or the completion of any period of incarceration resulting therefrom, whichever date is later, occurred five or more years prior to the date of the credentials application, unless the licensee has been convicted of any offense within five years immediately preceding the date of the credentials application.

- (c) The licensee provides to the health care facility a listing and description of all malpractice claims and lawsuits pending or closed during the previous ten years, including the information listed in this section and any further relevant information requested by the health care facility. 243 CMR 4.05 applies whether or not the transaction giving rise to the malpractice claim arose at the health care facility where the licensee is seeking or renewing appointment, employment, practice, association for the purpose of providing patient care, or privileges. 243 CMR 4.05 also applies whether or not the malpractice claim is filed with an insurance carrier, a court, or another entity to which the malpractice claim is presented.
- (d) The health care facility has established criteria for documenting and analyzing, and so documents and analyzes, where available, a licensee's:
  - (i) professional performance, judgment and clinical skills;
  - (ii) mental and physical status;
  - (iii) compliance with continuing education requirements;
  - (iv) data dealing with utilization;
  - (v) adherence to health care facility and medical staff by-laws, policies and procedures;
  - (vi) malpractice claims filed against the licensee; and
  - (vii) information regarding any criminal proceedings.
- (e) The licensee authorizes his medical malpractice liability insurance carrier or carriers to release to the health care facility the following information, described in M.G.L. c. 112, § 5C, as to claims or actions for damages pending or closed during the previous ten years, whether or not there has been a final disposition:
  - (i) the policy number of the licensee against whom the claim is made;
  - (ii) the name, address and age of the claimant or plaintiff;
  - (iii) the nature and substance of the claim;
  - (iv) the date and place at which the claim arose;
  - (v) the amounts paid, if any, and the date and manner of disposition, judgment, settlement, or otherwise;

- (vi) the date and reason for final disposition, if no judgment or settlement; and
  - (vii) such additional information as the Board shall require pursuant to M.G.L. c.112, § 5C(g).
- (f) The licensee provides to the health care facility the name of any health care facility where the licensee has had employment, practice, association for the purpose of providing patient care, or privileges. The licensee must also provide the reasons for any discontinuance of employment, practice, association or privileges at any of the named health care facilities.
- (g) The licensee authorizes release to the health care facility any information from any other health care facility where the licensee has had employment, practice, or association for the purpose of providing patient care, or privileges, if such information is relevant, either directly or indirectly to the licensee's competence to practice medicine.
- (h) The licensee authorizes the health care facility to exchange information with any other health care facility and with any professional organization with which the licensee has or had employment, practice, association or privileges, regarding any pending or final disciplinary action as defined in 243 CMR 1.01, which includes, but is not limited to, any voluntary or involuntary course of counseling, treatment or testing for drug or alcohol abuse.
- (i) The health care facility makes reasonable inquiry to other health care facilities, where the licensee has or has had employment, practice, association for the purpose of providing patient care, or privileges, regarding the licensee, before allowing the licensee to practice medicine at the health care facility. In the case of an initial application, the health care facility shall make reasonable inquiry of every health care facility where the licensee has had employment, practice, or association for the purpose of providing patient care, or privileges during at least the previous ten years. In the case of a renewal appointment, the health care facility shall make reasonable inquiry to every health care facility where the physician has had employment, practice, or association for the purpose of providing patient care, or privileges in the previous three years. "Reasonable inquiry" must include a written request for:
  - (i) an assessment of clinical skills, including an analysis of complication rates and other performance data;
  - (ii) information regarding any pending or final disciplinary action as defined in 243 CMR 1.01; and

(iii) information regarding malpractice litigation, and any other information relevant, either directly or indirectly, to the licensee's character or competence to practice medicine.

(j) In the case of an inquiry to a health care facility concerning a period of time when the licensee held a limited license under M.G.L. c. 112, § 9 (or performed equivalent post-graduate work outside of the Commonwealth), the health care facility where the licensee had his primary assignment may respond on behalf of its affiliated health care facilities where the licensee practiced medicine. The responding facility to which the request for information is directed should provide the requested information within thirty days. Said information as between the requesting and responding facilities, shall be subject to the confidentiality protections provided for under M.G.L. c. 111, §§ 204 & 205, and 243 CMR 4.04, if applicable.

(k) At any time during the three-year credentialing cycle, a health care facility where a licensee is credentialed may make reasonable inquiry, as defined in this section, of any other health care facilities where the licensee is credentialed. The licensee shall provide the required authorization for release of the information requested. The responding facility to which the request for information is directed should provide the requested information within thirty days. Said information as between the requesting and responding facilities, shall be subject to the confidentiality protections provided for under M.G.L. c. 111, §§ 204 & 205, and 243 CMR 4.04, if applicable.

(l) The health care facility, pursuant to its by-laws or by agreement with the licensee, will require the licensee to undergo a mental or physical examination, if requested by:

(i) the executive committee of the medical staff;

(ii) the credentials committee; or

(iii) by such other supervisory body, which includes members of the medical staff, as may be authorized in the facility's by-laws to make such request; and if there is a known mental or physical impairment, to provide evidence that the impairment does not interfere with the licensee's competence to practice medicine.

(3) In the event of an emergency as described in 243 CMR 4.05(1)(c), each health care facility shall implement an emergency management or preparedness plan which shall detail the manner in which physicians are provided credentials to respond to the emergency. Prior to an emergency, as part of their emergency management or preparedness plan, each health care facility shall make reasonable efforts to identify physicians who are credentialed by other facilities that may be utilized during an emergency. The emergency credentialing process shall include:



- (a) verification of the physician's name, date of birth, and social security number;
- (b) name and address of the physician's primary hospital affiliation, privilege status and primary office address;
- (c) the physician's clinical specialty and board certification;
- (d) the physician's malpractice insurance carrier;
- (e) a valid Massachusetts Medical License wallet card or proof of valid licensure by another state or the District of Columbia and at least one of the following forms of identification:
  - (1) a valid hospital picture identification card, or
  - (2) a valid federal, state, or municipal emergency services identification card;
- (f) rapid verification of the information provided by the physician to the health care facility to the extent communication is possible;
- (g) immediate discontinuance of privileges when the emergency has been terminated unless authorized by the Governor or his designee or the Chairman of the Board or his designee.

