

Administrative Procedures – Emergency Rule Filing

Instructions:

In accordance with Title 3 Chapter 25 of the Vermont Statutes Annotated and the “Rule on Rulemaking” ([CVR 04-000-001](#)) adopted by the Office of the Secretary of State, this emergency filing will be considered complete upon filing and acceptance of these forms with the Office of the Secretary of State, the Legislative Committee on Administrative Rules and a copy with the Chair of the Interagency Committee on Administrative Rules.

All forms requiring a signature shall be original signatures of the appropriate adopting authority or authorized person, and all filings are to be submitted at the Office of the Secretary of State, no later than 3:30 pm on the last scheduled day of the work week.

The data provided in text areas of these forms will be used to generate a notice of rulemaking in the portal of “Proposed Rule Postings” online, and the newspapers of record if the rule is marked for publication. Publication of notices will be charged back to the promulgating agency.

This emergency rule may remain in effect for a total of 180 days from the date it first takes effect.

Certification Statement: As the adopting Authority of this rule (see 3 V.S.A. § 801(b)(11) for a definition), I believe there exists an imminent peril to public health, safety or welfare, requiring the adoption of this emergency rule.

The nature of the peril is as follows (*PLEASE USE ADDITIONAL SHEETS IF SPACE IS INSUFFICIENT*). This Rule allows the State to automatically issue waivers to hospitals consistent with CMS waivers. In a declared health emergency, the lack of hospital availability could be life threatening.

I approve the contents of this filing entitled:

Hospital Licensing Rule

_____, on _____.

(signature) (date)

Printed Name and Title:

Michael K. Smith

Secretary

RECEIVED BY: _____

- Coversheet
- Adopting Page
- Economic Impact Analysis
- Environmental Impact Analysis
- Strategy for Maximizing Public Input
- Scientific Information Statement (if applicable)
- Incorporated by Reference Statement (if applicable)
- Clean text of the rule (Amended text without annotation)
- Annotated text (Clearly marking changes from previous rule)

Emergency Rule Coversheet
Agency of Human Services

Emergency Rule Coversheet

1. TITLE OF RULE FILING:

Hospital Licensing Rule

2. ADOPTING AGENCY:

Vermont Department of Health

3. PRIMARY CONTACT PERSON:

(A PERSON WHO IS ABLE TO ANSWER QUESTIONS ABOUT THE CONTENT OF THE RULE).

Name: David Englander

Agency: Vermont Department of Health

Mailing Address: Vermont Department of Health, 108 Cherry Street, Burlington, VT 05402

Telephone: 802 863 - 7280 Fax: 802 951 - 1275

E-Mail: ahs.vdhrules@vermont.gov

Web URL *(WHERE THE RULE WILL BE POSTED)*:

<https://www.healthvermont.gov/about-us/laws-regulations/public-comment>

4. SECONDARY CONTACT PERSON:

(A SPECIFIC PERSON FROM WHOM COPIES OF FILINGS MAY BE REQUESTED OR WHO MAY ANSWER QUESTIONS ABOUT FORMS SUBMITTED FOR FILING IF DIFFERENT FROM THE PRIMARY CONTACT PERSON).

Name: Brendan Atwood

Agency: Vermont Department of Health

Mailing Address: Vermont Department of Health, 108 Cherry Street, Burlington, VT 05402

Telephone: 802 863 - 7280 Fax: 802 951 - 1275

E-Mail: ahs.vdhrules@vermont.gov

5. RECORDS EXEMPTION INCLUDED WITHIN RULE:

(DOES THE RULE CONTAIN ANY PROVISION DESIGNATING INFORMATION AS CONFIDENTIAL; LIMITING ITS PUBLIC RELEASE; OR OTHERWISE EXEMPTING IT FROM INSPECTION AND COPYING?) No

IF YES, CITE THE STATUTORY AUTHORITY FOR THE EXEMPTION:

PLEASE SUMMARIZE THE REASON FOR THE EXEMPTION:

6. LEGAL AUTHORITY / ENABLING LEGISLATION:

Emergency Rule Coversheet

(THE SPECIFIC STATUTORY OR LEGAL CITATION FROM SESSION LAW INDICATING WHO THE ADOPTING ENTITY IS AND THUS WHO THE SIGNATORY SHOULD BE. THIS SHOULD BE A SPECIFIC CITATION NOT A CHAPTER CITATION).

3 V.S.A. §801(b) (11); 18 V.S.A. Ch.42, 18 V.S.A. Ch.43 and 18 V.S.A. Ch. 43a.

7. EXPLANATION OF HOW THE RULE IS WITHIN THE AUTHORITY OF THE AGENCY:

18 V.S.A. § 1908 (a) states, "The licensing agency shall adopt and enforce rules and standards with respect to the different types of hospitals to be licensed hereunder as may be designed to further the accomplishment of the purposes herein set forth."

