5122-2-25 **Morbidity, mortality and sentinel event.**

(A) The purpose of this rule shall be:

(1) To define and establish investigation and reporting mechanisms for the death or morbidity of any patient on Ohio department of mental health (ODMH) ~~hospital~~ BHO rolls or being served by a ~~stand-alone~~ community support network (CSN), or any former patient whose death, if known, occurred within thirty days of discharge from an ODMH ~~hospital~~ BHO ~~or CSN program~~ in order to determine whether appropriate care and treatment were provided by ODMH staff.

(2) To define and establish investigation and reporting mechanisms for sentinel event and root cause analysis (RCA). The goal of the RCA is to assist in reducing the risk of similar sentinel event occurrences in the future.

(B) The provisions of this rule shall apply to all IBHS BHOs ~~hospitals including their constituent inpatient and outpatient programs, and to stand-alone CSNs under the managing responsibility of the Ohio department of mental health~~.

(C) Confidentiality

Central office and/or ~~hospital~~ BHO quality assurance committees shall perform the morbidity, mortality and sentinel event reviews. All proceedings, records, information, data, reports, recommendations, evaluations, opinions, and findings of the ~~hospital~~ BHO and central office morbidity, mortality, and sentinel event reviews 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, 2305.252, 2305.251, 2305.28, 5122.31, and 5122.32 of the Revised Code.

(D) The following definitions shall apply to this rule in addition to or in place of those appearing in rule 5122-1-01 of the Administrative Code:

(1) "BHO" means a behavioral healthcare organization. It is one of five state mental healthcare systems which represent nine ODMH hospital sites across the state of Ohio. A broad array of mental health services are provided in acute and long term environments and through community support networks (CSNs). CSNs provide community mental health services through a contract with a mental health board.

~~(1) "CSN" means community support network.~~

(2) "JCAHO" means the joint commission on accreditation of healthcare

organizations.

~~(3) "JCAHO reportable sentinel event" means a sentinel event that the JCAHO categorizes as reportable on a voluntary basis.~~

~~(4)~~(3) "Morbidity" means those situations, as determined by a physician, where, except for the presence of appropriate and effective medical/psychiatric care, the patient would have died. Injuries resulting in loss of life or function are included.

~~(5)~~(4) "Root cause analysis" means a process for ~~identiying~~ identifying the most basic or causal factor or factors that underlie variations in performance, including the occurrence of a sentinel event.

~~(6)~~(5) "Mortality" means death.

~~(7)~~(6) "Root cause" means a basic deficiency or failure in a process that, if eliminated or corrected, would systematically decrease the risk of an undesirable event from occurring/recurring. Root causes involve both process problems (localized) or problems within the entire system (systemic) that allow or create deficiencies which cause or could cause unwanted occurrences.

~~(8)~~(7) "Sentinel event" means an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. The risk thereof includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome. Serious injury includes loss of limb or function.

~~(9) "Stand alone CSN" means a CSN where clinical supervision is provided by CSN supervisors and the hospital performs administrative and billing functions.~~

(E) ODMH morbidity and mortality quality assurance committee

(1) Membership

(a) Chairperson - ODMH medical director/designee

(b) ODMH assistant medical director;

(c) Chief, office of quality assurance/improvement;

(d) Central office quality assurance/improvement review staff; and

(e) Others, as deemed appropriate (e.g., security consultant, office of legal services.

(2) Functions

(a) To review all ~~hospital~~ BHO morbidity/mortality/sentinel event reports for completeness;

(b) To determine whether appropriate policies and procedures were followed in the filing of ~~hospital~~ BHO morbidity/mortality/sentinel event reports;

(c) To determine if any form of inservice education should occur;

(d) To recommend to BHO morbidity and mortality committees methods to reduce future incidents ~~areas for continuous quality improvement~~;

(e) To analyze statewide data and develop reports regarding morbidity/mortality/sentinel events including trends and patterns;

(f) To develop a written report, at least annually, for the director of the department;

(g) To develop, review, and revise, as needed, the department administrative rule on morbidity, mortality and sentinel events; and

(h) To determine if a specialized review process or subcommittee should be established to review individual cases.

(3) Meetings

The committee shall meet quarterly, or more often if deemed necessary, at the direction/request of the chair/designee.

(4) Reports

Summary reports, as deemed appropriate, will be developed and maintained by the office of quality assurance/improvement.

(F) ~~Hospital~~ BHO ~~and CSN~~ morbidity and mortality quality assurance committee.

Each ~~hospital/CSN~~ BHO shall establish a morbidity and mortality quality assurance committee. The committee shall function as part of the ~~hospital's~~ BHO's quality assurance program and shall be under the direction of the ~~hospital medical director~~ BHO chief clinical officer. The ~~hospital medical director~~ BHO chief clinical officer, or his/her designee, shall chair the committee.

(1) Membership

The members of the committee shall be appointed by the chief executive officer and shall consist of at least the following members:

(a) ~~Hospital medical director~~ BHO chief clinical officer or physician designee;

(b) Quality assurance coordinator/director;

(c) Director of nursing services or registered nurse designee;

(d) BHO Chief executive officer or ~~designeee~~ designee from administration; and

(e) Others may be appointed on a permanent or on an as needed basis depending on the circumstances surrounding the case or because of involvement with the patient's treatment regime (e.g., security department, staff/supervisors, physician, nurse, client advocate, risk manager, pharmacist, medical records administrator, CSN program director/supervisor/staff, etc.)

