Ohio Administrative Code

Rule 5122-2-25 Morbidity and mortality events.

Effective: September 30, 2018

(A) Purpose: To improve treatment outcomes and patient, staff and community safety by defining and establishing criteria for review, reporting and follow-up of patient safety morbidity and mortality events.

(B) The following definitions apply to this rule:

(1) "Director" means the chief executive and administrative officer of the Ohio department of mental health and addiction services.

(2) Morbidity/mortality events (M&Ms) mean events that result in death, permanent harm, severe temporary harm, or significant potential for any of these outcomes affecting either:

(a) Patients receiving services at an Ohio department of mental health and addiction services (department) regional psychiatric hospital (RPH) or community support network (CSN) program; or,

(b) RPH/CSN onsite staff, licensed independent practitioners (non-staff), vendors, or visitors.

(3) Severe temporary harm is a critical, potentially life-threatening condition lasting for a limited time with no permanent residual effect, but requires at least one of the following:

(a) Transfer to a higher level of care or monitoring for a prolonged period of time;

(b) Transfer to a higher level of care for a life-threatening condition; or,

(c) Major surgery, procedure, or treatment to resolve the condition.

(C) M&M events include, but are not limited to, the following:

(1) Suicide attempt or completed suicide by a current RPH/CSN patient or one who was discharged from the RPH/CSN care within the past thirty days. A suicide attempt is defined as deliberate action(s) taken by a patient which were intended to cause their death or actions that may have led to death regardless of the patients intent.

(2) Assault resulting in death, permanent or severe temporary harm of a patient currently receiving services at a RPH/CSN or of a staff member, licensed independent practitioner, vendor, or visitor.

(3) Alleged rape of a patient while being treated or on the premises of the RPH or CSN where one or more of the following circumstances apply:

(a) Staff-witnessed sexual contact;

(b) Sufficient clinical evidence obtained by the RPH to support allegations of nonconsensual sexual contact; or,

(c) Admission by the perpetrator that sexual contact occurred on the premises.

(4) Rape of a staff member, licensed independent practitioner, visitor or vendor while on site at a hospital or a CSN.

(5) Elopement of a patient from an RPH leading to death, permanent harm, or severe temporary harm to the patient and/or to person(s) in the community.

(6) All elopements of patients/clients under a forensic legal status and jail transfers under a civil legal status prior to completion of treatment and discharge from an inpatient unit or CSN

(7) Any death of a current RPH/CSN patient or one who was discharged from the RPH/CSN care within the past thirty days excluding deaths related to the natural course of the patients illness or underlying condition

(8) Any serious injury or illness resulting in permanent harm, severe temporary harm, or significant potential for either that resulted from clinical care or lack of clinical care.

(9) Abduction of a patient receiving care, treatment, and services at an RPH/CSN.

(D) Procedure for M&M review: (attachment A)

(1) Notification:

(a) Immediately following a M&M event, the RPH chief executive officer (CEO) or their designee shall report the event to the director, the medical director of the department, and the hospital services (HS) assistant director or their designees via phone or e-mail.

(b) The RPH shall attempt to report the event to the patient and guardian, and shall attempt to notify the patient's family, if the patient has provided consent.

(2) Initial review by RPH M&M committee:

(a) An initial review shall be completed on each M&M event by the RPH chief clinical officer (CCO) or their designee and at least two other RPH M&M committee members inclusive of treating practitioners.

(b) This review shall:

(i) Review the event and events/circumstance preceding the event.

(ii) Establish a plan for immediate action(s) to address the safety of the patient(s) involved in the event and minimize risk of recurrence.

(iii) Identify other patients who might be at similar risk and establish a plan for immediate action(s) to minimize risk of a similar event affecting them.

(iv) Determine what information is required to complete a full root cause analysis (RCA).

(v) Determine whether the morbidity or mortality event is a center for medicare and medicaid

services (CMS) reportable event. If the event is a CMS reportable event, the RPH CEO and CCO shall initiate discussion with the assistant director of hospital services, the medical director and the chief legal counsel to determine course of action.

(vi) Submit the initial review utilizing the department initial review form (attachment B) to hospital services M&M committee (HS M&M) no later than five p.m. of the second day of business following the event or discovery of the event.

(3) Root cause analysis by RPH M&M committee:

(a) A RCA is a process or identifying the basic or causal factors that underlie variation in performance leading to the occurrence or possible occurrence of a serious adverse event. It focuses on systems and processes, not on individual performance, and progresses from special causes in clinical processes to common causes in organizational processes and systems. It identifies improvements in processes and/or systems that decrease the likelihood of such events occurring in the future.

(b) An RCA of the M&M event shall occur and be submitted to the HS M&M within thirty days of the event or discovery of the event using the department RCA report form (attachment C).

(c) The RPH M&M committee may designate subcommittees, which may include staff at all levels closest to the issue of a given case, individuals with specific expertise, and those with decision-making authority to provide the committee with specific information and/or recommendations. It is understood that the details of care provided outside of the RPH. (e.g. general hospital care, group home, own home, etc.) may not be accessible to the RPH for review.

