Commonwealth of Massachusetts Board of Registration in Medicine
Quality and Patient Safety Division

ELEMENTS OF THE PATIENT CARE ASSESSMENT PLAN - CLINICS

All section references are to Quality and Patient Safety (QPS) regulations, set forth at Chapter 243 of the Code of Massachusetts Regulations, sections 3.01-3.14. The following provisions must be in your PCA Plan:

1. Facility Bylaws [3.07(1)(3), 3.09(1), 3.11(1)] and Medical Staff Bylaws [3.07(1)(2)(3)], 3.09(1)] The facility and medical staff bylaws must either authorize all the elements from regulations designated above or contain a general statement as follows: "The clinic shall establish and maintain a qualified Patient Care Assessment Program that complies with the requirements of 243 CMR 3.00 et seq. and that has been approved by the Massachusetts Board of Registration in Medicine. Said bylaws specifically incorporate those provisions of the hospital's Patient Care Assessment Plan, as from time to time amended, which, pursuant to 243 CMR 3.00 et seq., must be established by or described in these bylaws."

2. Governing Body Responsibility [3.03(1)(a)] The Governing body shall be responsible for the organization and functioning of each PCA Committee and its related activities. The governing body shall ensure the adequacy of resources and support systems for the PCA Program.

3. Patient Care Assessment Committee [3.06(1)(a)(b)(c)] 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. The PCA Plan must describe your patient care assessment committee membership. The committee must include at least one member from the governing body of the clinic.

4. Patient Care Assessment Coordinator [3.06(2)] The governing body of the clinic must appoint an individual PCA Coordinator (or group of individuals, to collectively carry out the duties of the PCA Coordinator), who shall be charged with the responsibility of implementing – by delegation, oversight of otherwise – the clinic's qualified patient care assessment program. The name(s) of the PCA Coordinator shall be reported to the Board of Registration in Medicine within 10 days of appointment or replacement. 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.

5. Policies governing responsibilities of the PCA Coordinator and Committee [3.03(1)(e)] The clinic must develop and include as part of its PCA Plan the responsibilities of its PCA Committee and Coordinator.

6. Credentialing [3.14 and 3.05(1)(2)(3)] The following statement must be present as a policy in your PCA Plan: The clinic shall undertake and repeat at least biennially all the credentialing requirements set forth in 243 CMR 3.05 and 3.14. Please refer to the regulations provided for specific requirements.

7. Internal Incident Reporting System [3.07(3)(a-d)] The clinic shall develop and implement an internal incident reporting system based upon the affirmative duty of all health care providers to report injuries and incidents in writing to the Patient Care Assessment Coordinator. The system will include the analysis and tendering of data collected through the use of three systems: (1) focused occurrence reporting criteria, (2) focused occurrence screening criteria, and (3) the major incident reporting system.

As part of the internal incident reporting system, procedures shall be in writing and given to all employees involved in patient care within five days of new employment. Within 30 days, new employees involved in patient care will receive orientation and training, including information pertaining to patient rights (M.G.L. c. 111, sec. 70E). Every year, all employees involved in the PCA Program will be provided with three hours of education and training in patient care assessment and quality assurance techniques, with emphasis on timely and accurate incident reporting.

8. Focused Occurrence Reporting Criteria [3.07(3)(b)(d)] and Focused Occurrence Screening Criteria [3.07(3)(c)(d)) These criteria should be designed to reveal, through a chart review process, adverse or potentially adverse patient occurrences that might not otherwise be evident . Please submit the list of criteria which your hospital has designated as focused occurrence reporting and screening criteria. Please note that these are two separate sets of criteria as defined below: Focused Occurrence Reporting Criteria – incidents, which shall be reported to the PCA Coordinator within 24 hours of occurrence. For example, major transfusion reaction, wrong surgical procedure performed, etc.

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Focused Occurrence Screening Criteria – criteria or events which one uses to screen medical records. Screening criteria should focus on the potentially adverse events that are more likely to be examined through chart review, for example, documentation of informed consent, transfers to the I.C.U., follow-up of abnormal lab results, etc.

9. Major Incident Reporting [3.08(1)(2)(3)(4)(5)] The clinic shall report all Major Incidents as defined in 243 CMR 3.08 to the Board of Registration in Medicine on a quarterly basis.

10. Maintenance of Reports [3.07(3)(h)] All incident reports, summary reports and written recommendations to and from the Patient Care Assessment Coordinator shall be maintained for three years.

11. Patient Complaint System [3.07(3)(f)] The clinic shall develop a Patient Complaint policy and system for 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.

12. Informed Consent Policy [3.10(a)(b)(c)(d)] The clinic must develop and submit as part of their PCA Plan a policy on Informed Consent which complies with 243 CMR 3.10(1). (Please refer to the regulations for specific requirements of the policy).

13. Impaired Health Care Provider Provision [3.09(1)] The following elements must be present in a policy as part of your PCA Plan: The clinic must develop a procedure for ongoing review and counseling of health care providers impaired by drugs or alcohol or arrange for and monitor participation in other established review and counseling programs. The procedure developed above will not relieve the clinic or any health care provider at the clinic from his or her obligation to report impaired physicians to the Board of Registration in Medicine, under M.G.L. c. 112, sec.5F.

14. Prescription Practice and Medication Errors [3.10(3)] All licensees shall adhere to the requirements for the safe administration of drugs and biologicals, set forth in the current accreditation manual published by the accreditation body of the clinic.

15. Medical Records [3.10(2)(a)(b)] The health care facility shall prohibit the alteration of medical records when such alteration distorts any facts or circumstances reflected in the original writing. Medical records shall meet requirements set forth in the current accreditation manual published by the accreditation body of the clinic.

16. Guidelines in Specialties [3.10(4)(a)], (if applicable) Anesthesiology: All licensees shall adhere to the Standards for Basic Intra-Operative Monitoring established by the American Society of Anesthesiologists.

17. Facility Equipment Committee [3.07(3)(m)] The governing body must 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.

18. Summary Suspension [3.11(1)(b)] Violation of any health care facility bylaw or regulation as part of a Qualified Patient Care 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.

19. M.G.L.c.112, sec 5F[3.11(1)(a)] At least annually, every health care provider as defined by M.G.L.c.111, sec. 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, sec. 5F.

20. Documentation of Disciplinary Action [3.07(3)(i)] All disciplinary actions against physicians taken by the clinic must be in writing and be reported to the Board of Registration in Medicine on the required reporting forms to the appropriate division of the Board.

21. Comprehensive Evaluation [3.07(3)(1)] At the request of the Board of Registration in Medicine, the clinic will provide for the administration of a reasonable and comprehensive evaluation of a physician's clinical skills, competence and judgment.

22. Audit Authority [3.07(3)(k)] The clinic grants the Department of Public Health and the Board of Registration in Medicine access and audit authority overqualified PCA program information and records during normal business hours.

23. Patient Rights [3.11(1)(c)] The clinic will provide to all patients, prior to or within 24 hours of admission, written notice, in plain language, of their rights established by M.G.L. c. 111, sec 70E. These rights will be conspicuously posted in the clinic. All patients will 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.