FINAL PROPOSED RULE $\#\frac{\partial 1}{\partial 1}$

Administrative Procedures – Final Proposed Rule Filing Instructions:

In accordance with Title 3 Chapter 25 of the Vermont Statutes Annotated and the "Rule on Rulemaking" adopted by the Office of the Secretary of State, this filing will be considered complete upon filing and acceptance of these forms with the Office of the Secretary of State, and the Legislative 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.

PLEASE REMOVE ANY COVERSHEET OR FORM NOT REQUIRED WITH THE CURRENT FILING BEFORE DELIVERY!

Certification Statement: As the adopting Authority of this rule (see 3 V.S.A. § 801 (b) (11) for a definition), I approve the contents of this filing entitled:

Hospital Licensing Rule

/s/ Michael K. Smith

(signature)

on 10/19/2021

(date)

Printed Name and Title: Michael K. Smith Secretary, Agency of Human Services

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)
- \Box ICAR Minutes
- □ Copy of Comments
- □ Responsiveness Summary

Revised May 5, 2020

Final Proposed Coversheet

- 1. TITLE OF RULE FILING: Hospital Licensing Rule
- 2. PROPOSED NUMBER ASSIGNED BY THE SECRETARY OF STATE 21P-027
- 3. ADOPTING AGENCY: Vermont Department of Health

4. PRIMARY CONTACT PERSON:

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

Name: Brendan Atwood

Agency: Vermont Department of Health

Mailing Address: 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/lawsregulations/public comment

5. 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: David Englander

Agency: Vermont Department of Health

Mailing Address: 108 Cherry Street, Burlington, VT 05402 Telephone: 802 863 - 7280 Fax: 802 951 - 1275

E-Mail: ahs.vdhrules@vermont.gov

6. 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:

7. LEGAL AUTHORITY/ENABLING LEGISLATION:

Final Proposed 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.

8. 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."

- 9. THE FILING HAS NOT CHANGED SINCE THE FILING OF THE PROPOSED RULE.
- 10. THE AGENCY HAS NOT INCLUDED WITH THIS FILING A LETTER EXPLAINING IN DETAIL WHAT CHANGES WERE MADE, CITING CHAPTER AND SECTION WHERE APPLICABLE.
- 11. SUBSTANTIAL ARGUMENTS AND CONSIDERATIONS WERE NOT RAISED FOR OR AGAINST THE ORIGINAL PROPOSAL.
- 12. THE AGENCY HAS NOT INCLUDED COPIES OF ALL WRITTEN SUBMISSIONS AND SYNOPSES OF ORAL COMMENTS RECEIVED.
- 13. THE AGENCY HAS NOT INCLUDED A LETTER EXPLAINING IN DETAIL THE REASONS FOR THE AGENCY'S DECISION TO REJECT OR ADOPT THEM.
- 14. CONCISE SUMMARY (150 words or Less):

This rule allows hospitals that have been granted waivers 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.

Additionally, two requirements for psychiatric hospitals were added to this rule as required by CMS to

Final Proposed Coversheet

ensure compliance with agreements Vermont has made with CMS in the Serious Mental Illness Institution for Mental Disease (SMI IMD) waiver.

15. EXPLANATION OF WHY THE RULE IS NECESSARY:

In the current and any future pandemic there may well be a rapid increase in the need for hospital beds. Licensing of Vermont hospitals, while still maintaining high levels of care, could save lives. The new requirements for psychiatric hospitals are required to ensure compliance with a CMS waiver agreement.

16. EXPLANATION OF HOW THE RULE IS NOT ARBITRARY:

The proposal is narrowly tailored to ensure no duplication of effort during an emergency, and to ensure compliance with Vermont's waiver agreement with CMS.

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

Hospitals and patients.

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

There may be cost savings associated with hospitals not needing to request a Vermont waiver. This impact is anticipated to be de minimis and is not measurable.

19. A HEARING WAS NOT HELD.

20. 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.

Date: 9/21/2021

Time: 10:00 AM

Street Address: 108 Cherry Street, Burlington, VT, Rm. 2A Zip Code: 05401

Date: Time: AM Street Address: Zip Code: Final Proposed Coversheet Date: Time: AM Street Address: Zip Code: Date: Time: AM Street Address: Zip Code:

21. DEADLINE FOR COMMENT (NO EARLIER THAN 7 DAYS FOLLOWING LAST HEARING): 9/28/2021

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

CMS

COVID-19

Patients

Psychiatric hospital

SMI IMD Waiver

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*):

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

State of Vermont Agency of Administration 109 State Street Montpelier, VT 05609-0201 www.aoa.vermont.gov [phone] 802-828-3322 [fax] 802-828-3320 Office of the Secretary

INTERAGENCY COMMITTEE ON ADMINISTRATIVE RULES (ICAR) MINUTES

Meeting Date/Location:July 12, 2021, Physical Location: 109 State Street, 5th Floor Conference Room,
Montpelier VT; Virtual Meeting: Microsoft TeamsMembers Present:Chair Kristin Clouser, Dirk Anderson. Diane Bothfeld, Jennifer Mojo, John Kessler,
Matt Langham, Diane Sherman

Members Absent: Ashley Berliner, Clare O'Shaughnessy

Minutes By: Melissa Mazza-Paquette and Diane Bothfeld

- 2:12 p.m. meeting called to order, welcome and introductions.
- Review and approval of minutes from the <u>June 14,2021</u> meeting.
- No additions/deletions to agenda. Agenda approved as drafted.
- No public comments made.
- Note: The following emergency rules were supported by ICAR Chair Clouser:
 - 1. 'Access to Health Care Services Related to COVID-19' by the Department of Financial Regulation on 6/30/21.

- 2. 'Interim Rules for Clinical Pharmacy' by the Secretary of State, Office of Professional Regulation on 7/7/21.
- 3. PUC Emergency Rule 2.600 COVID-19 Emergency Procedures' by the Public Utility Commission on 7/9/21.
- Presentation of Proposed Rules on pages 2-7 to follow.
 - 1. Hemlock Woolly Adelgid Quarantine, Agency of Agriculture, Food and Markets, page 2
 - Vermont Joint Quarantine No. 1 (Scleroderris Canker), Agency of Agriculture, Food and Markets, page 3
 - 3. Hospital Licensing Rule, Agency of Human Services, page 4
 - 4. Administrative Rules for Veterinarians, Secretary of State, Office of Professional Regulation, page 5
 - 5. Independent School Program Approval, State Board of Education, page 6
 - 6. Vermont Use of Public Waters Rules, Agency of Natural Resources, page 7
- Next scheduled meetings:
 - Wednesday, July 14, 2021 Review of ICAR Forms with the Office of the Secretary of State
 - Monday, August 9, 2021 at 2:00 p.m. Monthly ICAR meeting
- 3:49 p.m. meeting adjourned.



