VERMONT
DEPARTMENT OF HEALTH

PROPOSED RULE

Patient Safety Surveillance and Improvement System

Table of Contents

I. General Provisions
- **1.1 Purpose**
- **1.2 Authority**
- **1.3 Scope**
- **1.4 Effective Date**
- **1.5 Definitions**
- **1.6 Protection and Disclosure of Information**
- **1.7 Reporting Methods**
- **1.8 Hospital Contribution Formula**
- **1.9 Hospital Record Retention**
- **1.10 Enforcement**

II. Hospital Policies, Procedures and Reporting Related to All Adverse Events and Near Misses
- **2.1 Identification, Tracking and Analysis**
- **2.2 Causal Analyses**
- **2.3 Corrective Action Plans**
- **2.4 Disclosures to Patients**
- **2.5 List of Reportable Adverse Events**
- **2.6 Submitting Reportable Adverse Event Reports**

III. Hospital Policies, Procedures and Reporting Related to Intentional Unsafe Acts
- **3.1 Identification of Intentional Unsafe Acts**
- **3.2 Intentional Unsafe Act Criteria**
- **3.3 Reporting Intentional Unsafe Acts**
- **3.4 Reporting Intentional Unsafe Acts to Relevant State and Federal Licensing and Law Enforcement Authorities**

IV. Compliance Monitoring
- **4.1 Routine Periodic Monitoring**
- **4.2 Focused Compliance Review**

I. General Provisions

1.1 Purpose

This rule implements the Patient Safety Surveillance and Improvement System created by 18 V.S.A. Chapter 43A.

1.2 Authority

This rule is adopted under the authority of 3 VSA §§ 801(b)(11) and 3003(a) and 18 VSA §§ 102 and 1914.

1.3 Scope

This rule shall apply to all facilities licensed by the Vermont Board of Health pursuant to 18 V.S.A. Chapter 43.

1.4 Effective Date

All provisions of this rule shall be effective on _____, 2007.

1.5 Definitions

1. "Adverse event" means any untoward incident, therapeutic misadventure, iatrogenic injury, or other undesirable occurrence directly associated with care or services provided by a health care provider or health care facility.

2. "Causal analysis" means a formal root cause analysis, similar analytic methodologies or any similarly effective but simplified processes that use a systematic approach to identify the basic or causal factors that underlie the occurrence or possible occurrence of a reportable adverse event, adverse event, or near miss.

3. "Commissioner" means the commissioner of the Vermont Department of Health.

4. "Corrective action plan" means a plan to implement strategies intended to eliminate or significantly reduce the risk of a recurrence of an adverse event and to measure the effectiveness of such strategies.

5. "Department" means the Vermont Department of Health.

6. "Hospital" shall have the same meaning as in 18 V.S.A. § 1902(1).

7. "Hospital staff" means a health care provider, employee or volunteer providing services at the hospital.

8. "Health care provider" shall have the same meaning as in 18 V.S.A. § 9402(8).

9. "Intentional unsafe act" means an adverse event or near miss that results from:
   (A) a criminal act;
   (B) a purposefully unsafe act;
   (C) alcohol or substance abuse; or
   (D) patient abuse.

10. "Near miss" means any process variation that did not affect the outcome, but for which a recurrence carries a significant chance of a serious adverse outcome.

11. "NQF" refers to the National Quality Forum.

12. "Patient Safety Surveillance and Improvement System" refers to the Patient Safety Surveillance and Improvement System of the Vermont Department of Health.

13. "Reportable adverse event" means those adverse events a hospital is required to report to the Department as provided in this rule.

14. "Safety system" means the comprehensive patient safety surveillance and improvement system established pursuant to 18 V.S.A. Chapter 43A and this rule.

15. "Secure reporting system" means the Patient Safety Surveillance and Improvement System of the Department of Health secure electronic adverse event reporting system.

16. "Serious bodily injury" means bodily injury that creates a substantial risk of death or that causes substantial loss or impairment of the function of any bodily member or organ or substantial impairment of health or substantial disfigurement.