(4) The Patient Care Assessment Division and the Quality Improvement Committee at the Board of Registration in Medicine may require health care facilities to adopt certain credentialing and privileging criteria pursuant to the Board's authority under M.G.L. c. 112, § 5 and 243 CMR 4.00.

#### 4.06: Qualified Patient Care Assessment Program - Structure

(1) The health care facility shall establish a medical peer review committee, with responsibility for patient care assessment at the governing body level, to be known as the Patient Care Assessment Committee.

(2) The governing body shall assure the adequacy of resources and support systems for the Patient Care Assessment Committee functions. In lieu of establishing a single Patient Care Assessment Committee, the governing body may elect to establish or maintain separate board-level medical peer review committees to carry out the Patient Care Assessment Committee functions required by 243 CMR 4.00. Said separate board-level medical peer review committee(s) shall comply with the requirements of a Patient Care Assessment Committee as defined in 243 CMR 4.02. The health care facility may establish any other peer review committees as it deems appropriate.

(3) The Patient Care Assessment Committee or the committees carrying out patient care assessment committee functions shall:

- a) be comprised of persons not only from the medical staff;
- b) be consistent with the definition of medical peer review committee under 243 CMR 4.02; and
- c) carry out all or some of the following functions:
  - (i) the evaluation or improvement of the quality of health care rendered by providers of health care services;
  - (ii) the determination whether health care services were performed in compliance with the applicable standards of care;
  - (iii) the determination whether the cost of health care services rendered would be considered reasonable by the providers of health services in the area;
  - (iv) the determination whether a health care provider's actions call into question such health care provider's fitness to provide health care services;
  - (v) the determination whether there were higher costs due to extended length of stay or readmission to the health care facility due to an unexpected occurrence as defined in 243 CMR 4.02; or
  - (vi) the evaluation and assistance of health care providers impaired or allegedly impaired by alcohol, drugs, physical disability, mental instability or other causes.

(4) The governing body shall designate a Patient Care Assessment Coordinator, who shall be charged by the governing body with responsibility for implementing, by delegation, oversight, facilitating, coordinating, or otherwise, the health care facility's Qualified Patient Care Assessment Program and with ensuring compliance with 243 CMR 4.00. In lieu of appointing a single Patient Care Assessment Coordinator, the governing body of a health care facility may designate a committee to carry out the Patient Care Assessment Coordinator's functions as enumerated in 243 CMR 4.00. Thus, upon election of the health care facility's governing body, all references herein to "Patient Care Assessment Coordinator" may include the "Patient Care Assessment Committee." The Patient Care Assessment Coordinator shall be responsible to the Patient Care Assessment Committee or shall be the formal administrative link amongst any separate committees, which carry out the patient care assessment functions required by 243 CMR 4.00, and any other peer review committees.

(5) The Patient Care Assessment Coordinator shall prepare and provide detailed written instructions regarding operational procedures relevant to patient care assessment and compliance with 243 CMR 4.00. The Patient Care Assessment Coordinator shall provide such written instructions as are relevant to each health care provider at the health care facility. As part 243 CMR 4.03, the health care facility shall file the written instructions with the Patient Care Oversight Committee.

(6) The Patient Care Assessment Coordinator shall have unrestricted access to all records and information related to the Patient Care Assessment Coordinator's functions as per 243 CMR 4.00.

(7) The health care facility shall report the name of the Patient Care Assessment Coordinator to the Patient Care Oversight Committee and the Quality Improvement Committee within ten days of designation or replacement.

#### 4.07: QPCAP - Internal Occurrence Reporting and Occurrence Screening

(1) Pursuant to M.G.L. c. 111, § 203(a), the by-laws of both the health care facility and the medical staff shall contain provisions for reporting conduct of a health care provider that indicates incompetence in his specialty or conduct which might be inconsistent with or harmful to good patient care and safety. The Patient Care Assessment Coordinator shall be responsible for assuring investigation of such reports, and shall directly review the report, resolution and follow-up.

(2) Pursuant to M.G.L. c. 111, § 203(b), the by-laws of the medical staff shall provide that, whenever following review by a medical peer review committee, or equivalent body, at a health care facility, a determination is reached that a health care provider should be subject to a disciplinary action, as defined in 243 CMR 1.01, such committee shall immediately forward the recommendation to the executive committee of the medical staff and the health care facility's board of trustees or governing body for action. If the health care provider subject to the disciplinary action, as defined in 243 CMR 1.01, is not a licensee, then such action forwarded shall include referral to the appropriate department. Matters relating to non-physician health care providers may be assessed by medical peer review committees consisting entirely or predominantly of non-physician members.

(3) The health care facility and medical staff by-laws shall authorize the establishment of the following elements of a Qualified Patient Care Assessment Program:

(a) The development and implementation of an incident reporting system based upon an affirmative duty of all health care providers to report in writing to the Patient Care Assessment Coordinator, at a minimum, any unexpected occurrence and any health care provider conduct pursuant to 243 CMR 4.07(1). As part of the incident reporting system, procedures shall be detailed in writing and provided to all health care providers employed by, credentialed by or associated with the

health care facility for the purpose of providing care. All such health care providers, within five days of employment, completion of credentialing or association, shall receive written instructions, and within thirty days, shall receive orientation and training, in the operation of the system and their responsibilities within it. At least annually, all appropriate health care providers shall be provided at least six hours patient care assessment and quality assurance education and training, with emphasis upon the importance of accurate and timely incident reporting. All new health care providers' education and training and all annual training shall also include specific instruction in Patients' Rights pursuant to M.G.L. c. 111, § 70E.

