

## Hospital Licensing Rule

### 1.0 Authority

This rule is adopted pursuant to 18 V.S.A. Ch. 42, 18 V.S.A. Ch. 43 and 18 V.S.A. Ch. 43a.

### 2.0 Purpose

This rule sets forth the standards that apply to the licensing of Hospitals in Vermont. Specifically:

- 2.1 This rule applies to all Hospitals in Vermont not excluded from 18 V.S.A. Ch. 43 by 18 V.S.A. §1902 (1)(I).
- 2.2 Services, whether inpatient or outpatient, offered in separate buildings or on separate premises that do not by themselves meet the definition of a Hospital but in which services are provided and billed for under the same Centers for Medicare and Medicaid Services (CMS) Provider Number shall be considered services of the Hospital for the purpose of this rule.

### 3.0 Definitions

- 3.1 “Accreditation” means the formal recognition by an approved accrediting body such as the Joint Commission that indicates conformity with the accrediting body’s required set of standards and criteria.
- 3.2 “Board” means the State Board of Health which Board serves as the licensing agency contemplated by 18 V.S.A. Ch. 43.
- 3.3 “CMS” means the Centers for Medicare and Medicaid Services of the U.S. Department of Health and Human Services.
- 3.4 “CMS Conditions of Participation for Hospitals” or “CoPs” means the following current Centers of Medicare and Medicaid Services rules from the Code of Federal Regulations (CFR) and related laws and regulations, interpretive guidelines, appendices and requirements.
  - 3.4.1 Hospitals: 42 CFR 482.1-482.57
  - 3.4.2 Psychiatric Hospitals and units: 42 CFR 482.60-482.66
  - 3.4.3 Critical Access Hospitals: 42 CFR 485.601-485.645
- 3.5 “Commissioner” means the Commissioner of the Vermont Department of Health.

- 3.6 “Deemed Status” means the status granted to a Hospital by a CMS-approved national accrediting body, such as the Joint Commission, after it has surveyed the Hospital and determined it is in compliance with all CMS Conditions of Participation.
- 3.7 “Deficiency” means a policy, procedure, practice or any other action by a Hospital that results in the Hospital not being in compliance with this rule or with the CMS Conditions of Participation.
- 3.8 “Department” means the Vermont Department of Health.
- 3.9 “Hospital” means a place devoted primarily to the maintenance and operation of diagnostic and therapeutic facilities for inpatient medical or surgical care of individuals who have an illness, disease, or injury or physical disability or for obstetrics as defined at 18 V.S.A. § 1902 (1). It does not include nursing and convalescent homes, or any hospital operated by the United States government.
- 3.10 “Joint Commission” means an independent not for profit organization that accredits and certifies that healthcare organizations meet certain performance standards.
- 3.11 “Patients’ Bill of Rights” means the rights to which patients in Vermont Hospitals are entitled under the authority of 18 V.S.A. Ch. 42.
- 3.12 “Patient Complaint” means any expression of dissatisfaction of the care and treatment provided by a hospital, from a patient or the patient’s representative. In this Rule, the term includes patient “grievance” which in the CoPs and CMS State Operations Manual specifically refers to complaints presented to and resolved or attempted to be resolved within the hospital’s internal system.
- 3.13 “Plan of Correction” means a written plan that a licensee is required to submit to address any identified Deficiency to bring a Hospital into compliance with this rule.
- 3.14 “State Survey Agency” means the unit of Vermont state government designated by the Centers for Medicare and Medicaid Services to enforce the federal Conditions of Participation for Hospitals in Vermont.
- 3.15 “Validation Survey” means a survey conducted by the State Survey Agency on behalf of CMS to ensure that a Hospital with Deemed Status is in compliance with the conditions of participation.

