

Final Proposed Filing - Coversheet

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 shall 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:

Amyotrophic Lateral Sclerosis (ALS) Registry Rule

/s/ Todd W. Daloz _____, on 12/11/23
(signature) (date)

Printed Name and Title:

Todd W. Daloz
Deputy 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)
- ☐ ICAR Minutes
- ☐ Copy of Comments
- ☐ Responsiveness Summary

1. TITLE OF RULE FILING:

Amyotrophic Lateral Sclerosis (ALS) Registry Rule

2. PROPOSED NUMBER ASSIGNED BY THE SECRETARY OF STATE

23P036

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: Natalie Weill

Agency: Department of Health

Mailing Address: 108 Cherry St, Burlington, VT 05401

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

E-Mail: ahs.vdhrules@vermont.gov

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

<http://www.healthvermont.gov/about-us/laws-regulations/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: Brendan Atwood

Agency: Department of Health

Mailing Address: 108 Cherry St, Burlington, VT 05401

Telephone: 802-863-7282 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?) Yes

IF YES, CITE THE STATUTORY AUTHORITY FOR THE EXEMPTION:

18 V.S.A. § 174(a)(1).

PLEASE SUMMARIZE THE REASON FOR THE EXEMPTION:

18 V.S.A. § 174(a)(1) states: "All identifying information regarding an individual patient or health care provider is exempt from public inspection and copying under the Public Records Act and shall be kept confidential."

7. LEGAL AUTHORITY / ENABLING LEGISLATION:

(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. § 176.

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

3 V.S.A. § 801(b)(11) states, "'Adopting authority' means, for agencies that are attached to the Agenc[y] of...Human Services...the commissioner of [that] department." 18 V.S.A. § 176 states, "The Commissioner shall adopt rules pursuant to 3 V.S.A. chapter 25 to implement this chapter, including rules to govern the operation of the registry, data reported to the registry, and data release protocols."

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 implements the Vermont Amyotrophic Lateral Sclerosis (ALS) Registry created by 18 V.S.A. Chapter 4A that requires the Commissioner of Health to establish an ALS incidence registry system for the collection of information determining the incidence of ALS and related data.

15. EXPLANATION OF WHY THE RULE IS NECESSARY:

18 V.S.A. § 176 requires the Department to establish this registry and to adopt rules to govern the operation of the registry, data reported to the registry, and data release protocols.

16. EXPLANATION OF HOW THE RULE IS NOT ARBITRARY:

This rule creates the reporting requirements for the ALS Registry, as required by 18 V.S.A. § 176. The decisions made by the Department regarding these regulations are factually based, rationally connected to those factual bases, and would make sense to a reasonable person.

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

Health care providers

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

The only economic impact anticipated is based on the time it takes for providers to report ALS incidence data, which the Department expects to be de minimis. Only a few cases are anticipated to be reported each year.

19. A HEARING WAS 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: 11/14/2023

Time: 11:00 AM

Street Address: 108 Cherry St, Burlington, VT

Zip Code: 05401, Rm 2C

URL for Virtual: call in (audio only)

+1 802-828-7667, 62760364# United States, Montpelier

Phone Conference ID: 627 603 64#

Date:

Time: AM

Street Address:

Zip Code:

URL for Virtual:

Date:
Time: AM
Street Address:
Zip Code:
URL for Virtual:

Date:
Time: AM
Street Address:
Zip Code:
URL for Virtual:

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

11/21/2023

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

Amyotrophic Lateral Sclerosis

ALS

Registry

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:

Amyotrophic Lateral Sclerosis (ALS) Registry 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 if 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 **A NEW RULE** .

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

Not applicable.

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. If no impacts are anticipated, please specify “No impact anticipated” in the field.

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:

Amyotrophic Lateral Sclerosis (ALS) Registry 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:

Health care providers: the economic impacts are expected to be de minimis, based on the time it takes to report incidence data to the registry.

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:

No impact is anticipated.

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.*

Given there will be no impacts to school districts, those alternatives have not been considered.

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):

No impact is anticipated.

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.*

Given there will be no impacts to small businesses, those alternatives have not been considered.

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:

This rule is required to be adopted. The requirements are consistent for all providers regardless of the size of the business.