(b) Required Internal Incident Reports shall be generated by Focused Occurrence Reporting Criteria. The Focused Occurrence Reporting Criteria shall define unexpected occurrences that must be reported either at the time they are observed or within no more than 24 hours thereafter. The health care facility shall file its Focused Occurrence Reporting Criteria with the Quality Improvement Committee when adopted or amended by the health care facility. Upon request, the Quality Improvement Committee shall provide technical assistance in developing Focused Occurrence Reporting Criteria. The Quality Improvement Committee may require health care facilities to adopt certain criteria if the Quality Improvement Committee determines such a requirement to be in the best interest of public health.

(c) Required Internal Incident Reports may be generated through Occurrence Screening wherein all or a percentage of patients' medical records are reviewed shortly after discharge under Occurrence Screening Criteria. These criteria should be designed to reveal, through a chart review process, adverse or potentially unexpected patient occurrences that might not otherwise be evident. The health care facility shall file its Occurrence Screening Criteria with the Quality Improvement Committee when adopted or amended by the health care facility. Upon request, the Quality Improvement Committee shall provide technical assistance in developing Occurrence Screening Criteria. The Quality Improvement Committee may require health care facilities to adopt certain criteria if the Quality Improvement Committee determines such a requirement to be in the best interest of public health.

(4) The Patient Care Assessment Coordinator shall be responsible for the investigation and analysis of the frequency and causes of general categories and specific types of all Required Internal Incident Reports and any other incident reports, and shall also be responsible for:

(a) reviewing and acting upon incident reports to assure follow-up with individuals involved in the incident;

(b) the regular and systematic reviewing of all incident reports for the purposes of identifying trends or patterns, including but not limited to time, place, and person.

Upon emergence of any trend or pattern in incident occurrence, the Patient Care Assessment Coordinator shall develop written recommendations for appropriate corrective actions and performance improvement measures;

(c) creation of a random chart audit system to assure compliance with the incident reporting requirements;

(d) the development of written step-by-step procedures for the follow-up required by this section;

(e) the development of other appropriate measures to minimize the risk of injuries and incidents to patients;

(f) the central collection of, investigation of, analysis of, and timely response to patient complaints which relate to patient care and the quality of medical services;

(g) a requirement that all incident reports, summary reports and written recommendations to and from the Patient Care Assessment Coordinator shall be maintained for three years; and

(h) a requirement of documentation of any disciplinary action as defined in 243 CMR 1.01.

(5) All incident reports shall be in writing on a form developed by the health care facility for such purpose and shall contain at least the following information:

(a) the patient's name, locating information, admission date, age, sex, primary language, race and ethnicity;

(b) a clear and concise description of the incident, including time, date, and exact location;

(c) a listing of all persons known to be involved in the incident, including witnesses, along with locating information for each;

(d) the name, signature and position of the person completing the report, and the date and time that the report was completed;

(e) provisions acknowledging the authority of the Quality Improvement Committee, and the Patient Care Oversight Committee to access and audit Qualified Patient Care Assessment Program information and records during normal business hours; and

(f) provisions to require administration of a reasonable and comprehensive evaluation of a licensee's clinical skills, competence and judgment, upon request

of and for filing with the Quality Improvement Committee or the Patient Care Oversight Committee.

(6) The governing body shall establish a committee charged with overseeing safety and maintenance of facilities and equipment, and the Patient Care Assessment Coordinator shall receive periodic reports from this committee.

(7) No later than 45 days after the end of each six-month calendar period (or more often, if the governing body so requires), the Patient Care Assessment Coordinator or person serving in a similar capacity at the health care facility shall provide a report to the health care facility's governing body, with a copy of the report filed simultaneously with the Board's Quality Improvement Committee.

(a) The report shall describe the health care facility's internal incident reporting and occurrence screening activities, including, but not limited to, data, data analysis, trending, corrective actions, findings and recommendations for quality assurance, quality improvement, performance improvement, including recommendations related to credentialing, peer review, utilization review, risk management, and training and education.

(b) The following information shall be filed annually as part of the report, in addition to the requirements found in subsection (a) of this section:

- (i) a summary analysis of patient complaints and their disposition, including, but not limited to, data, data analysis, trending, corrective actions, findings and recommendations for quality assurance, quality improvement, performance improvement, including recommendations related to credentialing, peer review, utilization review, risk management, and training and education;
- (ii) the number and type of reports filed pursuant to 243 CMR 4.08;
- (iii) summary information on the handling of impaired physicians;
- (iv) data on internal incident reporting and occurrence screening specifically regarding medical residents; and
- (v) a summary of all cases discussed and reviewed by the Patient Care Assessment Committee(s), including findings, corrective action plans, performance improvement measures and recommendations made by the Patient Care Assessment Committee.

(c) Semi-annual and annual reports shall be submitted to the Quality Improvement Committee on a calendar year schedule no later than sixty (60) days after the expiration of the relevant time period.

4.08: QPCAP - Reporting to the Patient Care Assessment Division at the Board of Registration in Medicine

- (1) The requirement that health care facilities establish reporting and screening criteria for unexpected occurrences, as well as internal procedures for the review and analysis of these occurrences, is intended to promote peer review and other activities to assure quality patient care at each facility. To allow the Board to meet its statutory responsibility for the oversight of health care facility patient care assessment programs, each health care facility must report certain unexpected occurrences to the Quality Improvement Committee.
- (2) The following types of unexpected occurrences must be reported by the health care facility to the Quality Improvement Committee:
  1. surgery on the wrong body part;
  2. surgery on the wrong patient;
  3. wrong surgical procedure performed on a patient;
  4. object left in patient after surgery;
  5. death of a patient, who had been generally healthy, during or immediately after surgery for a localized problem;
  6. patient death or serious disability associated with the use of contaminated drugs, devices, or biologics;
  7. patient death or serious disability associated with the misuse or malfunction of a device;
  8. patient death or serious disability associated with intravascular air embolism;
  9. infant discharged to the wrong person;
  10. patient death or serious disability associated with patient disappearing for more than four hours;
  11. patient suicide or attempted suicide resulting in serious disability;
  12. patient death or serious disability associated with a medication error;

