

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.