Proposed Rule: Hospital Licensing Rule, Agency of Human Services Presented By: Brendan Atwood

Motion made to accept the rule by Diane Bothfeld, seconded by Diane Sherman, and passed unanimously with the following recommendations:

- 1. Proposed Rule Coversheet #10 and #11: Include more information regarding the economic burden.
- 2. Proposed Rule Coversheet #14: Complete hearing information.
- 3. Proposed Rule Coversheet #11: Licensing body impacts should be included.
- 4. Economic Impact, #9: Include more information, including what was examined and information added from the coversheet.
- 5. Economic Impact, #6 and #7: Unclear if the reference to #3 is appropriate. Elaborate that there are no additional parties in addition to those listed in #3.
- 6. Change all 'not applicable' to 'no impact' where appropriate.





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 eliminate the need to apply for a separate state waiver when granted a waiver by CMS under Section 1135 of the Social Security Act during an emergency. There may be cost savings associated with hospitals not needing to request a Vermont waiver. This impact is anticipated to be de minimis and is not measurable. Economic Impact Analysis

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

4. IMPACT ON SCHOOLS:

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 Covid pandemic resulted in significant school closures. The more needed hospital care that is available, along with many other public health measures, the faster schools can be fully re-opened, and/or remain open 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 and is the most efficient and effective approach available.

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):

None.

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.

Not applicable.

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: Not applicable.

9. SUFFICIENCY: EXPLAIN THE SUFFICIENCY OF THIS ECONOMIC IMPACT ANALYSIS. The Department has provided the information that is available with regards to the anticipated economic impact.

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

- 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.): Not applicable.
- 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.

Revised May 5, 2020

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:

A public hearing will be held. The rule will be posted on the Department of Health website: https://www.healthvermont.gov/about-us/lawsregulations/public-comment

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

The Department shared the rule with the Department of Vermont Health Access, The Vermont Association of Hospitals and Health Systems, The University of Vermont Medical Center, and the Board of Medical Practice.

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

Vermont Department Of Health Access

Board of Medical Practice

Annotated Texp

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 <u>per</u> 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

VERMONT DEPARTMENT OF HEALTH

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.

1

- 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 7.04 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 5.32 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.
- 5.1.6 <u>Any psychiatric hospital or psychiatric facility classified as an Institution</u> for Mental Disease for Medicaid purposes shall follow up with patients within 72 hours of discharge. This shall be done by the most effective means possible including via email, text, or phone. Hospitals shall continue to follow up with the patient until either contact is made, or at least 5 attempts every 24 hours for up to 72 hours have been made and documented.
- 5.1.7 Any psychiatric hospital or psychiatric facility classified as an Institution for Mental Disease for Medicaid purposes shall use a widely recognized, publicly available patient assessment tool to determine appropriate level of care and length of stay for their patients.

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

- 5.4.1 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.
- 5.4.2 Each Hospital shall provide a copy of its Emergency Preparedness Plan to the Department for review if requested.
- 5.4.3 All Vermont Hospitals shall comply with the <u>all applicable</u> 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



- 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.

6.3 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

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- 7.5.1 The Department shall determine whether a Plan of Correction submitted pursuant to Section 7.34 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 that the Department:
 - 7.5.2.1 Accepts the Plan of Correction; or
 - 7.5.2.2 Requests 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<u>5</u>.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 rule.
- 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



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



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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 serves as the licensing agency per 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

VERMONT DEPARTMENT OF HEALTH

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.



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- 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 7.4 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 5.2 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.
- 5.1.6 Any psychiatric hospital or psychiatric facility classified as an Institution for Mental Disease for Medicaid purposes shall follow up with patients within 72 hours of discharge. This shall be done by the most effective means possible including via email, text, or phone. Hospitals shall continue to follow up with the patient until either contact is made, or at least 5 attempts every 24 hours for up to 72 hours have been made and documented.
- 5.1.7 Any psychiatric hospital or psychiatric facility classified as an Institution for Mental Disease for Medicaid purposes shall use a widely recognized, publicly available patient assessment tool to determine appropriate level of care and length of stay for their patients.

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.



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5.4 Emergency Preparedness Planning

- 5.4.1 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.
- 5.4.2 Each Hospital shall provide a copy of its Emergency Preparedness Plan to the Department for review if requested.
- 5.4.3 All Vermont Hospitals shall comply with all applicable 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

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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.

6.3 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

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- 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

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- 7.5.1 The Department shall determine whether a Plan of Correction submitted pursuant to Section 7.4 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 related to each identified Deficiency that the Department:
 - 7.5.2.1 Accepts the Plan of Correction; or
 - 7.5.2.2 Requests 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 7.5.2.2 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 rule.
- 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



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



VERMONT GENERAL ASSEMBLY

The Vermont Statutes Online

Title 3 : Executive

Chapter 025 : Administrative Procedure

Subchapter 001 : General Provisions

(Cite as: 3 V.S.A. § 801)

§ 801. Short title and definitions

(a) This chapter may be cited as the "Vermont Administrative Procedure Act."

(b) As used in this chapter:

(1) "Agency" means a State board, commission, department, agency, or other entity or officer of State government, other than the Legislature, the courts, the Commander in Chief, and the Military Department, authorized by law to make rules or to determine contested cases.

(2) "Contested case" means a proceeding, including but not restricted to ratemaking and licensing, in which the legal rights, duties, or privileges of a party are required by law to be determined by an agency after an opportunity for hearing.

(3) "License" includes the whole or part of any agency permit, certificate, approval, registration, charter, or similar form of permission required by law.

(4) "Licensing" includes the agency process respecting the grant, denial, renewal, revocation, suspension, annulment, withdrawal, or amendment of a license.

(5) "Party" means each person or agency named or admitted as a party, or properly seeking and entitled as of right to be admitted as a party.

(6) "Person" means any individual, partnership, corporation, association, governmental subdivision, or public or private organization of any character other than an agency.

(7) "Practice" means a substantive or procedural requirement of an agency, affecting one or more persons who are not employees of the agency, that is used by the agency in the discharge of its powers and duties. The term includes all such requirements, regardless of whether they are stated in writing.