8. CONCISE SUMMARY (150 WORDS OR LESS):

This rule allows hospitals that have been granted wavier by the U.S. Centers for Medicare & Medicaid Services (CMS) under Section 1135 of the Social Security Act (during an emergency as defined 42 U.S.C. 1320b-5) to be automatically granted waivers for their Vermont licenses. The 1135 waiver allows "the Secretary to ensure to the maximum extent feasible, in any emergency area and during an emergency period...that sufficient health care items and services are available to meet the needs of individuals..." In this instance, there is no need for Vermont to duplicate CMS's efforts.

9. EXPLANATION OF WHY THE RULE IS NECESSARY:

In the current pandemic, in this declared state of emergency (see Governor rescinds Order 01-20 and its addenda), there may well be a need to for a surge in hospital beds. Licensing of Vermont hospitals, while still maintaining high levels of care, could save lives.

10. EXPLANATION OF HOW THE RULE IS NOT ARBITRARY:

The proposal is narrowly tailored to ensure no duplication of effort during an emergency. See above.

11. LIST OF PEOPLE, ENTERPRISES AND GOVERNMENT ENTITIES AFFECTED BY THIS RULE:

Hospitals and patients.

12. BRIEF SUMMARY OF ECONOMIC IMPACT (150 WORDS OR LESS):

The rule itself imposes no economic impact. The fewer people get sick, or are treated in hospitals will mean less cost on the health care system, and the faster people can return to their daily lives, families, and loved ones.

13. A HEARING IS NOT SCHEDULED .

14. HEARING INFORMATION

(THE FIRST HEARING SHALL BE NO SOONER THAN 30 DAYS FOLLOWING THE POSTING OF NOTICES ONLINE).

IF THIS FORM IS INSUFFICIENT TO LIST THE INFORMATION FOR EACH HEARING PLEASE ATTACH A SEPARATE SHEET TO COMPLETE THE HEARING INFORMATION NEEDED FOR THE NOTICE OF RULEMAKING.

Date:

Time: AM

Street Address:

Zip Code:

Date:

Time: AM

Street Address:

Zip Code:

15. DEADLINE FOR COMMENT (NO EARLIER THAN 7 DAYS FOLLOWING LAST HEARING):

16. EMERGENCY RULE EFFECTIVE: 03/27/2020

17. EMERGENCY RULE WILL REMAIN IN EFFECT UNTIL

(A DATE NO LATER THAN 180 DAYS FOLLOWING ADOPTION OF THIS EMERGENCY RULE):

09/23/2020

18. NOTICE OF THIS EMERGENCY RULE SHOULD BE PUBLISHED IN THE WEEKLY NOTICES OF RULEMAKING IN THE NEWSPAPERS OF RECORD.

19. KEYWORDS (PLEASE PROVIDE AT LEAST 3 KEYWORDS OR PHRASES TO AID IN THE SEARCHABILITY OF THE RULE NOTICE ONLINE).

Hospital

CMS

COVID-19

Patients

Administrative Procedures – Adopting Page

Instructions:

This form must accompany each filing made during the rulemaking process:

Note: To satisfy the requirement for an annotated text, an agency must submit the entire rule in annotated form with proposed and final proposed filings. Filing an annotated paragraph or page of a larger rule is not sufficient. Annotation must clearly show the changes to the rule.

When possible the agency shall file the annotated text, using the appropriate page or pages from the Code of Vermont Rules as a basis for the annotated version. New rules need not be accompanied by an annotated text.

1. TITLE OF RULE FILING:

Hospital Licensing Rule

2. ADOPTING AGENCY:

Vermont Department of Health

3. TYPE OF FILING (*PLEASE CHOOSE THE TYPE OF FILING FROM THE DROPDOWN MENU BASED ON THE DEFINITIONS PROVIDED BELOW*):

- **AMENDMENT** - Any change to an already existing rule, even if it is a complete rewrite of the rule, it is considered an amendment as long as the rule is replaced with other text.
- **NEW RULE** - A rule that did not previously exist even under a different name.
- **REPEAL** - The removal of a rule in its entirety, without replacing it with other text.

This filing is **AN AMENDMENT OF AN EXISTING RULE** .

4. LAST ADOPTED (*PLEASE PROVIDE THE SOS LOG#, TITLE AND EFFECTIVE DATE OF THE LAST ADOPTION FOR THE EXISTING RULE*):

July 1, 2017 Secretary of State Rule Log #17-034.

