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S.90

Introduced by Senators Lyons, Terenzini, Campion, Chittenden, Cummings,
Hardy, Hooker and Perchlik

Referred to Committee on Health and Welfare

Date: February 24, 2021

Subject: Health; amyotrophic lateral sclerosis; registry

Statement of purpose of bill as introduced: This bill proposes to establish an
amyotrophic lateral sclerosis registry.

An act relating to establishing an amyotrophic lateral sclerosis registry

It is hereby enacted by the General Assembly of the State of Vermont:

~~Sec. 1, 18 V.S.A., chapter 4A, is added to read:~~

CHAPTER 4A. AMYOTROPHIC LATERAL SCLEROSIS REGISTRY

§ 171. DEFINITIONS

As used in this chapter:

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

(2) “Health care facility” has the same meaning as in section 9432 of
this title.

1 ~~(2) "Health care provider" has the same meaning as in section 9432 of~~
2 ~~this title.~~

3 § 172. ESTABLISHMENT OF AMYOTROPHIC LATERAL SCLEROSIS
4 REGISTRY

5 (a) The Commissioner shall establish a uniform statewide population-based
6 amyotrophic lateral sclerosis registry system for the collection of information
7 determining the incidence of amyotrophic lateral sclerosis and related data.

8 Pursuant to 3 V.S.A. chapter 25, the Commissioner shall adopt rules necessary
9 to effect the purposes of this chapter, including the data to be reported and the
10 effective date after which reporting by health care facilities and health care
11 providers shall be required.

12 (b) All cases of amyotrophic lateral sclerosis diagnosed or treated in the
13 State shall be reported to the representative of the Department of Health
14 authorized by the Commissioner to compile the amyotrophic lateral sclerosis
15 data, or any individual, agency, or organization designated to cooperate with
16 that representative.

17 (c) The Commissioner shall establish a training program for the personnel
18 of participating health care facilities and a quality control program for
19 amyotrophic lateral sclerosis data. The Commissioner shall collaborate in
20 studies with clinicians and epidemiologists and publish reports on the results of
21 such studies. The Commissioner shall cooperate with the National Institutes of

1 ~~Health and the Centers for Disease Control and Prevention in providing~~
2 amyotrophic lateral sclerosis incidence data.

3 § 173. PARTICIPATION IN PROGRAM

4 (a) Any health care facility diagnosing or providing treatment to patients
5 with amyotrophic lateral sclerosis shall report each case of amyotrophic lateral
6 sclerosis to the Commissioner or his or her authorized representative in a
7 format prescribed by the Commissioner within 180 days of admission or
8 diagnosis. If the facility fails to report in a format prescribed by the
9 Commissioner, the Commissioner's authorized representative may enter the
10 facility, obtain the information, and report it in the appropriate format. In
11 these cases, the facility shall reimburse the Commissioner or the authorized
12 representative for the cost of obtaining and reporting the information.

13 (b) Any health care provider diagnosing or providing treatment to patients
14 with amyotrophic lateral sclerosis shall report each case to the Commissioner
15 or his or her authorized representative within 180 days of diagnosis.

16 (c) All health care facilities and health care providers who provide
17 diagnostic or treatment services to patients with amyotrophic lateral sclerosis
18 shall report to the Commissioner any further demographic, diagnostic, or
19 treatment information requested by the Commissioner concerning any person
20 now or formerly receiving services. Additionally, the Commissioner or his or
21 her authorized representative shall have physical access to all records that

1 ~~would identify cases of amyotrophic lateral sclerosis or would establish~~
2 ~~characteristics of the amyotrophic lateral sclerosis, treatment of the~~
3 ~~amyotrophic lateral sclerosis, or medical status of any identified patient with~~
4 ~~amyotrophic lateral sclerosis. Willful failure to grant access to such records~~
5 ~~shall be punishable by a fine of up to \$500.00 for each day access is refused.~~
6 ~~Any fines collected pursuant to this subsection shall be deposited in the~~
7 ~~General Fund.~~

8 § 174. CONFIDENTIALITY

9 (a)(1) All information reported pursuant to this chapter is exempt from
10 public inspection and copying under the Public Records Act and shall be kept
11 confidential.