(d) The RPH shall develop specific risk reduction strategies to reduce likelihood of a similar event occurring in the future, including target dates for implementation and a plan to evaluate the effectiveness of these interventions as well as for sustainability.

(e) The RPH M&M committee, quality assurance and/or risk management committees shall review hospital M&M event reports and risk reduction strategies on a regular basis to evaluate the effectiveness of their interventions on patient and staff safety and further refine the interventions, as indicated.

(f) If the event is a death, a death certificate and coroner's report (if available) shall be reviewed, and its impact, if any, on the findings of the RPH M&M committee shall be noted on the department RCA form. If the coroner's report is not available at the time the RCA findings are reviewed by the HS M&M, a follow-up review of this information by the RPH M&M committee following the receipt of the coroner's report shall occur. An amended RCA form shall be completed and forwarded to the HS M&M within seven days of receipt of the coroners report.

(g) Progress on each identified risk reduction strategy shall be reported at each scheduled HS M&M meeting until all are complete.

(4) All reviews shall be reviewed and approved by the RPH CCO or designee prior to submission.

(5) Based upon findings of initial reviews and full reviews, the HS M&M or medical director may issue an alert to RPH CEOs, CCOs, clinical nurse managers, quality improvement directors, and chief operating officers (COOs) recommending safety actions to minimize risk to patients in all RPHs and CSNs.

(6) For all other serious events not meeting criteria for an M&M event as described in this rule, a criminal or administrative investigation shall occur in accordance with RPH internal policy (e.g., theft, fires, equipment failure, etc.), as appropriate.

(E) Hospital services M&M committee:

(1) Membership (a member may fulfill more than one role):

(a) Chair department medical director or their designee;

(b) Vice-chair: department assistant medical director;

(c) Director;

(d) Assistant director of HS or their designee;

(e) Deputy director of HS;

(f) Chief legal counsel or their designee;

(g) Department quality assurance/improvement director;

(h) Department medical director office mental health administrator for M&M;

(i) CCO or their designee from each RPH. Designees shall be physicians;

(j) Quality improvement director or their designee from each RPH.

(k) Other members:

(i) At least one RPH CEO

(ii) At least one RPH nurse executive

(iii) One pharmacist

(iv) One primary care physician

(v) One chief operating officer (COO)

(vi) One CSN representative

(vii) Others as appropriate

(l) All members shall be appointed annually by the director. The chair may appoint ad hoc members for specific cases/purposes.

(2) Committee operations:

(a) The HS M&M committee shall:

(i) Review all hospital morbidity/mortality events.

(ii) Evaluate individual reports for content, completeness and timeliness.

(iii) Be available to support RPHs in their M&M processes, as requested.

(iv) Evaluate M&Ms for trends that may require further assistance or resources to improve patient care and RPH safety in individual RPHs or throughout the system

(v) Prepare alerts on events or trends identified in M&Ms that may require immediate system response to improve safety.

(vi) Determine if a specialized review process or subcommittee should be established to review individual events or trends.

(vii) Develop, review, and revise as needed, the department administrative rule on morbidity and mortality events.

(viii) Develop an annual report regarding M&M events including trends or patterns of performance. This report shall be presented to the director annually.

(b) The committee shall meet at least quarterly.

(c) Meeting minutes and summary reports, as deemed appropriate, will be developed and maintained by the office of the medical director.

(F) Regional psychiatric hospital morbidity and mortality quality assurance committees (RPH M&M).

(1) Each RPH shall establish an M&M committee/subcommittee under the medical executive

committee. The committee shall function as part of the hospital's performance improvement program. The hospital CCO or designee shall chair the committee.

(2) Membership:

(a) Chair - RPH CCO or their designee, who is a physician;

(b) RPH quality assurance/improvement (QA/QI) director;

(c) RPH risk manager/safety officer/patient safety coordinator/designee;

(d) RPH nurse executive or registered nurse designee;

(e) RPH CEO or designee from administration;

(f) For each M&M event the committee shall include RPH staff involved with the patient's treatment, such as:

(i) Physicians

(ii) Nurses

(iii) Therapeutic program workers

(iv) Staff/supervisors

(v) Pharmacists

(vi) CSN program administrator

(vii) Client rights officer

(viii) Others as relevant

(3) Committee operations:

(a) The RPH M&M committee shall review each morbidity or mortality event, as described above, and document the review on forms maintained securely by the hospital QA/QI director.

(b) Meetings shall be held at least quarterly, more frequently as needed. The meeting minutes of the RPH M&M committee shall be maintained securely by the hospital's QA/QI director. Names and titles of all staff present shall be indicated, as well as the date and time of the meeting. If a staff member is representing another staff person, this shall be indicated in the minutes. A copy of the minutes may be requested by the office of quality assurance/improvement in central office.

(G) All proceedings, records, information, data, reports, recommendations, evaluations, opinions, and findings of the hospital and central office morbidity and mortality events review committees are strictly confidential and are not subject to disclosure or discovery or introduction in evidence in any civil action, as specified in sections 1751.21, 2305.24, 2305.25, 2305.251, 2305.252, 2305.253, 2305.28, 5122.31, and 5122.32 of the Revised Code.