(8) "Procedure" means a practice that has been adopted in writing, either at the election of the agency or as the result of a request under subsection 831(b) of this title. The term includes any practice of any agency that has been adopted in writing, whether or not labeled as a procedure, except for each of the following:

(A) a rule adopted under sections 836-844 of this title;

(B) a written document issued in a contested case that imposes substantive or procedural requirements on the parties to the case;

(C) a statement that concerns only:

(i) the internal management of an agency and does not affect private rights or procedures available to the public;

(ii) the internal management of facilities that are secured for the safety of the public and the individuals residing within them; or

(iii) guidance regarding the safety or security of the staff of an agency or its designated service providers or of individuals being provided services by the agency or such a provider;

(D) an intergovernmental or interagency memorandum, directive, or communication that does not affect private rights or procedures available to the public;

(E) an opinion of the Attorney General; or

(F) a statement that establishes criteria or guidelines to be used by the staff of an agency in performing audits, investigations, or inspections, in settling commercial disputes or negotiating commercial arrangements, or in the defense, prosecution, or settlement of cases, if disclosure of the criteria or guidelines would compromise an investigation or the health and safety of an employee or member of the public, enable law violators to avoid detection, facilitate disregard of requirements imposed by law, or give a clearly improper advantage to persons that are in an adverse position to the State.

(9) "Rule" means each agency statement of general applicability that implements, interprets, or prescribes law or policy and that has been adopted in the manner provided by sections 836-844 of this title.

(10) "Incorporation by reference" means the use of language in the text of a regulation that expressly refers to a document other than the regulation itself.

(11) "Adopting authority" means, for agencies that are attached to the Agencies of Administration, of Commerce and Community Development, of Natural Resources, of Human Services, and of Transportation, or any of their components, the secretaries of those agencies; for agencies attached to other departments or any of their components, the commissioners of those departments; and for other agencies, the chief officer of the agency. However, for the procedural rules of boards with quasi-judicial powers, for the Transportation Board, for the Vermont Veterans' Memorial Cemetery Advisory Board, and for the Fish and Wildlife Board, the chair or executive secretary of the board shall be the adopting authority. The Secretary of State shall be the adopting authority for the Office of Professional Regulation.

(12) "Small business" means a business employing no more than 20 full-time

employees.

(13)(A) "Arbitrary," when applied to an agency rule or action, means that one or more of the following apply:

(i) There is no factual basis for the decision made by the agency.

(ii) The decision made by the agency is not rationally connected to the factual basis asserted for the decision.

(iii) The decision made by the agency would not make sense to a reasonable person.

(B) The General Assembly intends that this definition be applied in accordance with the Vermont Supreme Court's application of "arbitrary" in Beyers v. Water Resources Board, 2006 VT 65, and In re Town of Sherburne, 154 Vt. 596 (1990).

(14) "Guidance document" means a written record that has not been adopted in accordance with sections 836-844 of this title and that is issued by an agency to assist the public by providing an agency's current approach to or interpretation of law or describing how and when an agency will exercise discretionary functions. The term does not include the documents described in subdivisions (8)(A) through (F) of this section.

(15) "Index" means a searchable list of entries that contains subjects and titles with page numbers, hyperlinks, or other connections that link each entry to the text or document to which it refers. (Added 1967, No. 360 (Adj. Sess.), § 1, eff. July 1, 1969; amended 1981, No. 82, § 1; 1983, No. 158 (Adj. Sess.), eff. April 13, 1984; 1985, No. 56, § 1; 1985, No. 269 (Adj. Sess.), § 4; 1987, No. 76, § 18; 1989, No. 69, § 2, eff. May 27, 1989; 1989, No. 250 (Adj. Sess.), § 88; 2001, No. 149 (Adj. Sess.), § 46, eff. June 27, 2002; 2017, No. 113 (Adj. Sess.), § 3; 2017, No. 156 (Adj. Sess.), § 2.)

The Vermont Statutes Online

Title 18: Health

Chapter 42: Bill Of Rights For Hospital Patients And Patient Access To Information

Subchapter 1: Bill Of Rights For Hospital Patients

§ 1851. Definitions

As used in this subchapter:

(1) "Hospital" means a hospital required to be licensed under chapter 43 of this title.

(2) "Patient" means a person admitted to a hospital on an inpatient basis. (Added 1985, No. 163 (Adj. Sess.), § 1; amended 2019, No. 53, § 1.)

§ 1852. Patients' bill of rights; adoption

(a) The General Assembly hereby adopts the "Bill of Rights for Hospital Patients" as follows:

(1) The patient has the right to considerate and respectful care at all times and under all circumstances with recognition of his or her personal dignity.

(2) The patient shall have an attending physician who is responsible for coordinating a patient's care.

(3) The patient has the right to obtain, from the physician coordinating his or her care, complete and current information concerning diagnosis, treatment, and any known prognosis in terms the patient can reasonably be expected to understand. If the patient consents or if the patient is incompetent or unable to understand, immediate family members or a guardian may also obtain this information. The patient has the right to know by name the attending physician primarily responsible for coordinating his or her care.

(4) Except in emergencies, the patient has the right to receive from the patient's physician information necessary to give informed consent prior to the start of any procedure or treatment, or both. Such information for informed consent should include the specific procedure or treatment, or both, the medically significant risks involved, and the probable duration of incapacitation. Where medically significant alternatives for care or treatment exist, or when the patient requests information concerning medical alternatives, the patient has the right to such information. The patient also has the right to know the name of the person responsible for the procedures or treatment, or both.

(5) The patient has the right to refuse treatment to the extent permitted by law. In

the event the patient refuses treatment, the patient shall be informed of the medical consequences of that action, and the hospital shall be relieved of any further responsibility for that refusal.

(6) The patient has the right to every consideration of privacy concerning the patient's own medical care program. Case discussion, consultation, examination, and treatment are confidential and shall be conducted discreetly. Those not directly involved in the patient's care must have the permission of the patient to be present. This right includes the right, upon request, to have a person of one's own sex present during certain parts of a physical examination, treatment, or procedure performed by a health care professional of the opposite sex; and the right not to remain disrobed any longer than is required for accomplishing the medical purpose for which the patient was asked to disrobe. The patient has the right to wear appropriate personal clothing and religious or other symbolic items so long as they do not interfere with diagnostic procedures or treatment.

(7) The patient has the right to expect that all communications and records pertaining to his or her care shall be treated as confidential. Only medical personnel, or individuals under the supervision of medical personnel, directly treating the patient, or those persons monitoring the quality of that treatment, or researching the effectiveness of that treatment, shall have access to the patient's medical records. Others may have access to those records only with the patient's written authorization.

(8) The patient has the right to expect that within its capacity a hospital shall respond reasonably to the request of a patient for services. The right shall include if physically possible a transfer to another room or place if another person in that room or place is disturbing the patient by smoking or other unreasonable actions. When medically permissible a patient may be transferred to another facility only after receiving complete information and explanation concerning the needs for and alternatives to such a transfer. The institution to which the patient is to be transferred must first have accepted the patient for transfer.

(9) The patient has the right to know the identity and professional status of individuals providing service to him or her, and to know which physician or other practitioner is primarily responsible for his or her care. This includes the patient's right to know of the existence of any professional relationship among individuals who are treating him or her, as well as the relationship to any other health care or educational institutions involved in his or her care.