Administrative Procedures – Economic Impact Analysis

Instructions:

In completing the economic impact analysis, an agency analyzes and evaluates the anticipated costs and benefits to be expected from adoption of the rule; estimates the costs and benefits for each category of people enterprises and government entities affected by the rule; compares alternatives to adopting the rule; and explains their analysis concluding that rulemaking is the most appropriate method of achieving the regulatory purpose.

Rules affecting or regulating schools or school districts must include cost implications to local school districts and taxpayers in the impact statement, a clear statement of associated costs, and consideration of alternatives to the rule to reduce or ameliorate costs to local school districts while still achieving the objectives of the rule (see 3 V.S.A. § 832b for details).

Rules affecting small businesses (excluding impacts incidental to the purchase and payment of goods and services by the State or an agency thereof), must include ways that a business can reduce the cost or burden of compliance or an explanation of why the agency determines that such evaluation isn't appropriate, and an evaluation of creative, innovative or flexible methods of compliance that would not significantly impair the effectiveness of the rule or increase the risk to the health, safety, or welfare of the public or those affected by the rule.

1. TITLE OF RULE FILING:

Hospital Licensing Rule

2. ADOPTING AGENCY:

Vermont Department of Health

3. CATEGORY OF AFFECTED PARTIES:

LIST CATEGORIES OF PEOPLE, ENTERPRISES, AND GOVERNMENTAL ENTITIES POTENTIALLY AFFECTED BY THE ADOPTION OF THIS RULE AND THE ESTIMATED COSTS AND BENEFITS ANTICIPATED:

Hospitals: The rule will speed the time it takes to receive a license in the current emergency.

Patients: The fewer patients get very ill, and the faster they are treated, the quicker then return to their normal lives.

4. IMPACT ON SCHOOLS:

Economic Impact Analysis

INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON PUBLIC EDUCATION, PUBLIC SCHOOLS, LOCAL SCHOOL DISTRICTS AND/OR TAXPAYERS CLEARLY STATING ANY ASSOCIATED COSTS:

The current emergency has resulted in significant school closes. The more needed hospital care that is available, along with many other public health measures, the faster schools can be re-opened safely.

5. **ALTERNATIVES:** *CONSIDERATION OF ALTERNATIVES TO THE RULE TO REDUCE OR AMELIORATE COSTS TO LOCAL SCHOOL DISTRICTS WHILE STILL ACHIEVING THE OBJECTIVE OF THE RULE.*

This rule does reduce and ameliorate costs.

6. **IMPACT ON SMALL BUSINESSES:**

INDICATE ANY IMPACT THAT THE RULE WILL HAVE ON SMALL BUSINESSES (EXCLUDING IMPACTS INCIDENTAL TO THE PURCHASE AND PAYMENT OF GOODS AND SERVICES BY THE STATE OR AN AGENCY THEREOF):

See 3.

7. **SMALL BUSINESS COMPLIANCE:** *EXPLAIN WAYS A BUSINESS CAN REDUCE THE COST/BURDEN OF COMPLIANCE OR AN EXPLANATION OF WHY THE AGENCY DETERMINES THAT SUCH EVALUATION ISN'T APPROPRIATE.*

See 3.

8. **COMPARISON:**

COMPARE THE IMPACT OF THE RULE WITH THE ECONOMIC IMPACT OF OTHER ALTERNATIVES TO THE RULE, INCLUDING NO RULE ON THE SUBJECT OR A RULE HAVING SEPARATE REQUIREMENTS FOR SMALL BUSINESS:

See 3.

9. **SUFFICIENCY:** *EXPLAIN THE SUFFICIENCY OF THIS ECONOMIC IMPACT ANALYSIS.*

This rule is tailored to have a positive economic impact as described above.

Administrative Procedures – Environmental Impact Analysis

Instructions:

In completing the environmental impact analysis, an agency analyzes and evaluates the anticipated environmental impacts (positive or negative) to be expected from adoption of the rule; compares alternatives to adopting the rule; explains the sufficiency of the environmental impact analysis.

Examples of Environmental Impacts include but are not limited to:

- Impacts on the emission of greenhouse gases
- Impacts on the discharge of pollutants to water
- Impacts on the arability of land
- Impacts on the climate
- Impacts on the flow of water
- Impacts on recreation
- Or other environmental impacts

1. TITLE OF RULE FILING:

Hospital Licensing Rule

2. ADOPTING AGENCY:

Vermont Department of Health Vermont Department of Health

3. GREENHOUSE GAS: *EXPLAIN HOW THE RULE IMPACTS THE EMISSION OF GREENHOUSE GASES (E.G. TRANSPORTATION OF PEOPLE OR GOODS; BUILDING INFRASTRUCTURE; LAND USE AND DEVELOPMENT, WASTE GENERATION, ETC.):*

4. WATER: *EXPLAIN HOW THE RULE IMPACTS WATER (E.G. DISCHARGE / ELIMINATION OF POLLUTION INTO VERMONT WATERS, THE FLOW OF WATER IN THE STATE, WATER QUALITY ETC.):*

Not applicable.

