

## **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.