(10) The patient has the right to be advised if the hospital proposes to engage in or perform human experimentation affecting the patient's care or treatment. Participation by patients in clinical training programs or in the gathering of data for research purposes shall be voluntary. The patient has the right to refuse to participate in such research projects. (11) The patient has the right to expect reasonable continuity of care. The patient has the right to be informed by the attending physician of any continuing health care requirements following discharge.

(12) The patient has the right to receive an itemized, detailed, and understandable explanation of charges regardless of the source of payment and to be provided with information about financial assistance and billing and collections practices.

(13) The patient has the right to know what hospital rules and regulations apply to his or her conduct as a patient.

(14) Whenever possible, guardians or parents have the right to stay with their children 24 hours per day. Whenever possible, agents, guardians, or immediate family members have the right to stay with terminally ill patients 24 hours per day.

(15) A patient who does not speak or understand the predominant language of the community has a right to an interpreter if the language barrier presents a continuing problem to patient understanding of the care and treatment being provided. A patient who is hard of hearing has a right to an interpreter if the impairment presents a continuing problem to patient understanding of the care and treatments being provided.

(16) The patient has the right to receive professional assessment of pain and professional pain management.

(17) The patient has the right to be informed in writing of the availability of hospice services and the eligibility criteria for those services.

(18) The patient has the right to know the maximum patient census and the full-time equivalent numbers of registered nurses, licensed practical nurses, and licensed nursing assistants who provide direct care for each shift on the unit where the patient is receiving care.

(b) Failure to comply with any provision of this section may constitute a basis for disciplinary action against a physician under 26 V.S.A. chapter 23. A complaint may be filed with the Board of Medical Practice.

(c) A summary of the hospital's obligations under this section, written in clear language and in easily readable print, shall be distributed to patients upon admission and posted conspicuously at each nurse's station. Such notice shall also indicate that as an alternative or in addition to the hospital's complaint procedures, the patient may directly contact the licensing agency or the Board of Medical Practice. The address and telephone number of the licensing agency and Board of Medical Practice shall be included in the notice. (Added 1985, No. 163 (Adj. Sess.), § 1; amended 1989, No. 219 (Adj. Sess.), § 4; 1999, No. 91 (Adj. Sess.), § 35; 2005, No. 55, § 5, eff. Sept. 1, 2005; 2005, No. 153 (Adj. Sess.), § 2; 2009, No. 25, § 6; 2013, No. 96 (Adj. Sess.), § 94; 2017, No. 113 (Adj. Sess.), § 64; 2019, No. 53, § 1.)

§ 1853. Repealed. 2015, No. 23, § 152(2).

Subchapter 2: Access To Information

§ 1854. Public access to information

(a) A hospital shall make public the maximum patient census and the number of registered nurses, licensed practical nurses, and licensed nursing assistants providing direct patient care in each unit during each shift. Each unit's information shall be reported in full-time equivalents, with either every eight hours or 12 hours worked by a registered nurse, licensed practical nurse, or licensed nursing assistant during the shift as one full-time equivalent. The reporting of this information shall be in a manner consistent with the requirements for public reporting for measures of nurse staffing selected by the Commissioner of Health under subdivision 9405b(a)(4) of this title, but shall not in any way change what is required to be posted as set forth in this subsection. Each unit's information shall be posted in a prominent place that is readily accessible to patients and visitors in that unit at least once each day. The posting shall include the information for the preceding seven days.

(b) The hospital shall provide a telephone number to the public for requesting public information, including information required under this section and sections 1852 and 9405b of this title. The information shall be provided within 24 hours of the request. (Added 2005, No. 153 (Adj. Sess.), § 3; amended 2007, No. 27, § 1, eff. May 16, 2007; 2011, No. 78 (Adj. Sess.), § 2, eff. April 2, 2012; 2015, No. 152 (Adj. Sess.), § 9.)

§ 1855. Ambulatory surgical patients; explanation of charges

- (a) As used in this section:
 - (1) "Ambulatory surgical center" has the same meaning as in section 9432 of this title.
 - (2) "Hospital" means a hospital required to be licensed under chapter 43 of this title.

(b) A patient receiving outpatient surgical services or an outpatient procedure at an ambulatory surgical center or hospital shall receive an itemized, detailed, and understandable explanation of charges regardless of the source of payment and shall be provided with information about the ambulatory surgical center's or hospital's financial assistance and billing and collections practices. (Added 2019, No. 53, § 1.)

VERMONT GENERAL ASSEMBLY

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Title 18: Health

Chapter 43: Licensing Of Hospitals

§ 1901. Policy

The purpose of this chapter is to provide for the development, establishment, and enforcement of standards for the construction, maintenance, and operation of hospitals, which, in the light of advancing knowledge, will promote safe and adequate treatment of persons in hospitals. (Amended 1963, No. 154, § 1.)

§ 1902. Definitions

The following words and phrases, as used in this chapter, shall have the following meanings unless otherwise provided:

(1) "Hospital" means a place devoted primarily to the maintenance and operation of diagnostic and therapeutic facilities for in-patient medical or surgical care of individuals who have an illness, disease, injury, or physical disability, or for obstetrics.

(A) "General hospital" is a hospital of which not more than 50 percent of the total patient days during the year are customarily assignable to the following categories of cases: chronic, convalescent and rest, drug and alcoholic, epilepsy, developmental and psychiatric disabilities and mental conditions, and tuberculosis, and which provides adequate and separate facilities and equipment for the performance of surgery and obstetrics, or either, and for diagnostic X-ray and laboratory services.

(B) "Psychiatric hospital" means a hospital for the diagnosis and treatment of mental illness.

(C) "Tuberculosis facility" means a hospital (excluding preventoria), or the separate tuberculosis unit of a general, psychiatric, or chronic disease hospital for the diagnosis and treatment of tuberculosis.

(D) "Chronic disease facility" means a hospital, or the separate chronic disease unit of a general hospital, for the treatment of chronic illness, including the degenerative diseases. The term does not include facilities primarily for the care of individuals with mental conditions and psychiatric disabilities or tuberculosis, nursing homes, and institutions the primary purpose of which is domiciliary care.

(E) "Maternity hospital" means a hospital which receives maternity patients exclusively, for care during pregnancy, during delivery, or within ten days after delivery.

(F) "Nonprofit hospital" means any hospital owned and operated by a

corporation or association, no part of the net earnings of which is applied, or may lawfully be applied, to the benefit of any private shareholder or individual.

(G) "Proprietary hospital" means any hospital operated for individual gain or reward.

(H) "Psychiatric facility" means a type of psychiatric hospital, or separate unit of a general hospital, where patients may obtain diagnostic services and receive intensive treatment for mental illness and where only a minimum of continued treatment facilities will be afforded.

