

Emergency Filing - Coversheet

Instructions:

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

All forms shall be submitted to the Office of the Secretary of State, no later than 3:30 pm on the last scheduled day of the work week.

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

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

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

The nature of the peril is as follows (*PLEASE USE ADDITIONAL SHEETS IF SPACE IS INSUFFICIENT*). 18 V.S.A. § 176 requires the Department to establish this registry by 7/1/23. The regular ALS Registry rule will not be adopted for several months. Without this e-rule, some incidence data may not be reported as required.

I approve the contents of this filing entitled:

Amyotrophic Lateral Sclerosis (ALS) Registry Rule

/s/ Todd W. Daloz _____, on 8/7/23
(signature) (date)

Printed Name and Title:

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)

Todd W. Daloz
Deputy Secretary
Agency of Human Services

1. TITLE OF RULE FILING:

Amyotrophic Lateral Sclerosis (ALS) Registry Rule

2. ADOPTING AGENCY:

Vermont Department of Health, AHS

3. 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, AHS

Mailing Address: 108 Cherry Street, Burlington, VT 05401

Telephone: 802-863-728 Fax: 802-951-127

E-Mail: ahs.vdhrules@vermont.gov

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

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

4. SECONDARY CONTACT PERSON:

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

Name: Natalie Weill

Agency: Vermont Department of Health, AHS

Mailing Address: 108 Cherry Street, Burlington, VT 05401

Telephone: 802-863-728 Fax: 802-951-127

E-Mail: ahs.vdhrules@vermont.gov

5. RECORDS EXEMPTION INCLUDED WITHIN RULE:

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

IF YES, CITE THE STATUTORY AUTHORITY FOR THE EXEMPTION:

PLEASE SUMMARIZE THE REASON FOR THE EXEMPTION:

6. LEGAL AUTHORITY / ENABLING LEGISLATION:

(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.

7. 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."

8. 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.

9. 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 by 7/1/23.

10. EXPLANATION OF HOW THE RULE IS NOT ARBITRARY AS DEFINED IN 3 V.S.A. § 801(b)(13(A):

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.

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

Health care providers

12. 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.

13. A HEARING IS NOT SCHEDULED.

14. HEARING INFORMATION

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

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

Date:

Time: AM

Street Address:

Zip Code:

URL for Virtual:

Date:

Time: AM

Street Address:

Zip Code:

URL for Virtual:

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

16. EMERGENCY RULE EFFECTIVE: 08/15/2023

17. EMERGENCY RULE WILL REMAIN IN EFFECT UNTIL

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

02/11/2024

18. NOTICE OF THIS EMERGENCY RULE SHOULD NOT BE PUBLISHED IN THE WEEKLY NOTICES OF RULEMAKING IN THE NEWSPAPERS OF RECORD.

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

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, AHS

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 **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, AHS

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, AHS

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, AHS

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)

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 “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.
- 3.4 “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.
- 4.2 A reporting health care provider shall include in the report the data elements listed below if available. Those marked with an “*” are required to be reported.
- 4.2.1 Patient Information:
- Patient’s First and Last Name*
 - Date of Birth*
 - Town of Residence*

- State of Residence*
- Years living in this town
- Mailing address*
- City*
- State*
- Zip code*
- Is residence a nursing home*
- If resided in current town for <10 years, previous town of residence
- If resided in current town for <10 years, previous state of residence
- If resided in current town for <10 years, years living in previous residence town

4.2.2 Patient Demographic Information

- Race*
- Ethnicity*
- Sex*
- Military Veteran*
- Military Branch
- Military service history
- Payer Type

4.2.3 Patient Occupation and Industry Information

- Current occupation*
- Current industry*
- Date of last employment
- Years in current occupation
- Previous occupation
- Previous industry
- Years in previous occupation

4.2.4 Diagnosis Related Information

- Name of provider who made initial ALS diagnosis
- Facility of provider who made initial ALS diagnosis
- Date of diagnosis
- Date of onset of symptoms
- Does the patient have dementia diagnosed by a neurologist
- Does the patient have a family history of ALS or other neurological diseases
- Did the patient test positive for an ALS genetic trait
- Description of ALS genetic trait positive test results
- El Escorial Criteria*
- History of concussion or other head trauma

- Description of head trauma
- Was ALS diagnosis confirmed*
- How was diagnosis confirmed*

4.2.5 Reporting Health Care Provider Information:

- Name of reporting Provider*
- Date of report*
- Mailing address of reporting Provider*
- City of reporting Provider*
- State of reporting Provider*
- Zip code of Reporting Provider*
- Phone number of reporting Provider*

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 request for data from the Registry shall be made using the form provided on the ALS Registry website.



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