13. patient death or serious disability associated with transfusion of blood or blood products of the wrong type;
14. maternal death or serious disability associated with labor or delivery in a low-risk pregnancy;
15. patient death or serious disability associated with the onset of hypoglycemia, a drop in blood sugar;
16. death or serious disability associated with failure to identify and treat hyperbilirubinemia, a blood abnormality, in newborns;
17. severe pressure ulcers acquired in the hospital;
18. patient death or serious disability due to spinal manipulative therapy;
19. patient death or serious disability associated with an electric shock;
20. any occurrence in which a line designated for oxygen or other gas to be delivered to a patient contains the wrong gas or is contaminated by toxic substances;
21. patient death or serious disability associated with a burn incurred in the hospital;
22. patient death associated with a fall suffered in the hospital;
23. patient death or serious disability associated with the use of restraints or bedrails;
24. any instance of care ordered by or provided by someone impersonating a physician, nurse, pharmacist, or other licensed healthcare provider;
25. abduction of a patient;
26. sexual assault on a patient;
27. death or significant injury of a patient or staff member resulting from a physical assault in the hospital.

(3) The Quality Improvement Committee may make the reports described in section 243 CMR 4.08(2) public on or after July 1, 2010. Reports received by the Quality Improvement Committee prior to July 1, 2010 shall remain confidential. For purposes of this section, public shall mean that the Quality Improvement Committee shall only inform the Patient Care Oversight Committee of the name of the facility and type of unexpected occurrence listed in 243 CMR 4.08(2). In addition to the



information required in 243 CMR 4.08(4), all other information submitted by the health care facility to the Quality Improvement Committee concerning the unexpected occurrence pursuant to 243 CMR 4.08(2), shall remain subject to the confidentiality protections provided for under M.G.L. c. 111, §§ 204, and 205, and 243 CMR 4.04.

- (4) In addition to the unexpected occurrences in subsection (2) of this section, the following types of occurrences must also be reported by the health care facility to the Quality Improvement Committee:

(a) Any unexpected occurrences, related to system or process deficiencies, or health care provider concerns, which lead to death or 'major and enduring loss of function' for a recipient of health care services.

(b) For purposes of this section, 'major and enduring loss of function' refers to sensory, motor, physiological or psychological impairment not present at the time services were sought or began.

- (5) Health care facilities shall file said reports pursuant to 243 CMR 4.08(2) and (4) with the Quality Improvement Committee as soon as is reasonably and practically possible, but no later than 60 working days after discovery of the occurrence. The report shall be filed in a format specified by the Quality Improvement Committee. The form will require the submission of certain information including, but not limited to a description of the occurrence, the results of the internal investigation, a description of the corrective actions or performance improvement measures taken by the health care facility, and any other information which is pertinent to understanding what happened, why it happened, and what steps were taken to prevent a future occurrence or improve the care of future patients. The reporting of the name(s) of the licensee(s) involved in the occurrence initially will be optional. If the health care facility chooses to withhold the name(s) of the involved licensee(s), the Quality Improvement Committee may require additional information to enable it to evaluate the licensee's background, skills and involvement in prior major occurrences. If at any time during the course of its investigation, the Quality Improvement Committee requires the name(s) of the involved licensee(s) in order to assess the adequacy of the response of the health care facility's Patient Care Assessment Program to the occurrence, the facility shall provide such name(s). Said names will remain confidential and subject to the provisions of 243 CMR 4.04.
- (6) After July 1, 2007, the Patient Care Oversight Committee shall issue annually an aggregate report of the occurrences reported by category in section 4.08(2) and 4.08(4) to the Joint Committee on Health Care Financing in the Massachusetts Legislature or its equivalent, and the Joint Committee on Consumer Affairs or its equivalent.
- (7) This section does not relieve the health care facility of any other reporting obligation required under law or regulation, including but not limited to M.G.L. c. 111, § 53B and regulations related thereto.

- (8) Pursuant to 243 CMR 4.12(7), the Quality Improvement Committee may fine a health care facility for failure to submit a complete report, failure to file a report or failure to file a report by the due date as established by this section.

#### 4.09: QPCAP - Impaired Health Care Providers

(1) The health care facility and medical staff by-laws must authorize a procedure for ongoing review and counseling of health care providers impaired by drugs or alcohol, or the health care facility must arrange for and monitor participation in other established review and counseling programs. The health care facility and medical staff by-laws must also authorize a procedure to ensure compliance with M.G.L. c. 112, § 5F, with specific regard to reporting impaired licensees to the Board.

(2) The Patient Care Assessment Coordinator must be kept apprised of any review and monitoring pursuant to this section.

(3) The Board may promulgate additional regulations relevant to reporting (to the appropriate board of registration), review and monitoring of impaired health care providers at a health care facility. Prior to such promulgation, the Board of Registration in Medicine may receive relevant proposals from appropriate local, state and national medical societies and organizations.

#### 4.10: QPCAP - Specified Requirements in the Practice of Medicine

(1) Informed Consent. A Qualified Patient Care Assessment Program must require licensees in the facility to adhere to the following guidelines relevant to Informed Consent:

(a) The health care facility must have written policies and procedures designed to address the informed consent process. At a minimum, the policies should address:

(i) medical procedures and treatments for which informed consent is required and the content of the information provided;

(ii) designation of persons responsible for obtaining informed consent from the patient;

(iii) the manner of documentation of consent, consistent with 243 CMR 4.10; and

(iv) designation of appropriate persons, other than the patient, from whom consent may be obtained, and the circumstances when consent may be obtained from a person other than the patient.