(I) The provisions of this subdivision (1) do not apply to any of the following institutions:

(i) Nursing and convalescent homes, boarding homes, homes for the aged, nurseries, and institutions used primarily for domiciliary care;

(ii) Any hospital conducted, maintained, or operated by the U.S. government or a duly authorized agency thereof.

(2) "Person" means any individual, firm, partnership, corporation, company, association, or joint stock association, and the legal successor thereof.

(3) "Governmental unit" means a state, or political subdivision thereof, or any department, division, board, or other agency of any of the foregoing.

(4) "Licensing agency" means the State Board of Health. (Amended 1959, No. 329 (Adj. Sess.), § 27, eff. March 1, 1961; 1963, No. 154, § 2; 2003, No. 122 (Adj. Sess.), § 141d; 2013, No. 96 (Adj. Sess.), § 96; 2017, No. 113 (Adj. Sess.), § 65.)

§ 1903. License

No person or governmental unit may establish, conduct, or maintain a hospital in this State without first obtaining a license in accordance with this chapter. (Amended 1963, No. 154, § 3; 2017, No. 113 (Adj. Sess.), § 66.)

§ 1904. Application, fee

(a) An application for a license shall be made to the licensing agency upon forms provided by it and shall contain such information as the licensing agency reasonably requires. Each application for license shall be accompanied by a license fee.

(b) Annual license fees.

(1) Base fee of \$7,667.00.

(2) Per-bed fee of \$25.00.

(3) The base fee for applicants presenting evidence of current accreditation by the Joint Commission on Accreditation of Health Care Organizations shall be reduced by \$2,750.00.

(c) Fees collected under this section shall be credited to a special fund established and managed pursuant to 32 V.S.A. chapter 7, subchapter 5, and shall be available to the Department to offset the costs of providing those services. (Amended 1963, No. 154, § 4; 2003, No. 163 (Adj. Sess.), § 2; 2007, No. 76, § 14; 2009, No. 134 (Adj. Sess.), § 26.)

§ 1905. License requirements

Upon receipt of an application for a license and the license fee, the licensing agency shall issue a license when it determines that the applicant and hospital facilities meet the following minimum standards:

(1) All hospitals receiving federal aid in their construction and equipment costs shall comply with Title VI of the Public Health Service Act and with Public Health Service regulations, Part 53, and with Appendix A of same, as amended.

(2) There shall be full compliance with safety and sanitary standards as required by State and local building and sanitary codes in order to assure maximum safety to patients and the public.

(3) All general hospitals shall provide adequate and separate facilities and equipment for the performance of surgery and obstetrics, or either, and for diagnostic X-ray and laboratory services.

(4) Remodeling or expansion of any hospital subject to the provisions of this statute shall be approved by the licensing agency prior to starting of such remodeling or expansion, whether or not federal aid is to be requested for the additional projects.

(5) All patients admitted to the hospital shall be under the care of a State registered and licensed practicing physician as defined by the laws of the State of Vermont. All hospitals shall use the uniform credentialing application form described in subsection 9408a(b) of this title.

(6) The nursing service of the hospital shall be directed at all times by a registered professional nurse currently licensed to practice nursing in Vermont.

(7) The care of maternity patients and newborns shall comply with such reasonable regulations as the licensing agency may establish and thereafter modify in the public interest.

(8) Professional case records shall be compiled for all patients and signed by the attending physician. These records shall be kept on file for a minimum of 10 years.

(9) Every hospital shall have an organized medical staff of not fewer than three members which shall meet as often annually as recommended by the Joint Commission on Accreditation of Hospitals.

(10) All employees shall have a preemployment screening by a licensed physician, licensed physician assistant, or licensed advanced practice registered nurse who is acting within his or her scope of practice, or by a designee acting under the direction of

one of these licensed health care professionals. This screening shall include medically indicated radiological, hematological, biochemical, immunological, or serological screenings to exclude the presence of a communicable disease prior to employment. These screenings may be repeated annually as a condition of employment and the results shall be made available, on request, to the licensing agency for review.

(11) All employees shall have such additional examinations, tests, and immunization treatments as the licensing agency may determine to be necessary in the public interest.

(12) Accounting records of all operating procedures shall be kept on a monthly basis and complete operating and financial statements shall be compiled at least once annually and kept on file for 20 years.

(13) The hospital grounds and buildings shall be subject to inspection by the licensing agency and other legalized authorities at all times.

(14) A license is not transferable or assignable and shall be issued only for the premises and persons named in the application.

(15) The licensee shall file an annual report containing such information as the licensing agency may reasonably require; a copy of the hospital's annual report to its governing board shall be provided to the licensing agency within 30 days after publication of this document.

(16) All new construction involving hospitals and related buildings on hospital premises shall comply with standards of the State Fire Marshal and State Board of Health, whether or not federal aid under Title VI of the Public Health Service Act is received for such construction.

(17) The Board of Health may, when circumstances warrant, issue a temporary license for such period or periods and subject to such conditions as the Board shall deem proper, subject to the limitation that such a temporary license shall not be issued for a total period of more than 36 months. Such circumstances shall include issues concerning indicators in the hospital's community report which may result in the Board's issuing a license conditioned upon corrective measures or a temporary license with conditions.

(18) All hospitals shall submit to the licensing agency a plan for implementing the provisions of section 1852 of this title and a plan for handling patient complaints, which shall become effective upon approval by the licensing agency. Plans under this subdivision shall include:

(A) the designation of a person or persons qualified as a patient representative;

(B) a method by which each patient shall be made aware of the complaint procedure;

(C) an appeals mechanism within the hospital itself;

(D) a published time frame for processing and resolving complaints and appeals within the hospital, and notification that further appeals of the hospital's resolution of complaints may be made to the licensing agency under chapter 43 of this title; and

(E) periodic reporting to the licensing agency of the nature of complaints filed, and action taken.

(19) All hospitals shall accept payment for compensation claims of uninsured crime victims paid for by the Victims Compensation Board established in 13 V.S.A. § 5352 at 70 percent of billed charges and shall not bill any balance to the uninsured crime victim.

(20) All hospitals shall comply with the rules adopted by the Commissioner pursuant to section 1914 of this title. License applications shall certify compliance with the rules.

(21) In conducting its reviews, the licensing agency shall evaluate the quality and financial indicators published by the Commissioner of Health under subsection 9405b(c) of this title.

