

243 CMR: BOARD OF REGISTRATION IN MEDICINE

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243 CMR 3.00: THE ESTABLISHMENT OF AND PARTICIPATION IN QUALIFIED PATIENT CARE ASSESSMENT PROGRAMS, PURSUANT TO M.G.L. c. 112, § 5, AND M.G.L. c. 111, § 203.

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3.01: Scope and Purpose

(1) The Board of Registration in Medicine, in promulgating 243 CMR 3.00, has as its primary goal, ensuring that patients in both institutional and office settings receive optimal care. Accordingly, 243 CMR 3.00 is intended to assist the physicians and health care institutions of the Commonwealth in their efforts to identify problems in practice before they occur and to put in place preventive measures designed to minimize or eliminate substandard practice. This enhancement of patient care assessment will be accomplished through the strengthening and formalizing of programs of credentialing, quality assurance, utilization review, risk management and peer review in institutions and by assuring that these functions are thoroughly integrated and overseen by the institutions' corporate and physician leadership. 243 CMR 3.00 contemplates active self-scrutiny and reporting of adverse incidents in in-patient and out-patient settings to permit individual physicians, institutions and the Board to recognize patterns requiring corrective action. Further, 243 CMR 3.00 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 and other tribunals 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 adverse patient outcomes and will contribute to the maintenance of an atmosphere of mutual trust between physicians and their patients. In so doing, 243 CMR 3.00 will concomitantly achieve the reduction or stabilization of

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the frequency, amount and cost of claims against physicians and institutions that was the goal of the legislature in M.G.L. c. 111, § 203, and M.G.L. c. 112, §§ 5 through 5K.

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. It is the explicit intent of 243 CMR 3.00 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 intends to formalize and enhance the functions of committees many or all institutions may already have in place. Such committees include, for example, groups responsible for efforts usually designated as Quality Assurance, Utilization Review, Risk Management, and Credentialing. Wherever already in existence, such committees need not be replaced or removed, so long as in the aggregate they henceforth provide, at minimum, for all of the functions enumerated by the Board of Registration in Medicine herein as the functions of a Qualified Patient Care Assessment Program.

A further purpose of 243 CMR 3.00 is to help the Board satisfy its data collection and disciplinary responsibilities and to assist health care providers in the fulfillment of their reporting obligations under M.G.L. c. 112, § 5F. Finally, 243 CMR 3.00 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.

(2) 243 CMR 3.00 is effective February 1, 2012.

3.02: Definitions

Board: The Board of Registration in Medicine, including, but not limited to, its Data Repository, Disciplinary Unit, Patient Care Assessment Unit, Legal Unit, Licensing Unit, and its agents and employees.

Disciplinary Action: Please *see* 243 CMR 1.01(2).

Governing Body: 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: any entity licensed pursuant to M.G.L. c. 111, § 51; any nursing home, within the meaning of M.G.L. c. 111, § 203(d); any state, county or municipal hospital; 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. The application of 243 CMR 3.00 to nursing homes and health maintenance organizations is limited as per 243 CMR 3.13 and 3.14.

Health Care Provider: As defined under M.G.L. c. 111, § 1, any doctor of medicine, osteopathy, or dental science, or a registered nurse licensed under the provisions of M.G.L. c. 112, or an intern, resident, fellow, or medical officer licensed under M.G.L. c. 112, a medical student, or a hospital, clinic or nursing home licensed under the provisions of M.G.L. c. 111 or a health maintenance organization within the meaning of M.G.L. c. 176G, § 1, and its licensed health professionals with employment, practice, association or privileges.

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Licensee: a person holding any type of license issued pursuant to M.G.L. c. 112, §§ 2 through 9B.

Medical Peer Review Committee: consistent with M.G.L. c. 111, § 1, 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, 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: a medical peer review committee, as defined by 243 CMR 3.02, and consistent with M.G.L. c. 111, §§ 1 and 204, that is created by the bylaws at the governing body level of a health care facility and which includes among its members not less than one governing body member, and other senior personnel essential to the quality of patient care, for example, higher level nursing administrators.

Patient Care Assessment Coordinator: 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 243 CMR 3.00. 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. 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 3.00. Thus, upon election of the health care facility's governing body, all references to Patient Care Assessment Coordinator may include Patient Care Assessment Committee.