(b) Consent should be obtained for all major therapeutic and diagnostic procedures where disclosure of significant medical information, including major risks involved, would assist a patient in making an intelligent decision whether to undergo the proposed procedure. It shall be a physician's responsibility to obtain the informed consent of the patient, and to discuss sufficient medical information to enable the patient to decide whether to undergo the proposed treatment. Although the physician is responsible for informing the patient, health care facility personnel may assist in completing documentation.

(c) A patient's consent shall be documented with sufficient clarity and detail so as to satisfy the reader that the patient was given and understood the medical information provided.

(2) Medical Records.

(a) The health care facility shall prohibit the alteration of medical records when such alteration distorts any facts or circumstances reflected in the original writing.

(b) Medical records shall meet the requirements set forth in the most recent Accreditation Manual for Hospitals published by the Joint Commission on Accreditation of Hospitals.

(3) Prescription Practice and Medication Errors. All licensees shall adhere to requirements for the safe administration of drugs and biologicals, set forth in the current Accreditation Manual for Hospitals, published by the Joint Commission on Accreditation of Hospitals.

(4) Guidelines in Specialties. All licensees shall adhere to guidelines endorsed by the Board of Registration in Medicine.

(5) Other Patient Care Assessment Standards. The Board may promulgate regulations relevant to Patient Care Assessment Standards in other medical specialties. The Board may also endorse or use as guidelines standards developed by local, state, or national specialty societies and organizations.

4.11: Qualified Care Assessment Safety Program - Licensee's Office Setting

(1) In the case of patient care provided in a licensee's office setting, the licensee must file an occurrence report in the manner prescribed by 243 CMR 4.08(5), with the health care

facility where the licensee has his or her primary affiliation, in the following circumstances:

- (a) Category I occurrences: unplanned transfer to a hospital precipitated by an invasive procedure performed in the licensee's office.
  - (b) Category II occurrences: an unexpected occurrence resulting from any procedure that requires the administration of minimal or moderate intravenous or intramuscular sedation/analgesia, thus making intra-operative and post-operative monitoring necessary; or from any procedure that requires, or reasonably should require, the use of deep sedation/analgesia, general anesthesia, or major conduction blockade, and/or in which the known complications of the proposed surgical procedure may be serious or life threatening.
- (2) The health care facility shall review such reported occurrences and shall file an occurrence report with the Quality Improvement Committee in the manner prescribed by 243 CMR 4.08(5). With respect to a licensee who is not a member of a health care facility medical staff, said licensee shall file such occurrence report in the manner prescribed by 243 CMR 4.08(5) directly with the Quality Improvement Committee.
- (3) The licensee's office setting shall be subjected to on-site audit by the Quality Improvement Committee to assure compliance with 243 CMR 4.00.
- (4) Any licensee performing invasive procedures in an office setting shall permit his insurer to conduct an annual on-site audit or assessment for patient care assessment, quality assurance and risk management, and report the results of the audit to the Quality Improvement Committee.
- (5) Upon a finding by the Quality Improvement Committee that a licensee or the health care facility failed to follow the requirements of 243 CMR 4.11, the Committee may impose a fine pursuant to 243 CMR 4.12(7).

#### 4.12: Miscellaneous Provisions

- (1) In addition, as part of its Qualified Patient Care Assessment Program, the health care facility's by-laws shall authorize the establishment of the following provisions:
- (a) At least annually, every health care provider, who is employed by or has privileges at the health care facility, or provides patient care on behalf of an HMO, shall receive written notice of the requirements and rights in M.G.L. c. 112, § 5F.
  - (b) Violation of any health care facility bylaw or regulation required as part of a Qualified Patient Care Assessment Program may be grounds for summary

suspension of employment, practice, association for the purpose of providing patient care, or privileges at the health care facility or on behalf of an HMO.

(2) Patients' Rights. Prior to or within 24 hours following admission to a health care facility, every patient (or the person from whom informed consent must be obtained) shall receive written notice, in plain language, of the rights established by M.G.L. c. 111, § 70E, except that if the patient is a member of a health maintenance organization and the health care facility is owned by or controlled by such organization, such notice shall be provided at the time of enrollment in such organization and also upon admittance to said facility. Such rights shall be conspicuously posted in the health care facility. In addition, all such patients shall be informed that they may file complaints with a designated office, person or committee established under 243 CMR 4.07, and of the existence of the Board, the Department of Public Health, and their addresses and telephone numbers.

(3) The health care facility shall maintain personnel records regarding its health care providers for a minimum of ten years.

(4) Where it appears that a health care facility has engaged in a pattern and practice of violating M.G.L. c. 111, § 203 or any provision of 243 CMR 4.00, or if there is any other indication of a serious violation, the Board, the Patient Care Oversight Committee or the Quality Improvement Committee shall report same to the Department of Public Health or Division of Insurance for such action as is warranted. In the event the Board, the Patient Care Oversight Committee or the Quality Improvement Committee finds that a health care facility has intentionally failed to comply with any requirements of 243 CMR 4.00, the Quality Improvement Committee, the Patient Care Oversight Committee or the Board may assess a fine on the health care facility pursuant to 243 CMR 4.12(7). If a health care facility has more than three fines in a two-year period, the name of the facility shall be disclosed to the public and the Board, Patient Care Oversight Committee or the Quality Improvement Committee may conduct an audit.

(5) The Patient Care Oversight Committee and the Quality Improvement Committee may request certain additional information from health care facilities consistent with the Board's authority to request data under M.G.L. c. 111, § 203 and M.G.L. c. 112, §§ 5 and 5I. Following review of a health care facility's Semi-Annual Report or Annual Report, or reports required to be submitted under 243 CMR 4.08, the Quality Improvement Committee may request, and the health care facility shall provide, additional information from the health care facility that would assist the Quality Improvement Committee in evaluating the health care facility's response to any reported unexpected occurrences, or the health care facility's response to the data collected, analyzed and reported in the Semi-Annual and Annual Reports. From time to time, the Quality Improvement Committee may also request, and the health care facility shall provide, certain de-identified medical records relevant to its review. Following review of a health care facility's Patient Care Assessment Plan and related information, the Patient Care Oversight Committee may request and the health care facility shall provide additional information from the health care facility that would assist the Patient Care Oversight Committee in evaluating the health care facility's Patient Care Assessment Plan.