(22) All hospitals shall provide oral and written notices to each individual that the hospital places in observation status as required by section 1911a of this title. (Amended 1959, No. 329 (Adj. Sess.), § 27, eff. March 1, 1961; 1963, No. 154, § 5; 1981, No. 238 (Adj. Sess.), § 1; 1985, No. 163 (Adj. Sess.), § 2; 2005, No. 215 (Adj. Sess.), §§ 75a, 323; 2007, No. 27, §§ 2, 3; 2011, No. 78 (Adj. Sess.), § 2, eff. April 2, 2012; 2015, No. 23, § 44; 2015, No. 54, § 4, eff. Dec. 1, 2015; 2015, No. 97 (Adj. Sess.), § 49; 2015, No. 152 (Adj. Sess.), § 4; 2017, No. 113 (Adj. Sess.), § 67; 2017, No. 199 (Adj. Sess.), § 1, eff. May 30, 2018.)

§ 1906. Revocation of license, hearing

The licensing agency, after notice and opportunity for hearing to the applicant or licensee, is authorized to deny, suspend, or revoke a license in any case in which it finds that there has been a substantial failure to comply with the requirements established under this chapter. Such notice shall be served by registered mail or by personal service setting forth the reasons for the proposed action and fixing a date not less than 60 days from the date of such mailing or service, at which the applicant or licensee shall be given opportunity for a hearing. After such hearing, or upon default of the applicant or licensee, the licensing agency shall file its findings of fact and conclusions of law. A copy of such findings and decision shall be sent by registered mail or served personally upon the applicant or licensee. The procedure governing hearings authorized by this section shall be in accordance with the usual and customary rules provided for such hearings.

§ 1907. Appeal

Any applicant or licensee, or the State acting through the Attorney General, aggrieved by the decision of the licensing agency after a hearing, may, within 30 days after entry of the decision as provided in section 1906 of this title, appeal to the Superior Court wherein the appellant is located. The court may affirm, modify, or reverse the decision of the licensing agency and either the applicant or licensee or licensing agency or State may appeal to the Supreme Court for such further review as is provided by law. Pending final disposition of the matter, the status quo of the applicant or licensee shall be preserved, except as the court otherwise orders in the public interest. (Amended 1971, No. 185 (Adj. Sess.), § 185, eff. March 29, 1972; 1973, No. 193 (Adj. Sess.), § 3, eff. April 9, 1974.)

§ 1908. Rules; exceptions

(a) 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; such rules and standards shall be modified, amended, or rescinded from time to time by the licensing agency as may be in the public interest.

(b) No such rules and standards shall be adopted or enforced which would have the effect of denying a license to a hospital solely by reason of the school or system of practice employed or permitted to be employed by physicians therein; provided that such school or system of practice is recognized by the laws of the State. Provided, however, that no rule or requirement shall be made under this chapter for any hospital conducted for those who rely upon treatment by spiritual means or prayer in accordance with the creed or tenets of any recognized church or religious denomination, except as to the sanitary and safe condition of the premises, cleanliness of operation, and its physical equipment. (Amended 2015, No. 23, § 106.)

§ 1909. Inspections

The licensing agency shall make or cause to be made such inspections and investigations as it deems necessary. If the licensing agency finds a violation as the result of an inspection or investigation, the licensing agency shall post a report on the licensing agency's website summarizing the violation and any corrective action required. (Amended 2019, No. 55, § 2.)

§ 1910. Records

(a) Information received by the licensing agency through filed reports, inspection, or as otherwise authorized by law shall:

(1) not be disclosed publicly in a manner that identifies or may lead to the identification of one or more individuals or hospitals;

(2) be exempt from public inspection and copying under the Public Records Act; and

(3) be kept confidential except as it relates to a proceeding regarding licensure of a hospital.

(b) The provisions of subsection (a) of this section shall not apply to the summary

reports of violations required to be posted on the licensing agency's website pursuant to section 1909 of this chapter. (Amended 2019, No. 55, § 3.)

§ 1911. Construction

This chapter shall not be construed in any way to restrict or modify any law pertaining to the placement and adoption of children or the care of unmarried mothers.

§ 1911a. Notice of hospital observation status

(a)(1) Each hospital shall provide oral and written notice to each Medicare beneficiary that the hospital places in observation status as soon as possible but no later than 24 hours following such placement, unless the individual is discharged or leaves the hospital before the 24-hour period expires. The written notice shall be a uniform form developed by the Department of Health, in consultation with interested stakeholders, for use in all hospitals.

(2) If a patient is admitted to the hospital as an inpatient before the notice of observation has been provided, and under Medicare rules the observation services may be billed as part of the inpatient stay, the hospital shall not be required to provide notice of observation status.

(b) Each oral and written notice shall include:

(1) a statement that the individual is under observation as an outpatient and is not admitted to the hospital as an inpatient;

(2) a statement that observation status may affect the individual's Medicare coverage for hospital services, including medications and pharmaceutical supplies, and for rehabilitative or skilled nursing services at a skilled nursing facility if needed upon discharge from the hospital; and

(3) a statement that the individual may contact the Office of the Health Care Advocate or the Vermont State Health Insurance Assistance Program to understand better the implications of placement in observation status.

(c) Each written notice shall include the name and title of the hospital representative who gave oral notice; the date and time oral and written notice were provided; the means by which written notice was provided, if not provided in person; and contact information for the Office of the Health Care Advocate and the Vermont State Health Insurance Assistance Program.

(d) Oral and written notice shall be provided in a manner that is understandable by the individual placed in observation status or by his or her representative or legal guardian.

(e) The hospital representative who provided the written notice shall request a signature and date from the individual or, if applicable, his or her representative or legal guardian, to verify receipt of the notice. If a signature and date were not obtained, the hospital representative shall document the reason. (Added 2015, No. 54, § 5, eff. Dec. 1,

2015.)

VERMONT GENERAL ASSEMBLY

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Title 18: Health

Chapter 43A: Patient Safety Surveillance And Improvement System

§ 1912. Definitions

As used in this chapter:

(1) "Adverse event" is 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) "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.

(4) "Hospital" shall have the same meaning as in subdivision 1902(1) of this title.

(5) "Health care provider" shall have the same meaning as in subdivision 9402(7) of this title.

(6) "Intentional unsafe act" shall mean 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.

(7) "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.

(8) "Reportable adverse event" means those adverse events a hospital is required to report to the Department pursuant to regulations adopted under this chapter.

(9) "Safety system" means the comprehensive patient safety surveillance and improvement system established pursuant to this chapter and the regulations adopted hereunder.

(10) "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. (Added 2005, No. 215 (Adj. Sess.), § 324.)

§ 1913. Creation; implementation

(a) The Commissioner shall establish a comprehensive patient safety surveillance and improvement system for the purpose of improving patient safety, eliminating adverse events in Vermont hospitals, and supporting and facilitating quality improvement efforts by hospitals. The Department may contract with a qualified organization having expertise in patient safety to develop and implement all or part of the safety system.