9. SUFFICIENCY: *DESCRIBE HOW THE ANALYSIS WAS CONDUCTED, IDENTIFYING RELEVANT INTERNAL AND/OR EXTERNAL SOURCES OF INFORMATION USED.*

The Department has provided the relevant information that is available.

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. If no impacts are anticipated, please specify “No impact anticipated” in the field.

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:

Amyotrophic Lateral Sclerosis (ALS) Registry 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.):*

No impact is anticipated.

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.):*

No impact is anticipated.

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

No impact is anticipated.

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

No impact is anticipated.

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

No impact is anticipated.

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

No impact is anticipated.

9. **SUFFICIENCY:** *DESCRIBE HOW THE ANALYSIS WAS CONDUCTED, IDENTIFYING RELEVANT INTERNAL AND/OR EXTERNAL SOURCES OF INFORMATION USED.*

This analysis considered the potential impacts of this rule to the areas listed above, and there will be none.

Public Input Maximization Plan

Instructions:

Agencies are encouraged to hold hearings as part of their strategy to maximize the involvement of the public in the development of rules. Please complete the form below by describing the agency's strategy for maximizing public input (what it did do, or will do to maximize the involvement of the public).

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

1. TITLE OF RULE FILING:

Amyotrophic Lateral Sclerosis (ALS) Registry Rule

2. ADOPTING AGENCY:

Vermont Department of Health

3. PLEASE DESCRIBE THE AGENCY'S STRATEGY TO MAXIMIZE PUBLIC INVOLVEMENT IN THE DEVELOPMENT OF THE PROPOSED RULE, LISTING THE STEPS THAT HAVE BEEN OR WILL BE TAKEN TO COMPLY WITH THAT STRATEGY:

The Department has solicited feedback on this rule from the Vermont Medical Society (VMS).

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

- Vermont Medical Society (VMS)
- Neurologist at the University of Vermont Medical Center (UVMC), Dr. Waqar Waheed
- Neurologist at Dartmouth Hitchcock Medical Center, Dr. Elijah Stommel
- Board of Medical Practice (BMP)
- Vermont Association of Hospitals and Health Systems
- The Centers for Disease Control and Prevention
- Michigan Department of Health and Human Services
- Maine Department of Health and Human Services



INTERAGENCY COMMITTEE ON ADMINISTRATIVE RULES (ICAR) MINUTES

Meeting Date/Location: September 11, 2023, virtually via Microsoft Teams

Members Present: Chair Sean Brown, Brendan Atwood, Jennifer Mojo, John Kessler, Diane Sherman, Michael Obuchowski, Nicole Dubuque, and Jared Adler (exited meeting at 4:00 PM)

Minutes By: Melissa Mazza-Paquette

- 2:00 p.m. meeting called to order, welcome and introductions.
- Review and approval of [minutes](#) from the August 14 and August 30, 2023 meetings.
- No additions/deletions to agenda. Agenda approved as drafted.
- Public comment made by Jay Greene of the Office of Racial Equity regarding the 'Amyotrophic Lateral Sclerosis (ALS) Registry Rule' proposed rule by the Vermont Department of Health:
 - Suggests that the reporting mechanism also incorporate options for non-binary people to be correctly reported in their gender identity on their legal documentation to the national data set as well.
- Presentation of Proposed Rules on pages 2-6 to follow:
 1. Judicial Nominating Board Rule Amendments, Judicial Nominating Board, page 2
 2. Suitability in Annuity Transactions (Reg. I-2023-01), Department of Financial Regulation, page 3
 3. Amyotrophic Lateral Sclerosis (ALS) Registry Rule, Vermont Department of Health, page 4
 4. Reporting of Offender Information, Agency of Human Services, Department of Corrections page 5
 5. Child Support Guidelines, Agency of Human Services, Department for Children and Families, Office of Child Support, page 6
- Due to the meeting running past the scheduled time and therefore lack of quorum, the following rules were moved to the October ICAR meeting:
 6. Residential Care Home and Assisted Living Residence Licensing Regulations, Agency of Human Services, Department of Disabilities, Aging, and Independent Living
 7. Independent School Program Approval Rules, State Board of Education
 8. Vermont Low Emission Vehicle and Zero Emission Vehicle Rules, Agency of Natural Resources
 9. Investigation and Remediation of Contaminated Properties Rule (IRule), Agency of Natural Resources
- Next scheduled meeting is October 9, 2023 at 2:00 p.m.
- 4:10 p.m. meeting adjourned.