12 (2)(A) All identifying information regarding an individual patient,
13 health care provider, or health care facility contained in records of interviews,
14 written reports, and statements procured by the Commissioner or by any other
15 person, agency, or organization acting jointly with the Commissioner in
16 connection with amyotrophic lateral sclerosis morbidity and mortality studies
17 is exempt from public inspection and copying under the Public Records Act,
18 shall be kept confidential, and used solely for the purposes of studying
19 amyotrophic lateral sclerosis.

1 ~~(P) Nothing in this section shall prevent the Commissioner from~~
2 publishing statistical compilations relating to morbidity and mortality studies
3 that do not identify individual cases or sources of information.

4 (b) Notwithstanding 1 V.S.A. § 317(e), the Public Records Act exemption
5 created in this section shall continue in effect and shall not be repealed through
6 operation of 1 V.S.A. § 317(e).

7 § 175. DISCLOSURE

8 (a) The Commissioner may enter into agreements to exchange confidential
9 information with any other amyotrophic lateral sclerosis registries in order to
10 obtain complete reports of Vermont residents diagnosed or treated in other
11 states and to provide information to other states regarding their residents
12 diagnosed or treated in Vermont.

13 (b) The Commissioner may furnish confidential information to other
14 states' amyotrophic lateral sclerosis registries or health researchers in order to
15 collaborate in a national amyotrophic lateral sclerosis registry or to collaborate
16 in amyotrophic lateral sclerosis control and prevention research studies.

17 However, before releasing confidential information, the Commissioner shall
18 first obtain from such state registries, agencies, or researchers an agreement in
19 writing to keep the identifying information confidential and privileged. In the
20 case of researchers, the Commissioner shall also first obtain evidence of the

1 ~~approval of their academic committee for the protection of human subjects~~
2 established in accordance with 45 C.F.R. part 46.

3 § 176. LIABILITY

4 (a) No action for damages arising from the disclosure of confidential or
5 privileged information may be maintained against any person, or the employer
6 or employee of any person, who participates in good faith in the reporting of
7 amyotrophic lateral sclerosis registry data or data for amyotrophic lateral
8 sclerosis morbidity or mortality studies in accordance with this chapter.

9 (b) No license of a health care facility or health care provider may be
10 denied, suspended, or revoked for the good faith disclosure of confidential or
11 privileged information in the reporting of amyotrophic lateral sclerosis registry
12 data or data for amyotrophic lateral sclerosis morbidity or mortality studies in
13 accordance with this chapter.

14 (c) Nothing in this section shall be construed to apply to the unauthorized
15 disclosure of confidential or privileged information when such disclosure is
16 due to gross negligence or willful misconduct.

17 Sec. 2. EFFECTIVE DATE

18 ~~This act shall take effect on July 1, 2021.~~

~~Sec. 1-18 V.S.A. chapter 4A is added to read:~~

CHAPTER 4A. AMYOTROPHIC LATERAL SCLEROSIS REGISTRY

§ 171. DEFINITIONS

~~As used in this chapter:~~

(1) "Amyotrophic lateral sclerosis" or "ALS" means a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord.

(2) "Health care facility" has the same meaning as in section 9432 of this title.

(3) "Health care provider" has the same meaning as in section 9432 of this title.

§ 172. ESTABLISHMENT OF AMYOTROPHIC LATERAL SCLEROSIS
REGISTRY

(a) The Commissioner shall establish a uniform statewide population-based amyotrophic lateral sclerosis registry system for the collection of information determining the incidence of amyotrophic lateral sclerosis and related data. Pursuant to 3 V.S.A. chapter 25, the Commissioner shall adopt rules necessary to effect the purposes of this chapter, including the data to be reported and the effective date after which reporting by health care facilities and health care providers shall be required.

(b) All cases of amyotrophic lateral sclerosis diagnosed or treated in the State shall be reported to the representative of the Department of Health authorized by the Commissioner to compile the amyotrophic lateral sclerosis data, or any individual, agency, or organization designated to cooperate with that representative.

(c) The Commissioner shall establish a training program for the personnel of participating health care facilities and a quality control program for amyotrophic lateral sclerosis data. The Commissioner shall collaborate in studies with clinicians and epidemiologists and publish reports on the results of such studies. The Commissioner shall cooperate with the National Institutes of Health and the Centers for Disease Control and Prevention in providing amyotrophic lateral sclerosis incidence data.