Qualified Patient Care Assessment Program: A health care facility's rules, standards and procedures, adopted pursuant to the facility's bylaws (unless otherwise required by statute), designed to establish effective programs in quality assurance, risk management, peer review, 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 3.00. 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.

3.03: Establishment of and Participation in Qualified Patient Care Assessment Program

(1) A Qualified Patient Care Assessment Program shall be described in a written plan, shall be reviewed and updated at least annually by the governing body of the health care facility, and

shall be submitted to the Board when adopted or amended. The plan shall include, at a minimum, procedures for compliance with 243 CMR 3.00, 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 incident reporting/auditing and incident reporting to the Board;
- (c) loss prevention and risk reduction activities including, but not limited to, policies/procedures regarding medication errors, credentialing, identification of and counseling 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; and
- (e) policies governing the responsibilities of the Patient Care Assessment Coordinator and Committee.

(2) Effective July 1, 1987, pursuant to M.G.L. c. 111, § 203(d), every hospital and nursing home, as a condition of licensure, shall establish a Qualified Patient Care Assessment Program.

(3) 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. However, to ease the transition and to enhance eventual compliance with 243 CMR 3.00, the Board hereby allows participation until July 1, 1987 in a pre-existing, Non-Qualified Patient Care Assessment Program. After June 30, 1987, all licensees must participate in a Qualified Patient Care Assessment Program.

(4) 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 243 CMR 3.10.

3.04: 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 3.00 and which relate to the functions of a "Medical Peer Review Committee" (as defined by M.G.L. c. 111, § 1), 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 243 CMR 3.00 and which also relate to the functions of a Medical Peer Review Committee (as defined by M.G.L. c. 111, § 1) 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).

(3) Information and records so designated by the Patient Care Assessment Coordinator pursuant to 243 CMR 3.04(2) may be maintained or utilized by the Board of Registration in Medicine, including but not limited to its Data Repository and its Disciplinary Unit, in its investigations or its other proceedings. Such information and records maintained or utilized by the Board shall remain confidential and not subject to subpoena, discovery or introduction into evidence, consistent with M.G.L. c. 111, § 204. However, such information and records may not remain confidential if disclosed in an adjudicatory proceeding, but the information and records shall be otherwise subject to any protections provided by M.G.L. c. 111, § 204.

(4) The provisions in 243 CMR 3.04 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.

3.05: Qualified Patient Care Assessment Program - 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. The health care facility must repeat these credentialing requirements at least every two 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.

(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.

(2) For the purposes of 243 CMR 3.05, Health Care Facility includes a substantially equivalent facility outside of the Commonwealth.

(3) 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 a copy of his or her 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:

1. an arrest, detention, or disposition, regarding any violation of law in which no conviction resulted;
2. a first conviction for any of the following misdemeanors: drunkenness, simple assault, speeding, minor traffic violations, affray, or disturbance of the peace; and
3. 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 243 CMR 3.05(3)(e) and any further relevant information requested by the health care facility. 243 CMR 3.05 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 3.05 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:

1. professional performance, judgment and clinical skills;
2. mental and physical status;
3. compliance with continuing education requirements;
4. data dealing with utilization;
5. adherence to health care facility and medical staff bylaws, policies and procedures;
6. malpractice claims filed against the licensee; and
7. information regarding any criminal proceedings.

(e) The licensee authorizes his or her 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:

1. the policy number of the licensee against whom the claim is made;
2. the name, address and age of the claimant or plaintiff;
3. the nature and substance of the claim;
4. the date and place at which the claim arose;
5. the amounts paid, if any, and the date and manner of disposition, judgment, settlement, or otherwise;
6. the date and reason for final disposition, if no judgment or settlement; and
7. 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, 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 by 243 CMR 1.01(2), 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, association for the purpose of providing patient care, or privileges during at least the previous ten years. In the case of a renewal appointment, reasonable inquiry shall be directed to every health care facility where the physician has had employment, practice, association for the purpose of providing patient care, or privileges in the previous three years. "Reasonable inquiry" must include up to three requests, in writing, for:

1. an assessment of clinical skills; and
2. information regarding any pending or final disciplinary action, malpractice litigation, and any other information relevant, either directly or indirectly, to the licensee's character or competence to practice medicine. 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.