(6) A health care facility may seek an extension of a due date, provided that such a request is made prior to the due date and upon demonstration of good cause to the Chair of the Quality Improvement Committee if it is an annual report, semi-annual report or report under 243 CMR 4.08, or to the Chair of the Patient Care Oversight Committee if it is a Patient Care Assessment Plan, written instructions for the Patient Care Assessment Plan, amendments to the Patient Care Assessment Plan, or report under 243 CMR 4.03.

(7) A health care facility that fails to provide any information required by these regulations, fails to provide this information in the time frame required, or fails to provide complete or accurate information, may be subject to an administrative fine to be determined by the Committee. A fine may be imposed for each day that the health care facility fails to comply with the Board's regulations. The health care facility will be notified via certified mail that there has been a violation of the Board's regulations, and the notice will specify the facts relied on by the Committee, and set forth the Committee's intention to impose a fine. The notice will inform the health care facility that they may request, within thirty days of the date from the date of the notice, a hearing before a single designated board member hearing officer. The purpose of the hearing is to determine, solely, whether there has been a violation of these regulations. A request for a hearing shall be made in writing and directed to the Executive Director of the Board.

#### 4.13: QPCAP - Health Maintenance Organizations

(1) Notwithstanding any other provisions in 243 CMR 4.05 through 243 CMR 4.08, a licensee may accept employment, practice, association for the purpose of providing patient care, or privileges at a Health Maintenance Organization ("HMO"), within the meaning of M.G.L. c. 176G, § 1, if the HMO has a Qualified Patient Care Assessment Program which meets or exceeds the criteria set forth below. The Board will consider such a Qualified Patient Care Assessment Program a "risk management program" within the meaning of M.G.L. c. 112, § 5, requiring physicians to participate in risk management programs as a condition of licensure. In addition, a "staff model" HMO is exempt from the requirements of 243 CMR 4.11, and a "staff model" HMO is not exempt from the requirements of 243 CMR 4.08.

(2) Credentialing. An HMO shall not appoint or hire, contract with, contract with any entity to obtain the services of, associate with for the purposes of providing patient care, or grant privileges to a licensee, unless the HMO first performs the following evaluation of the licensee. The following provisions apply with respect to a licensee who has been or within 90 days will be credentialed or re-credentialed pursuant to 243 CMR 4.05 by a licensed or state hospital within Massachusetts.

(3) Prior to the date on which a licensee commences to practice medicine on behalf of an HMO:

(a) In the case of a staff-model HMO, the HMO shall request and the licensee shall provide to the HMO a copy of his most recent application for an initial or renewal license issued by the Board.

(b) In the case of a staff-model or a non-staff-model HMO, the HMO shall request and the Massachusetts hospital where the licensee spends the greatest proportion of his time (the "primary hospital") shall provide to the HMO written confirmation that the licensee has been credentialed by the primary hospital pursuant to 243 CMR 4.05. The written confirmation shall be provided to the HMO within 30 days after the later of: receipt of the HMO's request or, subject to 243 CMR 4.13, the date on which the licensee is credentialed or re-credentialed pursuant to 243 CMR 4.05 by the primary hospital. The written confirmation shall describe each of the following known to the primary hospital:

- (i) pending or closed health care facility or public agency;
- (ii) disciplinary action, as defined in 243 CMR 1.01 against the licensee;
- (iii) alterations in privileges resulting, directly or indirectly, from concerns about the licensee's professional performance, judgment or clinical skills; and
- (iv) any other concerns relating to the licensee's professional performance, judgment, clinical skills, or mental or physical status, and any impairment of the licensee related to chemical dependency.

(c) The licensee shall provide to the HMO a release and waiver to allow the HMO access to any information in which the licensee has an interest that may be requested by the HMO pursuant to 243 CMR 4.13.

(d) At least once every three years, the HMO shall complete the following process. It shall be completed no later than 60 days after the licensee has been credentialed or re-credentialed pursuant to 243 CMR 4.05 by the primary hospital:

- (i) In the case of a staff-model HMO, the HMO and the licensee shall complete the process described in 243 CMR 4.13, if the process was not completed because the licensee first associated with the HMO prior to July 1, 1987, or if the licensee's license has been renewed since completion of that process.
- (ii) In the case of a staff-model or a non-staff-model HMO, the HMO shall complete the process described in 243 CMR 4.13.

(iii) The licensee shall provide to the HMO a release and waiver to allow the HMO access to any information in which the licensee has an interest that may be requested by the HMO pursuant to 243 CMR 4.13.

(2) If an HMO obtains adverse information regarding the licensee pursuant to 243 CMR 4.13, the HMO may request in writing and the primary hospital shall provide to the HMO within 30 days, in accordance with M.G.L. c. 111, § 204 and § 205 and M.G.L. c. 111, § 70E, such additional information as the HMO deems necessary to complete its credentialing of the licensee. (With regard to information about non-members of the HMO, the identities of particular patients may be redacted.) The HMO shall reimburse the primary hospital for the reasonable costs of providing information pursuant to 243 CMR 4.13.

(3) A licensee who has not been credentialed by a licensed or state hospital within Massachusetts pursuant to 243 CMR 4.05 shall be credentialed by the HMO pursuant to 243 CMR 4.05 prior to the date on which the licensee commences to practice medicine on behalf of the HMO, and every three years thereafter.

(4) The HMO shall perform an initial and biennial credentialing evaluation of the licensee, based on the information obtained pursuant to this section as applicable, and based on information developed by the HMO's Patient Care Assessment program. The evaluation shall include assessment of the licensee's professional performance, judgment and clinical skills.