**Proposed Rule: Amyotrophic Lateral Sclerosis (ALS) Registry Rule, Vermont Department of Health
Presented By: Brendan Atwood**

Motion made to accept the rule by Jen Mojo, seconded by Jared Atwood, and passed unanimously except for Brendan Atwood who abstained, with the following recommendations:

1. Proposed Filing – Coversheet, #8: Include what the registry will enable the Department to do.
2. Economic Impact Analysis, #3: Be as broad and thoughtful about that outreach as possible and include that information.
3. Public Input Maximization Plan, #4: Include others that have been or will be involved in the development of the proposed rule, such as the Board of Medical Practice, Dartmouth, Hitchcock and Eva Medical Center, etc.

Amyotrophic Lateral Sclerosis (ALS) Registry Rule

1.0 Authority

This rule is adopted pursuant to 18 V.S.A. § 176.

2.0 Purpose

This rule implements the Vermont Amyotrophic Lateral Sclerosis (ALS) Registry created by 18 V.S.A. chapter 4A that requires the Commissioner of Health to establish an ALS incidence registry system for the collection of information determining the incidence of ALS and related data.

3.0 Definitions

3.1 “Amyotrophic lateral sclerosis” or “ALS” means a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord.

3.2 “Commissioner” means the Commissioner of the Vermont Department of Health.

3.3 “Department” means the Vermont Department of Health.

3.4 “Health care provider” means a person, partnership, corporation, facility, or institution licensed or certified or authorized by law to provide professional health care service in this State to an individual during that individual’s medical care, treatment, or confinement.

3.5 “Registry” means the statewide amyotrophic lateral sclerosis incidence registry.

4.0 Data Reporting Requirements

4.1 A health care provider that screens for, diagnoses, or provides therapeutic services to patients with amyotrophic lateral sclerosis shall report to the Department all individuals diagnosed as having amyotrophic lateral sclerosis not later than six months from the date of diagnosis, unless the provider knows that a report for that patient has already been made to the Department.

4.2 The report shall include all of the data elements, if available, detailed on the ALS Registry reporting form provided by the Department. Those elements on the form marked with an “*” are required to be reported. The data elements include information related to:

- 4.2.1 Patient Identifiers and Demographics;
- 4.2.2 Patient Occupation and Industry;
- 4.2.3 ALS Diagnosis Information; and
- 4.2.4 Provider and Facility Identifiers.

5.0 Confidentiality and Data Release Requests

- 5.1 All identifying information regarding an individual patient or health care provider is exempt from public inspection and copying under the Public Records Act and shall be kept confidential.
- 5.2 Notwithstanding Section 5.1, the Commissioner may enter into data sharing and protection agreements with researchers or state, regional, or national amyotrophic lateral sclerosis registries for bidirectional data exchange, provided access under such agreements is consistent with the privacy, security, and disclosure protections in 18 V.S.A. chapter 4A. In the case of researchers, the Commissioner shall also first obtain evidence of the approval of their academic committee for the protection of human subjects established in accordance with 45 C.F.R. Part 46. The Commissioner shall disclose the minimum information necessary to accomplish a specified research purpose.
- 5.3 The Department may disclose aggregated and deidentified information from the registry.
- 5.4 All requests for data from the Registry shall be made using the form provided on the Department's ALS Registry website.

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STATE OF VERMONT
AGENCY OF HUMAN SERVICES

MEMORANDUM

TO: Sarah Copeland Hanzas, Secretary of State

FROM: Jenney Samuelson, Secretary, Agency of Human Services

A handwritten signature in blue ink, appearing to be 'Jenney Samuelson'.

DATE: January 31, 2023

SUBJECT: Signatory Authority for Purposes of Authorizing Administrative Rules

I hereby designate Deputy Secretary of Human Services Todd W. Daloz as signatory to fulfill the duties of the Secretary of the Agency of Human Services as the adopting authority for administrative rules as required by Vermont's Administrative Procedure Act, 3. V.S.A § 801 et seq.

Cc: Todd W. Daloz