(j) 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

1. the executive committee of the medical staff or
2. the credentials committee, or
3. 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.

3.06: Qualified Patient Care Assessment Program - Structure

(1) The health care facility shall establish a medical peer review committee, within the meaning of M.G.L. c. 111, § 1, with responsibility for patient care assessment at the governing body level, to be known as the Patient Care Assessment Committee.

(a) 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

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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 3.00. A governing board level committee shall include at least one member of the governing body.

(b) The health care facility may have any other peer review committees as it deems appropriate.

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

1. be comprised of persons not only from the medical staff; and
2. consistent with the definition of Medical Peer Review Committee under M.G.L. c. 111, § 1, carry out all or some of the following functions: 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, 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.

(2) 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 3.00. 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 3.00. 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 3.00. The health care facility shall report the name of the Patient Care Assessment Coordinator to the Board within ten days of designation or replacement. The Patient Care Assessment Coordinator may be a qualified physician or a qualified non-physician.

(3) The Patient Care Assessment Coordinator shall prepare and distribute detailed written instructions regarding operational procedures relevant to patient care assessment and compliance with 243 CMR 3.00. The Patient Care Assessment Coordinator shall distribute such written instructions as are relevant to each health care provider at the health care facility. As part of the annual report under 243 CMR 3.12(4), the health care facility shall file the written instructions with the Board.

(4) 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 3.00.

3.07: Qualified Patient Care Assessment Program - Internal Audits and Internal Incident Reporting

(1) Pursuant to M.G.L. c. 111, § 203(a), the bylaws of both the health care facility and the medical staff shall contain provisions for reporting conduct of a health care provider that indicates incompetency in his or her 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 he shall directly review the report, resolution and follow-up.

(2) Pursuant to M.G.L. c. 111, § 203(b), the bylaws 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, 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 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 bylaws 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 injuries and incidents in writing to the Patient Care Assessment Coordinator. As part of the incident reporting system, procedures shall be detailed in writing and disseminated to all employees of the health care facility involved in patient care. All new employees, within five days of employment, 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 employees shall be provided at least three hours patient care assessment and quality assurance education and training, with emphasis upon the importance of accurate and timely incident reporting. All new employees' education and training and all annual training shall also include specific instruction in Patients' Rights pursuant to M.G.L. c. 111, § 70E.

(b) No later than November 1, 1987, generation of Required Internal Incident Reports under the Focused Occurrence Reporting Criteria and other incident reports. The Focused Occurrence Reporting Criteria shall define specific adverse patient 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 Board when adopted or amended by the health care facility. Upon request, the Board shall provide technical assistance in developing Focused Occurrence Screening Criteria.

(c) No later than November 1, 1987, generation of Required Internal Incident Reports 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 adverse patient occurrences that might not otherwise be evident. The health care facility shall file its Occurrence Screening Criteria with the Board when adopted or amended by the health care facility. Upon request, the Board shall provide technical assistance in developing Occurrence Screening Criteria.

(d) 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:

1. Reviewing and acting upon incident reports to assure follow-up with individuals involved in the incident.
 2. The regular and systematic reviewing of all incident reports for the purposes of identifying trends or patterns as 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 patient protection/risk management/quality assurance education and training; and
 3. Creation of a random chart audit system to assure compliance with the incident reporting requirements. The Patient Care Assessment Coordinator shall establish written step-by-step procedures for the follow-up required by 243 CMR 3.07(3)(d) 1.
- (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) No later than 30 days after the end of each six-month period (or more often, if the governing body so requires), beginning with the period that ends on the dates set forth in 243 CMR 3.07(3)(g)1. through 3., the Patient Care Assessment Coordinator or person serving in a similar capacity at each health care facility listed below shall provide a summary report to the health care facility's governing body, with a copy of the report filed simultaneously with the Board. The report shall contain recommendations for quality assurance, risk management, patient care assessment and education. The ending date for the first six-month period shall be as follows:
1. December 31, 1988, for mental health clinics licensed by the Department of Public Health and subject to 105 CMR 140.500: *Applicability of 105 CMR 140.000 Subpart E*;
 2. February 28, 1989, for all other licensed clients, and for all hospitals that provide obstetrical services or are authorized to apply to the Board for limited licenses on behalf of interns and residents; and
 3. April 30, 1989, for all other hospitals, and all other health care facilities subject to 243 CMR 3.07. The information required to be reported to the Board pursuant to 243 CMR 3.11(4) (the Patient Care Assessment Program Annual Report) shall be incorporated into the first semi-annual report and each semi-annual report filed at 12-month intervals thereafter. The information required by 243 CMR 3.11(4) that is contained in the first semi-annual report shall cover the period from the filing of the previous annual report (or, in the case of mental health clinics identified in 243 CMR 3.07(3)(g)1., the prior 12-month period). The effect of 243 CMR 3.07(3)(g), effective November 25, 1988, is that the previously required quarterly report is now semi-annual, and the previous requirement for an annual report remains unchanged.
- (h) 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.
- (i) A requirement of documentation of any disciplinary action.
- (j) 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:
1. The patient's name, locating information, admission date, age and sex.
 2. A clear and concise description of the incident, including time, date, exact location.

3. A listing of all persons known to be involved in the incident, including witnesses, along with locating information for each.
4. The name, signature and position of the person completing the report, and the date and time that the report was completed.
- (k) Provisions to grant the Board and the Department of Public Health with access and audit authority over Qualified Patient Care Assessment Program information and records during normal business hours.
- (l) 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 Board.
- (m) 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.

3.08: Qualified Patient Care Assessment Program - Major Incident Reporting to the Board of Registration in Medicine

(1) Introduction. The requirement that health care facilities establish reporting and screening criteria for adverse events, as well as internal procedures for the review and analysis of incidents, is intended to promote quality assurance and peer review at each facility. In addition, to allow the Board to meet its own statutory responsibility for the oversight of quality assurance programs, each health care facility must report Major Incidents as defined in 243 CMR 3.08(2)(a) through (d) to the Board.

(2) The following types of Major Incidents must be reported by the health care facility to the Board:

- (a) Maternal deaths that are related to delivery.
- (b) Death in the course of, or resulting from, elective ambulatory procedures.
- (c) Any invasive diagnostic procedure or surgical intervention performed on the wrong organ, extremity or body part.
- (d) All deaths or major or permanent impairments of bodily functions other than those reported in 243 CMR 3.08(2)(a) through (c) that are not ordinarily expected as a result of the patient's condition on presentation.

The first three types of major incidents are specific outcomes that should be reported without regard to the underlying circumstances. The fourth type of major incident represents severe adverse outcomes that fall outside the realm of ordinarily expectable results, taking into account the nature of the underlying disease process and the recognized risks and benefits of appropriate medical responses to it. An event may be of this last type solely by virtue of its rarity as a natural outcome of the disease or intervention. Identification of an event as any one of the four types of major incidents, rare or not, does not necessarily indicate either that the outcome was preventable or that it resulted from substandard medical practice.

(3) Health care facilities shall file major incident reports with the Board on a quarterly basis. When reporting a major incident, health care facilities shall use the Board's form prescribed for that purpose. For each major incident, the form will require the submission of certain information including but not limited to a description of the major incident, the results of the internal investigation and a description of the corrective measures taken by the health care

facility. The reporting of the name(s) of the licensee(s) involved in the major incident initially will be optional. If the health care facility chooses to withhold the name(s) of the involved licensee(s), the Board may require additional information to enable it to evaluate the licensee's background, skills and involvement in prior major incidents. If at any time during the course of its investigation, the Board requires the name(s) of the involved licensee(s) in order to assess the adequacy of the response of the health care facility's PCA program to the major incident, the facility shall provide such name(s).

(4) If a health care facility is identified as deficient in the reporting of major incidents, the Board may request certain additional information from that facility consistent with its authority to request data under M.G.L. c. 111, § 203 and M.G.L. c. 112, §§ 5 and 5I.

(5) 243 CMR 3.08 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.

3.09: Qualified Patient Care Assessment Program - Impaired Health Care Providers

(1) The health care facility and medical staff bylaws 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 bylaws 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 243 CMR 3.09(1).