§ 173. PARTICIPATION IN PROGRAM

(a) Any health care facility diagnosing or providing treatment to patients with amyotrophic lateral sclerosis shall report each case of amyotrophic lateral sclerosis to the Commissioner or the Commissioner's authorized representative in a format prescribed by the Commissioner within 180 days of admission or diagnosis. If the facility fails to report in a format prescribed by the Commissioner, the Commissioner's authorized representative may enter the facility, obtain the information, and report it in the appropriate format. In these cases, the facility shall reimburse the Commissioner or the authorized representative for the cost of obtaining and reporting the information.

~~(b) Any health care provider diagnosing or providing treatment to patients with amyotrophic lateral sclerosis shall report each case to the Commissioner or the Commissioner's authorized representative within 180 days of diagnosis.~~

~~(c) All health care facilities and health care providers who provide diagnostic or treatment services to patients with amyotrophic lateral sclerosis shall report to the Commissioner any further demographic, diagnostic, or treatment information requested by the Commissioner concerning any person now or formerly receiving services. Additionally, the Commissioner or the Commissioner's authorized representative shall have physical access to all records that would identify cases of amyotrophic lateral sclerosis or would establish characteristics of the amyotrophic lateral sclerosis, treatment of the amyotrophic lateral sclerosis, or medical status of any identified patient with amyotrophic lateral sclerosis.~~

~~§ 174. CONFIDENTIALITY~~

~~(a)(1) All information reported pursuant to this chapter is exempt from public inspection and copying under the Public Records Act and shall be kept confidential.~~

~~(2)(A) All identifying information regarding an individual patient, health care provider, or health care facility contained in records of interviews, written reports, and statements procured by the Commissioner or by any other person, agency, or organization acting jointly with the Commissioner in connection with amyotrophic lateral sclerosis morbidity and mortality studies is exempt from public inspection and copying under the Public Records Act, shall be kept confidential, and used solely for the purposes of studying amyotrophic lateral sclerosis.~~

~~(B) Nothing in this section shall prevent the Commissioner from publishing statistical compilations relating to morbidity and mortality studies that do not identify individual cases or sources of information.~~

~~(b) Notwithstanding 1 V.S.A. § 317(e), the Public Records Act exemption created in this section shall continue in effect and shall not be repealed through operation of 1 V.S.A. § 317(e).~~

~~§ 175. DISCLOSURE~~

~~(a) The Commissioner may enter into agreements to exchange confidential information with any other amyotrophic lateral sclerosis registries in order to obtain complete reports of Vermont residents diagnosed or treated in other states and to provide information to other states regarding their residents diagnosed or treated in Vermont.~~

~~(b) The Commissioner may furnish confidential information to other states amyotrophic lateral sclerosis registries or health researchers in order to collaborate in a national amyotrophic lateral sclerosis registry or to collaborate in amyotrophic lateral sclerosis control and prevention research studies. However, before releasing confidential information, the Commissioner shall first obtain from such state registries, agencies, or researchers an agreement in writing to keep the identifying information confidential and privileged. 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.~~

~~§ 176. LIABILITY~~

~~(a) No action for damages arising from the disclosure of confidential or privileged information may be maintained against any person, or the employer or employee of any person, who participates in good faith in the reporting of amyotrophic lateral sclerosis registry data or data for amyotrophic lateral sclerosis morbidity or mortality studies in accordance with this chapter.~~

~~(b) No license of a health care facility or health care provider may be denied, suspended, or revoked for the good faith disclosure of confidential or privileged information in the reporting of amyotrophic lateral sclerosis registry data or data for amyotrophic lateral sclerosis morbidity or mortality studies in accordance with this chapter.~~

~~(c) Nothing in this section shall be construed to apply to the unauthorized disclosure of confidential or privileged information when such disclosure is due to gross negligence or willful misconduct.~~

~~Sec. 2. GRANT APPLICATIONS TO FUND AMYOTROPHIC LATERAL SCLEROSIS REGISTRY~~

~~The Department of Health shall seek and apply for grants to fund the amyotrophic lateral sclerosis registry established in 18 V.S.A. chapter 4A. As part of its fiscal year 2024 budget presentation, the Department shall describe any grants applied for or awarded for this purpose or other identified funding sources.~~