(5) Based on information received or developed by the HMO, the HMO shall provide in writing to any health care facility credentialing a licensee, upon written request by that facility, an assessment of the licensee's clinical skills, information regarding disciplinary actions and malpractice litigation, and other relevant information related to the licensee's competence to practice medicine.

(6) The HMO may summarize information obtained pursuant to 243 CMR 4.13 in order to fulfill the credentialing requirements of 243 CMR 4.00, but it shall not re-disclose such information without the prior written consent of the primary hospital from which it was received.

(7) The HMO's Qualified Patient Care Assessment Program may function as a system of "peer review," otherwise consistent with M.G.L. c. 111, § 204, shall be in writing, shall be submitted to the Board, and shall include the following functions:

(a) systems to identify, analyze and resolve patient risks, as they occur in a hospital or ambulatory setting if under the HMO's ownership or control, including at least one mechanism that identifies patient care problems which might indicate incompetency of a licensee or conduct inconsistent or harmful to good patient care;

(b) systems to identify, analyze and resolve patient grievances;



(c) the designation of personnel, including licensees, and/or committees to investigate, analyze and resolve patient risks and grievances and to recommend changes in policies, procedures and personnel as necessary. The analysis of patient risks and grievances shall include, at a minimum, a regular review for the purposes of identifying trends or patterns as to time, place and recurrent involvement of a licensee. Such personnel shall have unrestricted access to all patient records;

(d) the designation of personnel to coordinate the identification, analysis and resolution of patient risks, complaints and grievances and to assure that the Qualified Patient Care Assessment Program functions on an ongoing basis;

(e) the delineation of lines of authority and communication among all personnel and committees responsible for the administration and functions of the Qualified Patient Care Assessment Program, including the roles and responsibilities of the medical peer review committee(s) and the governing body of the HMO;

(f) procedures for educating all employees and licensees affiliated with the HMO, and involved in patient care, in the operation of the Qualified Patient Care Assessment Program and in their responsibilities and duties therein, including, but not limited to, training regarding responsibilities pursuant to M.G.L. c. 112, § 5F;

(g) the establishment of criteria to determine whether disciplinary action, as defined in 243 CMR 1.01, against a licensee is necessary as indicated by the analysis of patient care risks, complaints and grievances, and the creation of a medical peer review committee to make such determination in connection with the skills, competence, judgment and performance of a licensee;

(h) provisions to grant the Patient Care Oversight Committee, the Quality Improvement Committee and the Division of Insurance access and audit authority over Qualified Patient Care Assessment Program information and records during normal business hours;

(i) provisions to allow administration of a reasonable and comprehensive evaluation of a licensee's clinical skills, competence and judgment, upon request of and for filing with the Board or the Quality Improvement Committee.

#### 4.14: Medical Care Quality Reporting to the Board - Nursing Homes

(1) It is the policy of the Board under M.G.L. c. 111, § 203(e) to monitor the quality of medical care and advice delivered by licensees in the nursing home setting and to require that certain information related to potential deficiencies in such care be reported periodically to the Board. Accordingly, notwithstanding anything in 243 CMR 4.01

through 4.13 to the contrary, the following regulations (and any others specifically incorporated by reference, including the definitions set forth at 243 CMR 4.02) apply to nursing homes in the Commonwealth that provide Levels of Care I, II or III (or any combination of them), and to certain physicians who practice medicine or hold administrative positions in such nursing homes. A licensee of the Board may accept employment, be an independent contractor or provide patient care at any such nursing home only if the nursing home meets or exceeds the following requirements.

(2) Review of Professional Competence: Medical Directors and Advisory Physicians

A nursing home shall not appoint a medical director or advisory physician (or any individual performing a similar function) who is a licensee, unless the nursing home does the following:

(a) In the case of a licensee who, at the time of such appointment and at the time of each required biennial review thereafter, has staff privileges at a licensed or state-operated hospital in the Commonwealth, the nursing home shall inquire, prior to the appointment and at least biennially thereafter, of the status of the licensee's staff privileges at the hospital in the Commonwealth where the licensee spends the greatest proportion of his time (the "primary hospital"), and the primary hospital shall submit to the nursing home a written statement with regard to such status. Said statement shall either (i) note that the licensee's staff privileges are in full force and effect, or (ii) detail any modification in said privileges during the past three years, including any disciplinary action, as defined in 243 CMR 1.01, involving the licensee initiated or closed during the past three years. In the case of (ii), the nursing home shall assess the relevance of such modification and/or disciplinary action as defined in 243 CMR 1.01 on the licensee's performance, judgment and clinical skills.

(b) In the case of a licensee who does not have staff privileges at a hospital consistent with 243 CMR 4.14(2)(a), then the nursing home shall review the professional competence of such licensee by obtaining the following documents and making the following assessments:

(i) The nursing home shall verify that the licensee holds a current license to practice medicine, by inspecting the licensee's license card or requesting verification from the Board.

(ii) The nursing home shall require the licensee to provide and shall obtain and review a copy of the licensee's most recent application for initial or renewal registration to practice medicine in the Commonwealth, including all attachments and explanatory materials submitted with the application, whether required or voluntarily submitted.

(iii) To the extent allowed by M.G.L. c. 151B, § 4, the licensee may delete from such application information disclosing:

(A) an arrest, detention or disposition, regarding any alleged violation of law from which no conviction resulted;

(B) a first conviction for any of the following misdemeanors: drunkenness, simple assault, speeding, minor traffic violations, affray or disturbance of the peace; and

(C) any conviction for a misdemeanor where the date of such conviction or the completion of any period of incarceration resulting therefrom, whichever date is later, occurred five or more years prior to the date of the review of professional competence, unless the licensee has been convicted of any offense within five years immediately preceding the date of said review.

(iv) The nursing home shall require the licensee to provide and shall obtain and review a listing and description of all malpractice claims and malpractice lawsuits involving the licensee pending or closed during the previous ten years, including the information listed in this section and any further relevant information that it requests. This requirement applies, whether or not the transaction giving rise to the malpractice claim arose at the nursing home, and whether or not the malpractice claim is filed with or presented to an insurance carrier, a court or another entity.