#### **4.0 Application for a Hospital License**

- 4.1 No organization or individual may establish, conduct, or maintain operation of a Hospital in Vermont without being granted a license by the State Licensing Agency.
- 4.2 Every Vermont Hospital license shall expire on December 31 of each year unless otherwise revoked.
- 4.3 An application for a Hospital license, or renewal of a license, shall be submitted by a deadline set by the Department and in a form required by the Department and available on its webpage.
- 4.4 The application shall contain all information required by the Department and be accompanied by a license fee in the amount required by law and posted on the webpage. The required information shall include:
  - 4.4.1 Identifying information and all facility locations.
  - 4.4.2 Administrative officers and contact information for the person completing the application.
  - 4.4.3 Type of hospital, form of organization, and CMS designation.
  - 4.4.4 Certification and accreditation status.
  - 4.4.5 Numbers of beds and bassinets, including proposed distribution of beds by location and department.
  - 4.4.6 Verification of compliance with the requirements of the Patient's Bill of Rights, 18 V.S.A. § 1852, and any required explanation.
  - 4.4.7 Verification of other statutory requirements.
  - 4.4.8 Information regarding the plan for handling of patient complaints and the staff member responsible for that program.
  - 4.4.9 Information needed for calculation of the license fee per 18 V.S.A. § 1904.
  - 4.4.10 Provide the Hospital's current procedure for informing patients of their rights in accordance with 18 V.S.A. Ch. 42, and its plan for implementing the Patients' Bill of Rights.
  - 4.4.11 Applications for a Hospital license or renewal shall certify compliance with the Patient Safety Surveillance and Improvement System regulations adopted by the Commissioner pursuant to 18 V.S.A. Ch. 43a and with other safety and sanitary standards required by law.

- 4.5 Unless the Department specifies a different time or format for response, a Hospital that receives an inquiry from the Department regarding the licensing application shall furnish all information requested within ten (10) working days of receipt.

## **5.0 Requirements for Hospital Licensure in Vermont**

### **5.1 Compliance with CMS Conditions of Participation**

- 5.1.1 To be licensed and retain licensure in Vermont, each Hospital shall comply with all applicable CMS Conditions of Participation referenced in Section 3.4 of this rule or be operating under a Plan of Correction as described in Section 7.0 of this rule.
- 5.1.2 To demonstrate compliance with CoPs, each Vermont Hospital shall make themselves available for a comprehensive, on-site and unannounced survey by the State Survey Agency:
- 5.1.2.1 Occurring on average once every three years or at a frequency determined by CMS.
- 5.1.2.2 Whenever CMS requires a Validation Survey for an accredited Hospital with Deemed Status.
- 5.1.2.3 Whenever the Department or its designee determines that a survey is required as referenced in Section 5.3 of this rule.
- 5.1.3 As part of the annual Hospital licensing process, each Hospital shall provide to the Department any documents necessary to verify that the applicant Hospital has met the requirements of the CoPs.
- 5.1.4 A Hospital license is not transferable or assignable and shall be issued only for the premises and persons named in the application. A licensed Hospital contemplating a change of ownership or the elimination or significant reduction of clinical services shall provide at least ninety (90) days advance notice to the Licensing Agency.
- 5.1.5 The Hospital license shall be posted in a conspicuous place on the licensed facility's premises.

### **5.2 Demonstrating Compliance with CMS CoPs by Deemed Status**

- 5.2.1 As long as CMS recognizes that Hospitals accredited by the Joint Commission and with Deemed Status meet the compliance requirements of the CoPs, each Accredited Hospital with Deemed Status shall be

considered by the State Survey Agency and the Licensing Agency to have met the CoPs unless and until their accreditation is revoked or cancelled.

5.2.2 In the event that a Hospital relies on an accrediting body other than the Joint Commission to determine that it has met the CoPs, the Hospital must provide verification that CMS has approved the accrediting body to authorize Deemed Status.

5.2.3 A Hospital with Deemed Status shall make the institution available for a Validation Survey by the State Survey Agency when CMS requires a Validation Survey.

### **5.3 Health and Life Safety Regulatory Requirements**

In addition to conforming to all CoPs, each Vermont Hospital seeking licensure shall comply with Title VI of the Public Health Service Act and with Public Health Service regulations, Part 53, and with Appendix of A of same, as well as current state law and regulations including, but not limited to, the Department of Public Safety Rules on Vermont Fire and Building Safety Codes and other Vermont rules related to food safety and patient safety systems as defined at 18 V.S.A. Ch. 43a.