3.10: Qualified Patient Care Assessment Program - 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:

1. Medical procedures and treatments for which informed consent is required and the content of the information provided.
2. Designation of persons responsible for obtaining informed consent from the patient.
3. The manner of documentation of consent, consistent with 243 CMR 3.00.
4. 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.

(c) 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 the completion of documentation.

(d) 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) Alterations Prohibited. 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 current 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.

(a) Anesthesiology. All licensees shall adhere to any Standards for Basic Intra-Operative Monitoring established by the American Society of Anesthesiologists.

(b) Other Patient Care Assessment Standards. The Board views the Standards for Basic Intra-Operative Monitoring as an example of patient care assessment standards for other specialties. On or after November 1, 1987, the Board may promulgate regulations relevant to Patient Care Assessment Standards in other medical specialties. Prior to such promulgation, the Board of Registration in Medicine may receive suggested Patient Care Assessment Standards from appropriate local, state or national specialty societies and organizations.

3.11: Miscellaneous Provisions

(1) In addition, as part of its Qualified Patient Care Assessment Program, the health care facility's bylaws shall authorize the establishment of the following provisions:

(a) At least annually, every health care provider as defined by M.G.L. c. 111, § 1, 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.

(c) 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 3.07(3)(f), and of the existence of the Board, the Department of Public Health, and their addresses and telephone numbers.

(d) The health care facility shall require that the appropriate personnel respond promptly

and in no event in more than 30 days to a second health care facility's "reasonable inquiry" under 243 CMR 3.05 regarding a health care provider's application for employment, practice, association or privileges at the second health care facility. The health care facility shall maintain personnel records regarding its health care providers for a minimum of ten years.

(2) Where it appears that a health care facility has engaged in a pattern and practice of violating M.G.L. c. 111, § 203 or 243 CMR 3.00, or if there is any other indication of a serious violation, the Board shall report same to the Department of Public Health or Division of Insurance for such action as is warranted.

(3) Before taking formal enforcement action or referring a suspected violation to another agency for any enforcement action, the Board shall provide at least 30 days prior written notice to the health care facility to allow it to implement corrective measures, unless the Board, by majority vote, determines that the public health, safety or welfare necessitates earlier referral or enforcement action.

(4) The following information shall be filed annually as part of the report and according to the schedule described in 243 CMR 3.07(3)(g) (except all Health Maintenance Organizations shall file annual reports by January 31st of each year):

- (a) A summary analysis of patient complaints and their disposition.
- (b) The names of all full licensees who have terminated their relationship with the health care facility.
- (c) Any amendments to the Patient Care Assessment Plan and any proposed amendments thereto, pursuant to 243 CMR 3.03(1).
- (d) The number of Major Incident Reports filed pursuant to 243 CMR 3.08.
- (e) The written instructions for the Patient Care Assessment Plan, pursuant to 243 CMR 3.06(3).
- (f) Summary information on the handling of impaired physicians.

3.12: Qualified Patient Care Assessment Program - Health Maintenance Organizations

Notwithstanding any other provisions in 243 CMR 3.05 through 3.08, 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. 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 not exempt from the requirements of 243 CMR 3.08.

(1) 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.

- (a) 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 3.05 by a licensed or state hospital within Massachusetts.

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1. 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 or her 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 or her 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 3.05. 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 3.13(1)(a), the date on which the licensee is credentialed or re-credentialed pursuant to 243 CMR 3.05 by the primary hospital. The written confirmation shall describe each of the following known to the primary hospital:
 - i. pending or closed healthcare facility or public agency disciplinary actions against the licensee;
 - ii. alterations in privileges resulting, directly or indirectly, from concerns about the licensee's professional performance, judgment or clinical skills; and
 - iii. 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 3.12(1)(a)3.
 2. At least once every two 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 3.05 by the primary hospital:
 - a. In the case of a staff-model HMO, the HMO and the licensee shall complete the process described in 243 CMR 3.12(1)(a)1.a., 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.
 - b. In the case of a staff-model or a non-staff-model HMO, the HMO shall complete the process described in 243 CMR 3.12(1)(a)1.b.
 - 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 3.12(1)(a)3.
 3. If an HMO obtains adverse information regarding the licensee pursuant to 243 CMR 3.12(1)(a)1. or 2. or 243 CMR 3.12(1)(b) or (c), 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 3.12(1)(a)3.
- (b) A licensee who has not been credentialed by a licensed or state hospital within Massachusetts pursuant to 243 CMR 3.05 shall be credentialed by the HMO pursuant to 243 CMR 3.05 prior to the date on which the licensee commences to practice medicine on

behalf of the HMO, and biennially thereafter.