(b) The Department shall:

(1) collect data concerning the occurrence of reportable adverse events;

(2) aggregate and analyze data for the purpose of developing and implementing strategies to target and eliminate specific adverse events;

(3) verify that hospitals are in compliance with all the requirements of this chapter and regulations adopted hereunder;

(4) for reportable adverse events, verify that hospitals are conducting causal analyses and developing corrective action plans consistent with standards set by the Department, current patient safety science, and relevant clinical standards;

(5) provide technical assistance or assist hospitals in locating technical assistance resources for analyzing adverse events and near misses and developing and implementing corrective action plans; and

(6) encourage hospitals to utilize anonymous in-hospital reporting when possible.

(c) The Commissioner may retain or contract with such additional professional or other staff as needed to carry out responsibilities under this chapter.

(d) Beginning on July 1, 2007, expenses incurred for development and implementation of the safety system shall be borne as follows: 50 percent from General Fund monies and 50 percent by the hospitals.

(e) Not later than January 15, 2008, the Commissioner of Health shall provide an interim report to the Senate Committee on Health and Welfare and the House Committees on Human Services and on Health Care on the status of the safety system, its effectiveness in improving patient safety and health care quality in the State, and cost savings. Not later than January 15, 2009, the Commissioner shall make a final report to those Committees on those subjects and shall make recommendations regarding expansion of the system to include health care facilities other than hospitals.

(f) The authority granted to the Commissioner under this chapter is in addition to any

other authority granted to the Commissioner under law. (Added 2005, No. 215 (Adj. Sess.), § 324.)

§ 1914. Rulemaking

(a) The Commissioner shall adopt rules pursuant to 3 V.S.A. chapter 25 establishing the hospital obligations listed in section 1915 of this title and otherwise necessary for the implementation of the safety system.

(b) The rules shall list reportable adverse events, which shall include the "serious reportable events" published by the National Quality Forum. The Commissioner shall consult with experts and hospitals when making changes to the list of reportable adverse events and shall consider the implications of reporting requirements that may be established as a result of the federal Patient Safety and Quality Improvement Act of 2005. The Department shall consult with other regulatory agencies and departments and, to the extent possible, avoid imposing duplicative reporting requirements. (Added 2005, No. 215 (Adj. Sess.), § 324.)

§ 1915. Hospital obligations

The rules adopted pursuant to this chapter shall require hospitals to:

(1) develop, maintain, and implement internal policies and procedures that meet the standards of the Department to:

(A) identify, track, and analyze reportable adverse events, adverse events, and near misses;

(B) determine what type of causal analysis, if any, is appropriate;

(C) conduct causal analyses and develop corrective action plans; and

(D) disclose to patients, or, in the case of a patient death, an adult member of the immediate family, at a minimum, adverse events that cause death or serious bodily injury;

(2) report reportable adverse events to the Department;

(3) provide the Department with copies of its causal analysis and corrective action plan in connection with each reportable adverse event;

(4) for reportable adverse events that must also by law be reported to other departments or agencies, notify the Department of Health or provide a copy of any written report and provide any causal analysis information required by the Department;

(5) for the purpose of evaluating a hospital's compliance with the provisions of this chapter, provide the Commissioner and designees reasonable access to:

(A) information protected by the 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. (Added 2005, No. 215 (Adj. Sess.), § 324.)

§ 1916. Intentional unsafe acts

(a) A hospital shall notify the Department, within the time frames established by regulation, if the information available supports a reasonable, good faith belief that an intentional unsafe act as it pertains to patients has occurred.

(b) For intentional unsafe acts reportable to other departments or agencies, a hospital shall notify the Department of Health or provide a copy of any written report. Such reports shall not constitute a waiver of peer review or any other privilege.

(c) If the Department confirms or independently concludes, based on a reasonable, good faith belief, that an intentional unsafe act 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.

(d) There shall be no liability on the part of and no cause of action for damages shall arise against any individual or hospital for any act or proceeding related to activities undertaken or performed within the scope of the obligations imposed by this section, provided that the individual or hospital acts without malice and with the reasonable belief that the action is warranted by the facts known after making reasonable efforts to obtain all the facts.

(e) Nothing in this section shall prevent a hospital from conducting its own investigation or peer review. (Added 2005, No. 215 (Adj. Sess.), § 324; amended 2017, No. 113 (Adj. Sess.), § 68.)

§ 1917. Protection and disclosure of information

(a) All information made available to the Department and its designees under this chapter shall be confidential and privileged, exempt from the public access to records law, and, in any civil or administrative action against a provider of professional health services arising out of the matters which are subject to evaluation and review by the Department, immune from subpoena or other disclosure and not subject to discovery or introduction into evidence.

(b) No person with access to information made available to the Commissioner or his or her designees under this chapter shall be permitted or required to testify as to any findings, recommendations, evaluations, opinions, or other actions of the Department in any civil or administrative action against a provider of professional health services arising out of the matters which are subject to evaluation and review by the Department.

(c) Within the Department, access to peer review protected information shall be limited to individuals responsible for verifying compliance with the safety system and for providing necessary consultation and supervision to that program.

(d) Reports made to the Department pursuant to subdivision 1915(4) of this chapter shall not constitute a waiver of peer review or any other privilege.

(e) Hospitals may replace health care provider identifying information in peer review materials with a surrogate identifier that allows for tracking of adverse events involving the same provider without disclosing the provider's identity.

(f) Notwithstanding subsections (a) and (b) of this section:

(1) Hospitals and the Department staff responsible for verifying compliance with the safety system are authorized to disclose information necessary to comply with their reporting obligations in section 1916 of this chapter.

(2) The Department staff responsible for verifying compliance with the patient safety surveillance and improvement system may disclose information to others in the Department, and the Department may disclose information to the Board of Health and others responsible for carrying out the Department's enforcement responsibilities with respect to this chapter if the Department reasonably believes that a hospital deliberately or repeatedly has not complied with the requirements of this chapter and any rules adopted hereunder. The Commissioner, the Board of Health, and others responsible for carrying out the Department responsibilities with respect to this chapter are authorized to disclose such information during the course of any legal or regulatory action taken against a hospital for deliberate or repeated noncompliance with the requirements of this chapter and any rules adopted hereunder. Information disclosed under this subdivision shall otherwise maintain all applicable protections under this section and otherwise provided by law.

(g) Nothing in this section shall prohibit a hospital from making a good faith report to regulatory or law enforcement authorities based on information, documents, or records known or available to it from original sources. Information, documents, or records otherwise available from original sources are not to be construed as immune from discovery or use in any other action merely because they were made available to the Department's patient safety surveillance and improvement system. (Added 2005, No. 215 (Adj. Sess.), § 324; amended 2017, No. 113 (Adj. Sess.), § 69.)