~~Sec. 3. REPORT; REGISTRY EXPANSION~~

~~On or before December 1, 2022, the Department of Health shall submit a written report to the House Committees on Health Care and on Human Services and to the Senate Committee on Health and Welfare exploring the benefits of expanding the amyotrophic lateral sclerosis registry established in 18 V.S.A. chapter 4A by broadening the scope of neurodegenerative diseases addressed in the registry or by partnering with at least three neighboring states to collect data from a larger population, or both.~~

~~§ 170. EFFECTIVE DATES~~

~~(a) Except as provided in subsection (b) of this section, this act shall take effect on July 1, 2022.~~

~~(b) Sec. 1 (amyotrophic lateral sclerosis registry) shall take effect on July 1, 2023.~~

Sec. 1. 18 V.S.A. chapter 4A is added to read:

CHAPTER 4A. AMYOTROPHIC LATERAL SCLEROSIS REGISTRY

§ 171. DEFINITIONS

As used in this chapter:

(1) "Amyotrophic lateral sclerosis" or "ALS" means a progressive neurodegenerative disease that affects nerve cells in the brain and the spinal cord.

(2) "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) "Registry" means the statewide amyotrophic lateral sclerosis incidence registry.

§ 172. REGISTRY ESTABLISHED

The Commissioner shall establish, maintain, and operate a statewide amyotrophic lateral sclerosis incidence registry.

§ 173. DUTY OF HEALTH CARE PROVIDERS

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. The report shall include information on each individual's usual occupation and industry of employment and other elements determined by rule to be appropriate.

§ 174. CONFIDENTIALITY

(a)(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.

(2) Notwithstanding subdivision (1) of this subsection, 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 this chapter. 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.

(b) The Department may disclose aggregated and deidentified information from the registry.

§ 175. ANNUAL REPORT

Annually, on or before January 15, the Department shall submit a written report to the Governor, the House Committee on Human Services, and the Senate Committee on Health and Welfare containing the statewide prevalence and incidence estimates of amyotrophic lateral sclerosis, including any trends occurring over time across the State. Reports shall not contain information that directly or indirectly identifies an individual patient or health care provider.

§ 176. RULEMAKING

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.

§ 177. LIABILITY

(a) No action for damages arising from the disclosure of confidential or privileged information shall be maintained against any person, or the employer or employee of any person, who participates in good faith in the reporting of amyotrophic lateral sclerosis registry data or data for amyotrophic lateral sclerosis morbidity or mortality studies in accordance with this chapter.

(b) No license of a health care provider shall be denied, suspended, or revoked for the good faith disclosure of confidential or privileged information in the reporting of amyotrophic lateral sclerosis registry data or data for amyotrophic lateral sclerosis morbidity or mortality studies in accordance with this chapter.

(c) Nothing in this section shall be construed to apply to the unauthorized disclosure of confidential or privileged information when such disclosure is due to gross negligence or willful misconduct.

Sec. 2. DEPARTMENT OF HEALTH; EDUCATIONAL MATERIALS

(a) On or before December 31, 2022, the Commissioner of Health shall develop and make available written educational materials that provide information about the National Amyotrophic Lateral Sclerosis Registry, including:

(1) information regarding how to participate in the National Amyotrophic Lateral Sclerosis Registry and resources that can provide assistance with the registration process;

(2) information regarding the eligibility requirements for participation in the National Amyotrophic Lateral Sclerosis Registry; and

(3) contact information for the National Amyotrophic Lateral Sclerosis Registry and local and national research entities investigating the causes of amyotrophic lateral sclerosis.

(b) On or before December 31, 2022, the Department of Health, in cooperation with appropriate professional licensing boards and professional membership associations, shall ensure the educational materials developed pursuant to subsection (a) of this section are made available to all licensed health care providers in Vermont.

Sec. 3. GRANT APPLICATIONS TO FUND AMYOTROPHIC LATERAL SCLEROSIS REGISTRY

The Department of Health shall seek and apply for grants to fund the amyotrophic lateral sclerosis registry established in 18 V.S.A. chapter 4A. As part of its fiscal year 2024 budget presentation, the Department shall describe any grants applied for or awarded for this purpose or other identified funding sources, such as within existing budgets or from other external funding sources.

Sec. 4. EFFECTIVE DATES

This act shall take effect on July 1, 2022, except that Sec. 1 (amyotrophic lateral sclerosis registry) shall take effect on July 1, 2023.