(c) The HMO shall perform an initial and biennial credentialing evaluation of the licensee, based on the information obtained pursuant to 243 CMR 3.12(1)(a) and (b), 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.

(d) 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. The HMO may summarize information obtained pursuant to 243 CMR 3.12(1)(a)3. in order to fulfill the credentialing requirements of 243 CMR 3.01, but it shall not re-disclose such information without the prior written consent of the primary hospital from which it was received.

(2) Structure and Required Functions. 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 on-going 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 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 licensee.

(h) Provisions to grant the Board and the Division of Insurance with 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.

3.13: Medical Care Quality/Reporting to the Board - Nursing Homes

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 3.00 to the contrary the following (and any others specifically incorporated by reference, including the definitions set forth at 243 CMR 3.02) 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.

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

- (a) 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:

1. 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 or her 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:

- a. note that the licensee's staff privileges are in full force and effect; or
- b. detail any modification in said privileges during the past three years, including any disciplinary action involving the licensee initiated or closed during the past three years

In the case of 243 CMR 3.13(1)(a)1.b., the nursing home shall assess the relevance of such modification and/or disciplinary action on the licensee's performance, judgment and clinical skills.

2. In the case of a licensee who does not have staff privileges at a hospital consistent with 243 CMR 3.13(1)(a)1., then the nursing home shall review the professional competence of such licensee by obtaining the following documents and making the following assessments:

- a. 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.
- b. 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. 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 violation of law in 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 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.

c. 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 243 CMR 3.13(1)(a)2.d. 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.

d. The nursing home shall require the licensee to authorize his or her 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:

- (i) the name and age of the claimant or plaintiff;
- (ii) the nature and substance of the claim;
- (iii) the date and place at which the claim arose;
- (iv) the amounts paid, if any, and the date and manner of disposition, whether by judgment, settlement or otherwise; and
- (v) the date and reason for final disposition, if there was no judgment or settlement.

e. 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.

f. 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.

g. The nursing home shall make reasonable inquiry to each hospital, clinic and

nursing home identified by the licensee pursuant to 243 CMR 3.13(1)(a)2.e., 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:

- (i) 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
 - (ii) information regarding any pending or final disciplinary action and malpractice claim. 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.
- (b) 243 CMR 3.13(1)(a) shall be implemented as follows:
- 1. The professional competence of a licensee subject to 243 CMR 3.13(1)(a)1. shall be reviewed for the first time by the nursing home pursuant to 243 CMR 3.00 no later than 90 days following either the licensee's initial credentialing or his or her first re-credentialing by the primary hospital pursuant to 243 CMR 3.05, whichever occurs first.
 - 2. The professional competence of a licensee subject to 243 CMR 3.13(1)(a)2. shall be reviewed for the first time by the nursing home pursuant to 243 CMR 3.13(1)(a)2. no later than 180 days following the effective date of 243 CMR 3.13 or prior to the licensee's serving as medical director or advisory physician of the nursing home, whichever occurs later.

(2) 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 or her name and Massachusetts medical license number.

(3) Major Incident Reporting. When the nursing home files a report with the Department of Public Health pursuant to its patient abuse regulations (105 CMR 155.000: *Patient and Resident Abuse Prevention, Reporting, Investigation, Penalties and Registry*) or serious incident regulations (105 CMR 150.002(G)), and said report describes or involves either of the following major incidents, then the nursing home shall file a copy of the report with the Board (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:
 - 1. after said licensee has been contacted by the nursing home, if:
 - a. during the course of events that prompted the nursing home to contact the licensee, the resident dies or is transferred to a hospital; and
 - b. such death or transfer may have been prevented had the physician not failed to treat the resident; or