1.6 Protection and Disclosure of Information

1. All information made available to the Department and its designees pursuant to 18 V.S.A. Chapter 43A and this rule shall be confidential and privileged and exempt from the public access to records law as provided in 1 V.S.A. § 317(c)(37). All information submitted to the Patient Safety Surveillance and Improvement System shall be disclosed only as permitted or required by law.

2. The Patient Safety Surveillance and Improvement System shall maintain secure filing and storage of all electronic and non-electronic confidential and privileged records.

3. Within the Department, access to peer review protected information shall be limited to individuals designated by the Commissioner who are responsible for verifying compliance with the Safety System and for providing necessary consultation and supervision to that program. Reports made to the Department pursuant to 18 V.S.A. § 1915(4) shall not constitute a waiver of peer review or any other privilege.

1.7 Reporting Methods

1. The Department may establish a secure reporting system for submission of reports required by this rule.

2. Each hospital shall submit reports required by this rule to the Patient Safety Surveillance and Improvement System using a secure transmission method, such as to and from a secure fax number, certified mail or other documented delivery system or, if established by the Department, through the secure reporting system.

3. If a secure reporting system is established, a hospital may apply annually to the Department for a software license. Each hospital shall ensure that only authorized hospital staff has access to the secure reporting system and that the software is used exclusively for meeting the requirements of 18 V.S.A. Chapter 43A and this rule.

1.8 Hospital Contribution Formula

1. Annually, each hospital shall pay to the Department an amount determined using the total expense amounts from each hospital's budget approved by the Vermont Department of Banking, Insurance, Securities and Health Care Administration for the current fiscal year and calculated as follows: The individual hospital total expense divided by the total system expense for all hospitals and the resulting percentage multiplied by the amount of the general fund appropriation for the Patient Safety Surveillance and Improvement System for the fiscal year beginning July 1.

2. The total contributions from all hospitals shall equal 50% of the Patient Safety Surveillance and Improvement System budget and shall equal the general fund appropriation for that fiscal year.

3. No later than December 1, 2007, the Department will notify each hospital of the amount due for fiscal year 2008, which shall be paid to the Department no later than December 31, 2007. For each subsequent year,

the Department will notify each hospital of the amount due no later than June 1 and payment shall be made by the hospital to the Department no later than July 1 of that year. In the event that the legislature does not take final action on the general fund appropriation for the Patient Safety Surveillance and Improvement System by June 15, the Department will notify each hospital of the amount due within fifteen (15) days following final action on the appropriation and the hospital shall make payment within thirty (30) days of notification.

1.9 Hospital Record Retention

Each hospital shall retain all documents and data in any format relating to the investigation of any adverse event, near miss or intentional unsafe act for a period of at least seven (7) years and discarding or destruction of such documents and data in any format during that period is prohibited.

1.10 Enforcement

The Department may use all enforcement powers granted to it under Title 18 to ensure compliance with the requirements of 18 V.S.A. Chapter 43A and this rule.

II. Hospital Policies, Procedures and Reporting Related to All Adverse Events and Near Misses

2.1. Identification, Tracking and Analysis

Each hospital shall establish an internal reporting system and develop and implement policies and procedures to identify, track, and analyze reportable adverse events, non-reportable adverse events, and near misses and shall use that data to improve patient safety. The policies and procedures shall include:

1. Provisions to ensure that the internal reporting system is easily accessible to all hospital staff;

2. A process for how and when hospital staff submit reports through the internal reporting system;

3. A designated entity responsible for receiving internal reports;

4. A process and specific criteria for determining and implementing the appropriate level of analysis for non-reportable adverse events and near misses;

5. A process for review and ongoing monitoring of all internal reports to ensure timely identification of reportable adverse events;

6. The process for using internal report data and analyses of reports to improve quality of care and patient safety; and

7. A process for periodic education of hospital staff concerning internal reporting requirements.

2.2 Causal Analyses

A causal analysis shall be conducted on each reportable adverse event. A causal analysis shall include:

1. Interdisciplinary participation including individuals closely involved in the processes and systems under review;

2. A detailed description of the reportable adverse event including date, day of week, time and location and services involved and chronology of events;