(v) The nursing home shall require the licensee to authorize his medical malpractice liability insurance carrier or carriers to release to the nursing home the following information, described in M.G.L. c. 112, § 5C, as to claims or actions for damages pending or closed during the previous ten years, whether or not there has been a final disposition:

(A) the name and age of the claimant or plaintiff;

(B) the nature and substance of the claim;

(C) the date and place at which the claim arose;

(D) the amounts paid, if any, and the date and manner of disposition, whether by judgment, settlement or otherwise; and

(E) the date and reason for final disposition, if there was no judgment or settlement.

(vi) With respect to the past ten years, the nursing home shall obtain from the licensee the name and address of each hospital and clinic where the licensee has or has had employment, practice, association for the purpose of providing patient care, or privileges, and each nursing home where the licensee serves or has served as medical director or advisory physician (or

in any similar position). It shall also require that the licensee provide the reasons for any discontinuance of any such employment, practice, association or privileges at any such hospital, clinic or nursing home.

(vii) The nursing home shall obtain from the licensee authorization for release to the nursing home of any information from any other health care facility, including any nursing home, where the licensee has or has had employment, practice, association for the purpose of providing patient care or privileges, if such information is relevant, directly or indirectly, to the licensee's competence to practice medicine or to serve as medical director or advisory physician.

(viii) The nursing home shall make reasonable inquiry to each hospital, clinic and nursing home identified by the licensee pursuant to this section, with which the licensee has or has had employment, practice, association for the purpose of providing patient care or privileges during the following time periods: a) for an initial association with the nursing home, during the past ten years; b) for each subsequent biennial review of the licensee's professional competence, during the past three years, or during the period from the date of the immediately prior review to the present, whichever is shorter.

"Reasonable inquiry" shall include at least one written request for:

(A) an assessment of the licensee's character and competence to practice medicine, and, to the extent they are relevant to the position of medical director or advisory physician, as the case may be, an assessment of the licensee's clinical skills; and

(B) information regarding any pending or final disciplinary action and malpractice claim.

(ix) In the case of an inquiry concerning a period of time when the licensee held a limited license under M.G.L. c. 112, § 9 (or performed equivalent post-graduate work outside of the Commonwealth), the hospital where the licensee had his primary assignment may respond on behalf of its affiliated health care facilities where the licensee practiced medicine.

(x) The responding facility to which the request for information is directed pursuant to subsections (2)(b)(viii) and (2)(b)(ix) of this section should provide the requested information within thirty days. Said information between the requesting and responding facilities shall be subject to the confidentiality protections provided for under M.G.L. c.111, §§ 204 & 205, and 243 CMR 4.04, if applicable.

(3) This section shall be implemented as follows:

- (a) The professional competence of a licensee subject to 243 CMR 4.14 shall be reviewed for the first time by the nursing home pursuant to 243 CMR 4.00 no later than 90 days following either the licensee's initial credentialing or his first re-credentialing by the primary hospital pursuant to 243 CMR 4.05, whichever occurs first.
- (b) The professional competence of a licensee subject to 243 CMR 4.14 shall be reviewed for the first time by the nursing home pursuant to these regulations no later than 180 days following the effective date of 243 CMR 4.14 or prior to the licensee's serving as medical director or advisory physician of the nursing home, whichever occurs later.
- (4) Review of Professional Competence: All Other Licensees. Each licensee shall, within 30 days after first providing patient care or practicing medicine at or on behalf of the nursing home, furnish the nursing home with his name and Massachusetts medical license number.
- (5) Unexpected Occurrence Reporting. When the nursing home files a report with the Department of Public Health pursuant to its patient abuse regulations, serious occurrence regulations, or any similar or successor regulations, and said report describes or involves either of the following unexpected occurrences, then the nursing home shall file a copy of the report with the Quality Improvement Committee (with the original of such report to be filed with the Department of Public Health):
- (a) The failure of any licensee responsible for treatment of a nursing home resident to treat or prescribe a course of treatment for such resident, after said licensee has been contacted by the nursing home, if, during the course of events that prompted the nursing home to contact the licensee, the resident dies or is transferred to a hospital; and
- (i) such death or transfer may have been prevented had the physician not failed to treat the resident; or
- (ii) where the licensee is required by law to examine, treat or prescribe a course of treatment for such resident, if, during the course of events that would reasonably have been observed if the licensee had examined or prescribed a course of treatment for the resident, the resident dies or is transferred to a hospital.
- (b) Any medical treatment provided to a nursing home resident by a licensee, or any failure by a licensee to provide such treatment, where, directly or indirectly, such treatment or failure to treat seriously affects the health of a resident, or where it involves or may involve abuse, mistreatment or neglect. Examples of reportable occurrences, for illustrative purposes only, include an inadequately

treated decubitus ulcer, a medication error or an unevaluated change in mental status.

(6) Compliance Monitoring. Review of professional competence under 243 CMR 4.14 shall not be deemed "reasonable" under M.G.L. c. 111, § 203(e), and the Board's determination of reportable occurrences under M.G.L. c. 111, § 203(e) shall not be complete and in compliance with 243 CMR 4.14 unless the nursing home permits the Quality Improvement Committee during ordinary business hours to inspect and copy all resident and nursing home records and other information developed pursuant to 243 CMR 4.14, and upon reasonable notice, to interview appropriate personnel, unless otherwise prohibited by law. Nothing herein shall limit any statutory or regulatory powers of the Board, including but not limited to its subpoena power under M.G.L. c. 112, § 5.

(7) The enforcement provisions set forth in 243 CMR 4.12 shall apply to nursing homes.

REGULATORY AUTHORITY 243 CMR 4.00:

M.G.L. c. 13, § 10; c. 111, §§ 53B and 203; c. 112, §§ 2 through 9B.