2. 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 incidents, for illustrative purposes only, include an inadequately treated decubitus ulcer, a medication error or an unevaluated change in mental status.
- (4) Compliance Monitoring.
- (a) Review of professional competence under 243 CMR 3.13(1) shall not be deemed "reasonable" under M.G.L. c. 111, § 203(e), and the Board's determination of reportable incidents under M.G.L. c. 111, § 203(e) shall not be complete and in compliance with 243 CMR 3.13 unless the nursing home permits the Board during ordinary business hours to inspect and copy all resident and nursing home records and other information developed pursuant to 243 CMR 3.13, and, upon reasonable notice, to interview appropriate personnel, unless otherwise prohibited by law. Nothing in 243 CMR 3.00 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.
 - (b) The enforcement provisions set forth in 243 CMR 3.11(2) and (3) shall apply to nursing homes.

3.14: Qualified Patient Care Assessment Program-- Clinics

- (1) Credentialing. With the exception of 243 CMR 3.14(1)(b), the provisions of 243 CMR 3.05 do not apply to clinics licensed pursuant to M.G.L. c. 111, § 51; however, any such clinic 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 clinic first performs the following evaluation of the licensee.
- (a) 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 3.05 by a licensed or state hospital within Massachusetts.
 1. Prior to the date on which a licensee commences to practice medicine on behalf of a clinic:
 - a. the clinic shall request and the Massachusetts hospital where the licensee spends the greatest proportion of his or her time (the Primary Hospital) shall provide to the clinic written confirmation that the licensee has been credentialed by the primary hospital pursuant to 243 CMR 3.05. The written confirmation shall be provided to the clinic within 30 days after the later of: receipt of the clinic's request or, subject to 243 CMR 3.14(1)(a), the date on which the licensee is credentialed or re-credentialed pursuant to 243 CMR 3.05 by the primary hospital. The written confirmation shall describe each of the following known to the primary hospital:
 - i. pending or closed healthcare facility or public agency disciplinary actions against the licensee;
 - ii. alterations in privileges resulting, directly or indirectly, from concerns about

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- the licensee's professional performance, judgment or clinical skills; and
- iii. 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.
- b. The licensee shall provide to the clinic a release and waiver to allow the clinic access to any information in which the licensee has an interest that may be requested by the clinic pursuant to 243 CMR 3.14(1)(a)3.
- 2. At least once every two years, the clinic 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 3.05 by the primary hospital:
 - a. The clinic shall complete the process described in 243 CMR 3.14(1)(a)1.a.
 - b. The licensee shall provide to the clinic a release and waiver to allow the clinic access to any information in which the licensee has an interest that may be requested by the clinic pursuant to 243 CMR 3.14(1)(a)3.
- 3. If the clinic obtains adverse information regarding the licensee pursuant to 243 CMR 3.14(1)(a)1. or 2. or 243 CMR 3.14(1)(b) or (c), the clinic may request in writing and the primary hospital shall provide to the clinic 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 clinic deems necessary to complete its credentialing of the licensee (information identifying particular patients may be redacted). The clinic shall reimburse the primary hospital for the reasonable costs of providing information pursuant to 243 CMR 3.14(1)(a)3..
- (b) A licensee who has not been credentialed by a licensed or state hospital within Massachusetts pursuant to 243 CMR 3.05 shall be credentialed by the clinic pursuant to 243 CMR 3.05 prior to the date on which the licensee commences to practice medicine on behalf of the clinic, and biennially thereafter.
- (c) The clinic shall perform an initial and biennial credentialing evaluation of the licensee, based on the information obtained pursuant to 243 CMR 3.14(1)(a) or (b), as applicable, and based on information developed by the clinic's Patient Care Assessment program. The evaluation shall include assessment of the licensee's professional performance, judgment and clinical skills.
- (d) Based on information received or developed by the clinic, the clinic 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. The clinic may summarize information obtained pursuant to 243 CMR 3.14(1)(a) 3. in order to fulfill the credentialing requirements of 243 CMR 3.01, but it shall not re-disclose such information without the prior written consent of the primary hospital from which it was received.

REGULATORY AUTHORITY

243 CMR 3.00: M.G.L. c. 13, § 10; c. 111, §§ 51, 53B, 203 through 205 and c. 112, §§ 2 through 9B.