(2) Function

The function of the ~~hospital/CSN~~ BHO morbidity and mortality quality assurance committee shall be to review the specific circumstances which led to the patient's death, morbidity or sentinel event at the ~~hospital or CSN~~ BHO. The review, as described in paragraph (F)(5) of this rule, shall be documented on the "morbidity/mortality quality assurance report form." These forms shall be maintained in the ~~hospital~~ BHO quality assurance office. The forms, or any single portion, shall not be kept in the individual patient record.

(3) Meetings

Meetings may be called, at least quarterly or as needed, by the chairperson to review the progress of interventions/plans that have been developed. The minutes of the quality assurance morbidity and mortality committee meetings shall be maintained by the ~~hospital~~ BHO quality assurance office. 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 also shall be indicated in the minutes. A copy of the minutes may be requested by the office of quality assurance/improvement in central office.

(4) Agreements with general hospital

Each ~~hospital~~ BHO shall attempt to develop agreements with general hospitals that provide services to department ~~hospitals~~ BHOs. These agreements should include: time frames for the transfer of clinical information between both parties; notification in case of death; cause of death; treatment provided; and other information as agreed upon by both parties.

(5) ~~Hospital/CSN~~BHO review process

(a) Morbidity, mortality and sentinel event initial review

An initial review by the ~~medical director/~~chief clinical officer and at least two other committee members shall be accomplished as soon as possible. The purpose of the initial review is to determine if immediate action needs to be taken. The attending physician, or designee, shall attend the meeting and present the clinical history, events, and circumstances preceding death or morbidity. The patient's record shall be available at these meetings. Minutes shall be taken which shall include:

(i) Staff members in attendance;

(ii) Information reviewed; and

(iii) What action was taken.

Meeting minutes will be submitted to the ODMH medical director/designee within five days after discovery of the event.

(b) Morbidity, mortality and sentinel event full review

The full review shall include, as applicable, a root cause analysis of the

incident/event. The review of the case shall be completed within forty-five days of the event or its discovery. ~~In CSNs, the review will focus on the care provided by the staff and related care events.~~ It is understood that care provided outside of the BHO, (e.g., general hospital care, group home, own home, etc.), ~~living arrangements, general hospital care, etc.,~~ may not be accessible or under the authority of ODMH to review.

(i) The ~~hospital~~ BHO morbidity and mortality quality assurance committee may assign parts of the investigation to quality assurance subcommittees which include staff at all levels closest to the issue(s) and those with decision-making authority.

(ii) The root cause analysis shall focus primarily on systems and processes, not on individual performances.

(iii) The root cause analysis shall progress from special causes in clinical processes to common causes in organizational processes.

(iv) The root cause analysis shall identify changes which could be made in systems and processes, either through redesign or development of new systems or processes that should reduce the risk of such events recurring in the future.

(c) Review upon receipt of coroner's report

If a coroner's report is not available at the time of the full review, a follow-up review by the morbidity and mortality quality assurance committee is to be completed within thirty days of the receipt of the coroner's report. The coroner's report shall be reviewed, and its impact, if any, on the findings of the morbidity and mortality quality assurance committee shall be noted. This review shall be documented on the appropriate form. An amended root cause analysis shall be completed as indicated.

(6) Reports

(a) A copy of the full review, death certificate, and all corresponding meeting minutes shall be forwarded to the ODMH medical director/designee within forty-five days of the discovery of the incident. A copy of the coroner's report shall be forwarded after it is received by the ~~hospital/CSN~~ BHO.

~~(a)~~(b) The ODMH medical director/designee shall review the morbidity and mortality report, including the root cause analysis submitted, and may request that the ~~hospital~~ BHO further refine the analysis.

~~(G) Sentinel event incident report~~

~~If the CEO declares an event as a sentinel event, the CEO/designee shall then inform the ODMH medical director/designee and the deputy director of the integrated behavioral healthcare system (IBHS) of the event as soon as possible. The ODMH medical director/designee and the deputy director of the IBHS shall discuss with the CEO/designee details of the sentinel event. The CEO shall make the final determination on whether this sentinel event should be reported to the JCAHO.~~

~~(H)~~(G) Quality assurance review

(1) BHO ~~Hospital/CSN~~

(a) All morbidity, mortality and sentinel event investigation including root cause analysis are part of the quality assurance review process and reports shall be identified as quality assurance documents.

(b) ~~Hospital~~ BHO quality assurance and/or risk management committees shall review morbidity, mortality and sentinel event reports on a regular basis.

(c) The ~~hospital~~ BHO shall evaluate the effectiveness of the improvement made in the system and further refine the system as indicated.

(d) The ~~hospital~~ BHO shall report in January and July the status of ~~forward a copy of the~~ intervention plans, ~~plan after all~~ i.e., whether interventions have been implemented or interventions are still in the implementation stage, to the ODMH medical director/designee.

(2) ODMH

(a) All morbidity, mortality and sentinel event reports and their root cause analyses shall be reviewed by the ODMH morbidity and mortality quality assurance committee.

(b) An annual report concerning morbidity, mortality and sentinel events shall

be submitted to the ODMH director by the ODMH morbidity and mortality quality assurance committee.

Replaces: 5122-2-25

Effective: 06/02/2003

CERTIFIED ELECTRONICALLY

Certification

05/23/2003

Date

Promulgated Under: 111.15
Statutory Authority: 5119.01
Rule Amplifies: 5119.01
Prior Effective Dates: 1/1/96, 9/24/98, 12/1/00