3. A primary focus on systems and processes rather than individual performance;

4. A systematic and comprehensive assessment of factors contributing to the reportable adverse event, as applicable to the specific event; and

5. Consideration of literature relevant to the specific reportable adverse event.

2.3 Corrective Action Plans

A corrective action plan shall be developed and implemented for each reportable adverse event. A corrective action plan shall include:

1. Specific actions to correct the identified causes of the event to prevent a similar event occurring in the future;

2. Identified and measurable outcome(s);

3. A designated person(s) responsible for implementation and evaluation; and

4. A specific implementation plan with the following:
   A. Completion dates;
   B. Provisions for education of and communication with appropriate hospital staff; and
   C. A description of how the hospital's performance will be assessed and evaluated following full implementation.

2.4 Disclosures to Patients

Each hospital shall develop and implement policies and procedures requiring disclosures to patients, or, in the case of a patient death, an adult member of the immediate family, relating to, at a minimum, adverse events that cause death or serious bodily injury, including those resulting from intentional unsafe acts. Using appropriate professional expertise, the policies and procedures shall be designed to minimize trauma and protect the confidentiality and emotional health of all of the participants to the extent possible. The policies and procedures shall include:

1. Guidance regarding timely disclosure(s);

2. A description of the process for determining which individual(s) will be responsible for participating in the disclosures;

3. A description of resources available to assist individual(s) responsible for disclosures;

4. A description of requirements for documentation of the disclosure(s) in the patient medical record; and

5. A process for periodic education of appropriate hospital staff relating to patient disclosures policies.

Hospital patient disclosure policies and procedures may include provisions for disclosures to other than immediate family members in the absence of an adult member of the immediate family to the extent permitted by law.

2.5 List of Reportable Adverse Events

1. Reportable adverse events are the serious reportable events and specifications published and periodically amended by the National Quality Forum, which are incorporated in this rule by reference. The Department will provide a link from its website to the serious reportable events and specifications on the NQF website and will provide a printed copy on request.

2. The Department will notify each hospital when NQF publishes an amendment to the serious reportable events and specifications and immediately upon such notification the amended serious reportable events and specifications will be the reportable adverse events for purposes of this rule.

2.6 Submitting Reportable Adverse Event Reports

1. Each hospital shall submit the following required reports to the Patient Safety Surveillance and Improvement System relating to each reportable adverse event:

   A. Initial report. Each hospital shall submit an initial report as soon as reasonably possible and no later than seven (7) calendar days after discovery or recognition of the reportable adverse event.

   B. Causal analysis and corrective action plan. Each hospital shall submit the causal analysis and corrective action plan no later than sixty (60) calendar days from the submission of the initial report. The Patient Safety Surveillance and Improvement System will review the causal analysis and corrective action plan and may require the hospital to provide additional information, including periodic interim reports and/or modifications to the causal analysis or to the corrective action plan.

   C. The submissions required by this section shall be on a form approved by the Department, unless the reportable adverse event must also by law be reported to another department or agency, in which instance the hospital may notify the Department or provide a copy of any written report provided to the other department or agency. When the hospital submits a copy of a written report provided to another department or agency, the Patient Safety Surveillance and Improvement System will review the report and may require additional causal analysis information from the hospital.

2. A hospital may file a request for an extension of the filing date of any of the submissions due under this rule. Any request for extension shall be filed prior to the due date of the report. In its sole discretion, the Patient Safety Surveillance and Improvement System may grant or deny the request for all or some of the requested extension period.

3. No names of individuals shall be included in any submissions to the Patient Safety Surveillance and Improvement System required under Part II of this rule. The hospital shall make the complete file relating to the reportable adverse event available on-site at the hospital to the Patient Safety Surveillance and Improvement System upon request as part of routine periodic monitoring or a focused compliance review.

4. If a federal or state regulatory body or an accrediting body is engaged in a review of a reportable adverse event at a hospital and has approved a corrective action plan, then the hospital may file the approved corrective action plan with the Patient Safety Surveillance and Improvement System

and upon request of the hospital, and in the sole discretion of the Commissioner, the Commissioner may waive all or some of the submission requirements of this section.

