COMMONWEALTH OF MASSACHUSETTS
BOARD OF REGISTRATION IN MEDICINE

POLICY 2023-PCA01

POLICY ON PATIENT CARE ASSESSMENT REGULATORY REPORTING

Issued March 2023

Subject: Patient Care Assessment Program Reporting Changes
Date: March 2, 2023
Date of Implementation: September 1, 2023

Healthcare facilities in the Commonwealth of Massachusetts are required to comply with Patient Care Assessment (PCA) regulations (243 CMR 3.00-3.14). The regulations require submission of three quality assurance reports yearly (one annual and two semiannual reports) and the submission of Safety and Quality Review (SQR) major incident reports. To date, reports have only been accepted in a paper format. In order to improve efficiency and decrease the burden of regulatory reporting, the Board's Quality and Patient Safety Committee will accept these required reports submitted electronically via the electronic platform designated by the Board. The Board's Quality and Patient Safety Division will provide guidance documents to assist healthcare facilities with these changes.

Related Statutes:
M.G.L. c. 112, § 5.
M.G.L. c. 111, § 203(d).
M.G.L. c. 111, § 205(b).

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.

Health Care Facility: For purposes of this policy only, any entity licensed pursuant to M.G.L. c. 111, § 51; 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.

Patient Care Assessment Coordinator: A qualified physician or non-physician designated by a health care facility to implement and coordinate the facility's Patient Care Assessment Program established pursuant to 243 CMR 3.00. To be qualified, the Patient Care Assessment Coordinator shall demonstrate evidence of the necessary education, training and/or experience to carry out the functions and activities of the Patient Care Assessment Program.

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.

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Policy:

1. Healthcare facilities shall submit regulatory reports pursuant to 243 CMR 3.00-3.14 electronically, using the electronic platform designated by the Board, unless they have written confirmation of an exemption. Patient Care Assessment Coordinators are responsible for collaborating with the Board's Quality and Patient Safety Division staff to ensure their staff are educated as to the completion of the regulatory reports via the established electronic reporting platform.

2. Healthcare facilities for whom electronic reporting will be a hardship shall have the option to seek an exemption by submitting a written request to the Board's Quality and Patient Safety Division that describes the nature of the hardship. If the Board's Quality and Patient Safety Committee determines that the hardship warrants an exemption, it will provide written confirmation that the exemption has been approved. Health care facilities that have obtained a written exemption may submit paper reports.

3. The Board's Quality and Patient Safety Division will accept reports that meet the following criteria:
    a. Pursuant to 243 CMR 3.07(g) and 243 CMR 3.11(4), Annual and Semiannual Reports are required to be submitted as three distinct reports each year. 243 CMR 3.07(g), sets different reporting periods and due dates for the Annual and Semiannual Reports, dependent upon the healthcare facility type.
    In satisfaction of the foregoing reporting requirements, the Board's Quality and Patient Safety Division will now accept a single, annual submission to be referred to as the Patient Care Assessment Quality Assurance Report (PCA-QA Report), provided that it includes the following elements:

        i. A copy of the facility's Patient Care Assessment Plan, which shall be reviewed, updated, and submitted annually.
        ii. Patient complaint data:
            1. Total volume of patient and family complaints for the reporting period, with the total volume of complaints in each of the top three categories of patient and family complaints.
            2. Analysis, recommendations, and plans for corrective measures for any trends indicated by data.
        iii. Performance Improvement Activities (Major Tasks Completed).
        iv. Internal Reporting and Screening Systems:
            1. Focused Occurrence *Screening* Criteria data, analysis, and recommendations.
            2. Focused Occurrence *Reporting* Criteria data, analysis, and recommendations.
            3. Internal Incident Reporting System Data:

a. Total number of incident reports for the reporting period, with the total number of incident reports in each of the top three categories of incident reports.
b. Analysis, recommendations, and plans for corrective measures for any trends indicated by data.

v. Attestation that the following elements are in place and available upon request:
    1. Policy/protocol regarding the distribution of detailed written instructions regarding operational procedures relevant to patient care assessment and compliance with 243 CMR 3.00.
    2. Policy/protocol regarding the handling of impaired physicians.
vi. The reporting period is inclusive of the calendar year prior to the report's due date.
vii. The PCA-QA Report must be submitted annually on or before the following due dates:
    1. March 30th for ambulatory clinics and outpatient sites, and
    2. April 30th for hospitals.

b. Pursuant to 243 CMR 3.08(2)(a) through (d); 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; and (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. However, healthcare facilities may omit submission of SQR reports of patient falls and pressure injuries provided that:

i. The Healthcare facility has submitted a semiannual or PCA-QA report within the last 24 months that documents the existence and implementation of comprehensive prevention programs and/or protocols for prevention of patient falls and pressure injuries, and

ii. The specific patient fall or pressure injury incident is not inclusive of other adverse events.