5. LAND: *EXPLAIN HOW THE RULE IMPACTS LAND (E.G. IMPACTS ON FORESTRY, AGRICULTURE ETC.):*

Not applicable.

6. RECREATION: *EXPLAIN HOW THE RULE IMPACT RECREATION IN THE STATE:*

Not applicable.

7. CLIMATE: *EXPLAIN HOW THE RULE IMPACTS THE CLIMATE IN THE STATE:*

Not applicable.

Environmental Impact Analysis

8. **OTHER:** *EXPLAIN HOW THE RULE IMPACT OTHER ASPECTS OF VERMONT'S ENVIRONMENT:*

Not applicable.

9. **SUFFICIENCY:** *EXPLAIN THE SUFFICIENCY OF THIS ENVIRONMENTAL IMPACT ANALYSIS.*

Not applicable.

Administrative Procedures – Public Input

Instructions:

In completing the public input statement, an agency describes the strategy prescribed by ICAR to maximize public input, what it did do, or will do to comply with that plan to maximize the involvement of the public in the development of the rule.

This form must accompany each filing made during the rulemaking process:

1. TITLE OF RULE FILING:

Hospital Licensing Rule

2. ADOPTING AGENCY:

Vermont Department of Health

3. PLEASE DESCRIBE THE STRATEGY PRESCRIBED BY ICAR TO MAXIMIZE PUBLIC INVOLVEMENT IN THE DEVELOPMENT OF THE PROPOSED RULE:

4. PLEASE LIST THE STEPS THAT HAVE BEEN OR WILL BE TAKEN TO COMPLY WITH THAT STRATEGY:

5. BEYOND GENERAL ADVERTISEMENTS, PLEASE LIST THE PEOPLE AND ORGANIZATIONS THAT HAVE BEEN OR WILL BE INVOLVED IN THE DEVELOPMENT OF THE PROPOSED RULE:

The Vermont Association of Hospitals and Health Systems

University of Vermont Medical Center

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~~ unless
- 5.1.1.1 Operating under a Plan of Correction as described in Section 7.0 of this rule; or
- 5.1.1.2 Operating under a waiver granted under Section 1135 of the Social Security Act during an emergency as defined 42 U.S.C. Section 1320b-5.
- 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 on an inpatient basis 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.
- 6.2.4 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);
- 6.2.5 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.

6.2.6 Each Hospital applicant shall be prepared to demonstrate to the Licensing Agency that the Hospital has the following:

6.2.6.1 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;

6.2.6.2 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;

6.2.6.3 Maintains adequate records of consumer complaints and their resolution;

6.2.6.4 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.

6.2 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 7.7 and 7.8 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:
 - 7.9.1 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.
 - 7.9.2 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 Informing Patients of Investigation Completion

Upon completion of an investigation and determination as to whether an action is to be pursued under subsections 7.7 or 7.8 of this rule, the Complainant or his or her representative will be provided notice in writing. The notice shall state that the investigation is complete and whether a public proceeding regarding the license of the subject facility has resulted. Notice will be sent promptly and in no case more than 14

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days after the determination is made and shall include the time and place of any public proceeding.

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 unless
- 5.1.1.1 Operating under a Plan of Correction as described in Section 7.0 of this rule; or
 - 5.1.1.2 Operating under a waiver granted under Section 1135 of the Social Security Act during an emergency as defined 42 U.S.C. Section 1320b-5.
- 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 on an inpatient basis 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.
- 6.2.4 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);
- 6.2.5 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.

6.2.6 Each Hospital applicant shall be prepared to demonstrate to the Licensing Agency that the Hospital has the following:

6.2.6.1 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;

6.2.6.2 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;

6.2.6.3 Maintains adequate records of consumer complaints and their resolution;

6.2.6.4 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.

6.2 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 7.7 and 7.8 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:
 - 7.9.1 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.
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8.0 Informing Patients of Investigation Completion

Upon completion of an investigation and determination as to whether an action is to be pursued under subsections 7.7 or 7.8 of this rule, the Complainant or his or her representative will be provided notice in writing. The notice shall state that the investigation is complete and whether a public proceeding regarding the license of the subject facility has resulted. Notice will be sent promptly and in no case more than 14

days after the determination is made and shall include the time and place of any public proceeding.