III. Hospital Policies, Procedures and Reporting Related to Intentional Unsafe Acts

3.1 Identification of Intentional Unsafe Acts

Each hospital shall establish an internal reporting system and develop and implement policies and procedures for ensuring timely identification and reporting to the Patient Safety Surveillance and Improvement System of all intentional unsafe acts. The policies and procedures shall include:

1. Provisions to ensure that the internal reporting system is easily accessible to all hospital staff;

2. A process for how and when hospital staff submit reports of intentional unsafe acts through the internal reporting system;

3. A designated entity responsible for receiving internal reports;

5. A process for review and ongoing monitoring of all internal reports to ensure timely identification of intentional unsafe acts; and

6. A process for periodic education of hospital staff concerning internal reporting of intentional unsafe acts.

3.2 Intentional Unsafe Act Criteria

1. An act or omission by hospital staff resulting in an adverse event or near miss is an intentional unsafe act only if all of the following criteria are met:

   A. The act or omission was directly associated with patient care or services; and

   B. The act or omission affected or could have affected a patient or patients, regardless of whether an actual patient injury occurred; and

   C. The information available to the hospital supports a reasonable, good faith belief that the adverse event or near miss resulted from one or more of the following:

1. The act or omission was a criminal act, including circumstances where there may have been an intent to harm; or
2. The act or omission was purposefully unsafe as defined in Section 3.2.2; or
3. The act or omission took place while the individual involved was under the influence of alcohol or other substances; or
4. The act or omission was of a type or nature that Vermont law makes reportable to a designated department or agency as abuse, neglect or exploitation.

2. An act or omission by hospital staff resulting in an adverse event or near miss shall be considered to be purposefully unsafe only if it meets all of the following criteria:

A. There was a conscious act or omission or reckless behavior; and
B. The adverse event or near miss did not happen as a result of understandable accident or inadvertence; and
C. No reasonable person with similar qualifications, training and experience would have acted the same way under similar circumstances; and
D. There were no extenuating circumstances that could justify the act or omission.

3.3 Reporting Intentional Unsafe Acts

1. Each hospital shall report an intentional unsafe act to the Patient Safety Surveillance and Improvement System as soon as reasonably possible, but no later than seven (7) calendar days after the information available to the hospital supports a reasonable, good faith belief that an intentional unsafe act has occurred.

2. The report shall be submitted on a form approved by the Department or, if the intentional unsafe act has been reported in writing to another department or agency, the hospital may provide a copy of that written report. The Patient Safety Surveillance and Improvement System will review the report and may require additional information from the hospital. Each hospital shall provide the Department with all requested information relating to a report of an intentional unsafe act.

3. Complete names of individuals involved in the intentional unsafe act shall be provided in the report to the Patient Safety Surveillance and Improvement System.

3.4 Reporting Intentional Unsafe Acts to Relevant State and Federal Licensing and Law Enforcement Authorities

1. Each hospital shall promptly notify the Patient Safety Surveillance and Improvement System of each relevant state and federal licensing or other regulatory entity and each state and federal law enforcement authority that the hospital has notified of an intentional unsafe act.

2. If a hospital has reported an intentional unsafe act to all relevant state and federal licensing and other regulatory entities and all relevant state and federal law enforcement authorities and provided a copy of each report to the Patient Safety Surveillance and Improvement System, then the Department may take no further action to confirm or independently conclude whether an intentional unsafe act has occurred.

3. Whether to take any action to confirm or independently conclude whether an intentional unsafe act has occurred shall be in the sole of the Commissioner.

4. When the Department confirms or independently concludes, based on a reasonable good faith belief that an intentional unsafe act has occurred, it shall notify relevant state and federal licensing and other regulatory entities and, in the case of possible criminal activity, relevant state and federal law enforcement authorities, except that the Department is not required to notify authorities it has confirmed have already received notification of the intentional unsafe act.