§ 1918. Enforcement

(a) If the Commissioner determines that a hospital has failed to comply with any of the provisions of this chapter, the Commissioner may sanction the hospital as provided in this title. In evaluating compliance, the Commissioner shall place primary emphasis on assuring good faith compliance and effective corrective action by the facility, reserving punitive enforcement or disciplinary action for those cases in which the facility has displayed recklessness, gross negligence, or willful misconduct or in which there is evidence, based on other similar cases known to the Department, the Agency of Human

Services, or the Office of the Attorney General, of a pattern of significant substandard performance that has the potential for or has actually resulted in harm to patients.

(b) After notice and an opportunity for hearing, the Commissioner may impose on a hospital that knowingly violates a provision of this chapter or a rule or order adopted pursuant to this chapter a civil administrative penalty of not more than \$10,000.00 or, in the case of a continuing violation, a civil administrative penalty of not more than \$10,000.00 or one-tenth of one percent of the gross annual revenues of the health care facility, whichever is greater. A hospital aggrieved by a decision of the Commissioner under this section may appeal the Commissioner's decision pursuant to section 128 of this title. (Added 2005, No. 215 (Adj. Sess.), § 324.)

§ 1919. Inclusion of data in hospital community reports

The Commissioner shall consult with the Commissioner of Financial Regulation and with patient safety experts, hospitals, health care professionals, and members of the public and shall make recommendations to the Commissioner of Financial Regulation concerning which data should be included in the hospital community reports required by section 9405b of this title. Beginning in 2013, the community reports shall include at a minimum data from all Vermont hospitals of reportable adverse events aggregated in a manner that protects the privacy of the patients involved and does not identify the individual hospitals in which an event occurred together with analysis and explanatory comments about the information contained in the report to facilitate the public's understanding of the data. The Commissioner shall make such recommendations no more than 18 months after data collection is initiated. (Added 2005, No. 215 (Adj. Sess.), § 324; amended 2011, No. 171 (Adj. Sess.), § 24f, eff. Feb. 1, 2013.)



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Deadline For Public Comment

Deadline: Sep 28, 2021

The deadline for public comment has expired. Contact the agency or primary contact person listed below for assistance.

Rule Details

Rule Number:	21P027	
Title:	e: Hospital Licensing Rule.	
Туре:	be: Standard	
Status:	Status: Final Proposed	
Agency:	Department of Health, Agency of Human Services	
Legal Authority:	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.	
Summary:	This rule allows hospitals that have been granted waivers 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	

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	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 periodthat 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. Additionally, two requirements for psychiatric hospitals were added to this rule as required by CMS to ensure compliance with agreements Vermont has made with CMS in the Serious Mental Illness Institution for Mental Disease (SMI IMD) waiver.
Persons Affected:	Hospitals and patients.
Economic Impact:	There may be cost savings associated with hospitals not needing to request a Vermont waiver. This impact is anticipated to be de minimis and is not measurable.
Posting date:	Aug 18,2021

Hearing Information

	Information for Hearing # 1		
Hearing date:	09-21-2021 10:00 AM		
Location:	Vermont Dept. of Health		
Address:	108 Cherry Street		
City:	Burlington		
State:	VT		
Zip:	05401		
Hearing Notes:			

Contact Information

Information for Primary Contact

PRIMARY CONTACT PERSON - A PERSON WHO IS ABLE TO ANSWER QUE; ABOUT THE CONTENT OF THE RULE.

Level:	Primary
Name:	Brendan Atwood
Agency:	Department of Health, Agency of Human Services
Address:	108 Cherry Street
City:	Burlington
State:	VT
Zip:	05401

Telephone:	802-863-7280
Fax:	802-951-1275
Email:	ahs.vdhrules@vermont.gov

Website	https://www.healthvermont.gov/about-us/laws-regulations/public-comment
Address:	

Information for Secondary Contact

SECONDARY CONTACT PERSON - A SPECIFIC PERSON FROM WHOM COPI FILINGS MAY BE REQUESTED OR WHO MAY ANSWER QUESTIONS ABOUT : SUBMITTED FOR FILING IF DIFFERENT FROM THE PRIMARY CONTACT PEF

Level:	Secondary
Name:	David Englander
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City:	Burlington
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Keyword Information

Keywords:

CMS COVID-19 Patients Psychiatric hospital SMI IMD Waiver

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	St. Albans Messenger Ben Letourneau (<u>ben.letourneau@samessenger.com</u>)	Tel: 524-9771 ext. 117 FAX: 527- 1948 Attn: Ben Letourneau
	The Islander (<u>islander@vermontislander.com</u>)	Tel: 802-372-5600 FAX: 802-372-3025
	Vermont Lawyer (hunter.press.vermont@gmail.com)	Attn: Will Hunter
FROM:	APA Coordinator, VSARA Date of Fax:	August 18, 2021

FROIVE APA COORDINATOR, VSARA	Date of Fax:	August 18, 2021
RE: The "Proposed State Rules " ad copy to run e	on	August 26, 2021
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If you have questions, or if the printing schedule of your paper is disrupted by holiday etc. please contact VSARA at 802-828-3700, or E-Mail <u>sos.statutoryfilings@vermont.gov</u>, Thanks.

PROPOSED STATE RULES

By law, public notice of proposed rules must be given by publication in newspapers of record. The purpose of these notices is to give the public a chance to respond to the proposals. The public notices for administrative rules are now also available online at <u>https://secure.vermont.gov/SOS/rules/</u>. The law requires an agency to hold a public hearing on a proposed rule, if requested to do so in writing by 25 persons or an association having at least 25 members.

To make special arrangements for individuals with disabilities or special needs please call or write the contact person listed below as soon as possible.

To obtain further information concerning any scheduled hearing(s), obtain copies of proposed rule(s) or submit comments regarding proposed rule(s), please call or write the contact person listed below. You may also submit comments in writing to the Legislative Committee on Administrative Rules, State House, Montpelier, Vermont 05602 (802-828-2231).

Hospital Licensing Rule.

Vermont Proposed Rule: 21P027

AGENCY: Agency of Human Services, Department of Health

CONCISE SUMMARY: This rule allows hospitals that have been granted waivers 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. Additionally, two requirements for psychiatric hospitals were added to this rule as required by CMS to ensure compliance with agreements Vermont has made with CMS in the Serious Mental Illness Institution for Mental Disease (SMI IMD) waiver.

FOR FURTHER INFORMATION, CONTACT: Brendan Atwood, Vermont Dept. of Health 108 Cherry Street, Burlington, VT 05402 Tel: 802-863-7280 Fax: 802-951-1275 Email: ahs.vdhrules@vermont.gov URL: <u>https://www.healthvermont.gov/about-us/laws-regulations/public-comment</u>.

FOR COPIES: David Englander, Vermont Dept. of Health 108 Cherry Street, Burlington, VT 05402 Tel: 802-863-7280 Fax: 802-951-1275 Email: <u>ahs.vdhrules@vermont.gov</u>.