### **5.4 Emergency Preparedness Planning**

5.5.1 Until such time that CMS adopts Hospital Emergency Preparedness regulations, each Vermont Hospital shall have its own Emergency Preparedness Plan as required by CMS regulations at 42 CFR § 482.41(a) and the associated guidelines.

5.5.2 Each Hospital shall provide a copy of its Emergency Preparedness Plan to the Department for review if requested.

5.5.3 All Vermont Hospitals shall comply with the any adopted CMS regulations.

### **5.5 Patients' Rights**

A Hospital's application for licensure must contain a copy of its clear language version of its Bill of Rights and its policies and procedures for informing patients of their rights in accordance with 18 V.S.A. Ch. 42, and its policies and procedures for handling patient complaints. The specific requirements for these provisions are set out in Section 6.0 of this rule.

## **6.0 Hospital Response and Management of Complaints**

### **6.1 Patients' Rights**

Each Vermont Hospital shall:

- 6.1.1 Distribute to all patients upon admission a clear language and easily readable print copy of the Patients' Bill of Rights required by 18 V.S.A. Ch. 42.
- 6.1.2 Post conspicuously the Patients' Bill of Rights in areas frequented by patients and patient representatives and on its website
- 6.1.3 Comply with the Patient Rights provisions of 18 V.S.A. Ch. 42 and make available to the Department a copy of its clear language statement of its Patients' Bill of Rights in addition to any provisions for patients' rights in the CoPs.
- 6.1.4 Provide during each annual licensure application its current procedure for informing patients of their rights in accordance with 18 V.S.A. Ch. 42, and its plan for implementing the Patients' Bill of Rights.

### **6.2 Procedures for Responding to Patient Complaints**

The following information shall be included with the Bill of Rights distributed to each patient admitted to a Vermont Hospital:

- 6.2.1 A description of the procedure for filing and appealing a complaint to the Hospital, clearly labeled, "To file a complaint" or "What to do if you are not satisfied with our response to your complaint". Other descriptors such as "patient concerns" or "consumer feedback" may be used, but only in addition to "To file a complaint" or "What to do if you are not satisfied with our response to your complaint."
- 6.2.2 A notice that a complainant may directly contact the Licensing Agency, the Board of Medical Practice, or the licensing authorities for other health care professions as an alternative, or in addition to, the Hospital's complaint and appeal procedures. The notice shall include the address and phone numbers for the Boards and the Office of Professional Regulation.
- 6.2.3 A published time frame for processing and resolving complaints and appeals within the hospital and notice that further appeals may be made to the Licensing Agency.

- 6.2.3 A notice that the Hospital has designated a qualified person or persons to act as patient representative(s). The notice must include the title, qualifications and general duties of the patient representative(s) and the phone and e-mail contact information for the current patient representative(s);
- 6.2.4 A description of internal procedures for receiving, processing and resolving complaints from or filed on behalf of patients. Such procedures must ensure that the Hospital complies with the Conditions of Participation requirements for grievances.
- 6.2.5 Each Hospital applicant shall be prepared to demonstrate to the Licensing Agency that the Hospital has the following:
- 6.2.5.1 A procedure for ensuring notification to the Board of substantial revisions to its statement of the Patients Bill of Rights and procedures for implementing it;
- 6.2.5.2 The necessary procedures and resources in place to ensure that the Hospital can fulfill its obligations with respect to the Hospital Bill of Rights in a timely and adequate manner;
- 6.2.5.3 Maintains adequate records of consumer complaints and their resolution;
- 6.2.5.4 Documentation that the Hospital complies with all other applicable requirements pertaining to patients' rights, including but not limited to those related to patients who are hospitalized involuntarily.

### **6.3 Reporting Complaint Data**

At least annually, on a schedule and in a format acceptable to the Commissioner, a Hospital shall submit to the Department a report summarizing, in aggregate, the types of complaints filed with the Hospital by patients or their representatives in the past year. The report must contain:

- The number of inpatient days for the reporting period;
- The total number of complaints received; and
- The total number of complaints in each of the categories the Hospital uses to track complaints; and
- A brief narrative report describing examples of actions taken to resolve complaints in the past year.