IV. Compliance Monitoring

4.1 Routine Periodic Monitoring

1. The Patient Safety Surveillance and Improvement System will conduct routine periodic reviews to evaluate a hospital's compliance with the requirements of 18 V.S.A. Chapter 43A and this rule and specifically review the following:

   A. The hospital's policies and procedures with respect to near misses, non-reportable adverse events, reportable adverse events, and intentional unsafe acts; and
   B. The implementation of hospital policies and procedures with respect to near misses, non-reportable adverse events, reportable adverse events, and intentional unsafe acts; and
   C. The effectiveness of any corrective action plans implemented to address reportable adverse events or intentional unsafe acts.

2. During the routine periodic review the hospital shall demonstrate the following:

   A. That policies and procedures required by this rule have been adopted and implemented;
   B. A process to ensure timely compliance with reporting requirements of this rule;
   C. A description of how patient safety data and analyses are made available to hospital leadership;
   D. A process for periodically evaluating the effectiveness of the policies and procedures that relate to:
      1. Identifying, tracking and analyzing reportable adverse events, non-reportable adverse events and near misses;
      2. Identifying and reporting intentional unsafe acts; and
      3. Patient disclosures;
   E. Guidance relating to the setting or circumstances in which patient disclosures will be made; and
   F. That internal report data and analyses of reports are used to improve patient safety.

3. During the routine periodic review, hospitals shall provide the Patient Safety Surveillance and Improvement System with access to all information requested relating to and for the purpose of evaluating compliance with the requirements of 18 V.S.A. Chapter 43A and this rule, including, but not limited to, the following:

   A. Original medical records, documents and databases in any format;
   B. Interviews with hospital staff; and
   C. Observation of any area of the facility.

4. For the purpose of evaluating a hospital's compliance with the requirements of 18 V.S.A. Chapter 43A and this rule, the hospital shall provide the Patient Safety Surveillance and Improvement System with reasonable access to:

   A. information protected by provisions of the patient's privilege under 12 V.S.A. § 1612(a) or otherwise required by law to be held confidential; and
   B. the minutes and records of a peer review committee and any other information subject to peer review protection under 26 V.S.A. § 1443, including interviews with peer review participants.

5. The hospital shall provide copies of records and documents upon request by the Patient Safety Surveillance and Improvement System.

6. Routine periodic reviews will take place on site at the hospital and will generally be conducted every three years and more or less frequently as the Commissioner in his or her sole discretion deems appropriate.

7. The Patient Safety Surveillance and Improvement System will schedule routine periodic reviews with the hospital in advance.

8. The Patient Safety Surveillance and Improvement System may use any publicly available information as part of its compliance monitoring activities.

4.2 <u>Focused Compliance Review</u>

1. When, in the sole discretion of the Commissioner, circumstances warrant the Patient Safety Surveillance and Improvement System may conduct a focused compliance review of:

   A. Implementation of a specific corrective action plan of a reportable adverse event; or
   B. One or more specific hospital policies and procedures with respect to one or more specific near misses, adverse events, reportable adverse events and/or intentional unsafe acts; or
   C. Implementation of hospital policies and procedures with respect to one or more specific near misses, adverse events, reportable adverse events and/or intentional unsafe acts; or
   D. Compliance with the requirements of 18 V.S.A. Chapter 43A and this rule.

2. During a focused compliance review, the hospital shall provide the Patient Safety Surveillance and Improvement System with access to all information requested relating to the focus of the review, including but not limited to the following:

   A. All original medical records, documents and databases in any format.
   B. Interviews with hospital staff, which may or may not include other staff members.
   C. Observation of any area of the facility.

3. For the purpose of the focused compliance review, the hospital shall provide the Patient Safety Surveillance and Improvement System with reasonable access to:
   A. information protected by provisions of the patient's privilege under 12 V.S.A. § 1612(a) or otherwise required by law to be held confidential; and

B. the minutes and records of a peer review committee and any other information subject to peer review protection under 26 V.S.A. § 1443, including observed or unobserved interviews with peer review participants.

4. Upon request by the Patient Safety Surveillance and Improvement System the hospital shall provide copies of records and documents.

5. A focused compliance review may be unannounced and on-site at the hospital.

6. The Patient Safety Surveillance and Improvement System may use any publicly available information as part of its compliance monitoring activities.