## 7.0 Enforcement

- 7.1 The Board and the Commissioner may use any and all powers granted to them under Title 18 of the Vermont Statutes Annotated in the course of monitoring, investigating or otherwise ensuring compliance with the requirements of this regulation.
- 7.2 Notwithstanding a CMS-approved national accrediting body's determination that a Hospital has met CoPs through surveys or Deemed Status, the Department or its designee may independently review or investigate a Hospital and make its own recommendation to the Board as to whether a Hospital is in compliance with requirements for Hospital licensure under Vermont law.
- 7.3 If the Department determines that a Hospital is not in full compliance with any requirements of this regulation, it shall notify the Hospital of the Deficiency.
- 7.4 When notified of a Deficiency, a Hospital shall within 30 days, or such shorter period as may be specified in the notice for good cause, develop and submit a Plan of Correction for addressing any identified Deficiency and for achieving compliance with this rule.
- 7.5 Department Review and Response to Plan of Correction
- 7.5.1 The Department shall determine whether a Plan of Correction submitted pursuant to Section 7.3 of this rule is sufficient to effectively address each identified Deficiency and bring the Hospital in compliance with the requirements of this rule.
- 7.5.2 Within thirty (30) days after receipt of a Plan of Correction, the Department shall notify the Hospital of one of the following actions related to each identified Deficiency:
- 7.5.2.1 Accept the Plan of Correction
- 7.5.2.2 Request a revision to the Plan of Correction specifying the reasons for the request.
- 7.5.3 A Hospital required to submit a revised Plan of Correction pursuant to Section 7.4.2.2 of this rule shall develop and submit the revision within thirty (30) days during which time the Department shall make available a representative to review with the Hospital any proposed revisions.
- 7.6 If, after reviewing a revised Plan of Correction, the Department determines that a Hospital is not in full compliance with this rule or cannot comply with this rule or



the Hospital's Plan of Correction, the Department may find that the Hospital is in violation of this regulation.

- 7.7 If the Department finds that a Hospital is in violation of this regulation it may recommend to the Board of Health that it:
- 7.7.1 Modify a current license to make it subject to fulfillment of specified conditions, including requirements for the submission of written plans, progress reports and any other information required by the Department that demonstrates to the satisfaction of the Department and Board that the Hospital is actively and effectively taking all necessary steps to comply with its license conditions;
  - 7.7.2 Issue or renew a license subject to fulfillment of specified conditions, including requirements for the submission of written plans, progress reports and any other information required by the Department that demonstrates to the satisfaction of the Department and Board that the Hospital is actively and effectively taking all necessary steps to comply with its license conditions;
  - 7.7.3 Issue a temporary license to the Hospital for a total period not to exceed thirty-six consecutive months, specifying requirements for the submission of written plans, progress reports and any other information required by the Department that demonstrates to the satisfaction of the Department and Board that the Hospital is actively and effectively taking all necessary steps to come into full compliance within the period of time permitted by the temporary license.
- 7.8 If the Department finds that a Hospital is in substantial violation of this regulation it may recommend to the Board that it:
- 7.8.1 Not issue or renew the Hospital's license;
  - 7.8.2 Revoke the Hospital's license; and/or
  - 7.8.3 Impose, or recommend that the Department impose, any other penalties permitted by law.
- 7.9 In the event that the Board intends to take any of the actions set forth in subsections 7.6 and 7.7 above, the following due process procedures consistent with 18 V.S.A. Ch. 43 and 3 V.S.A. Ch. 25 relating to contested cases, shall be followed:
- 7.8.1 Notice shall be served on the Hospital by registered mail or by personal service, setting forth detailed reasons for the proposed action and fixing a date not less than sixty (60) days from the date of such mailing or service, or, not less than fourteen (14) days in the event of a determination of

patient jeopardy, at which the Hospital shall be given opportunity for a hearing.

- 7.8.2 The Hospital may, within thirty (30) days after issuance of the decision from the Board, appeal to the Vermont Superior Court in the county where the Hospital is located. The court may affirm, modify or reverse the decision of the Board and either the Hospital or the Board or the Department may appeal to the Vermont Supreme Court for such further review as is provided by law.

## **8.0 Effective Date**

This will need to be inserted at a later date.