**A** **BILL**

TO AMEND THE CODE OF LAWS OF SOUTH CAROLINA, 1976, TO ENACT “THE SOUTH CAROLINA PARKINSON’S DISEASE RESEARCH COLLECTION ACT” BY ADDING SECTION 44‑7‑3240 SO AS TO PROVIDE FOR THE COLLECTION OF DATA ON THE INCIDENCE OF PARKINSON’S DISEASE BY THE MEDICAL UNIVERSITY OF SOUTH CAROLINA AND TO ALLOW FOR DIAGNOSED PATIENTS TO PARTICIPATE VOLUNTARILY IN DATA COLLECTION; TO PROVIDE FOR THE CREATION OF A PARKINSON’S DISEASE ADVISORY BOARD AND TO PROVIDE FOR THE BOARD’S ROLES AND RESPONSIBILITIES; TO DEFINE TERMS; TO ESTABLISH REQUIREMENTS PERTAINING TO CONFIDENTIALITY AND DISSEMINATION OF COLLECTED INFORMATION AND RECORD KEEPING; TO REQUIRE REPORTING OF DATA BY HEALTH CARE FACILITIES AND PROVIDERS; TO ALLOW THE MEDICAL UNIVERSITY OF SOUTH CAROLINA TO ENTER INTO AGREEMENTS TO FURTHER THE PROGRAM; AND FOR OTHER PURPOSES.

Whereas, Parkinson’s disease is a chronic neurodegenerative disease that gradually worsens over time. It occurs when brain cells that make dopamine, a chemical that coordinates movement, stops working or die. There is no treatment to slow, stop, or reverse its progression, nor is there a cure; and

Whereas, there are one million people in the United State living with Parkinson’s disease and that number is expected to rise to 1.6 million by 2037 with a cost increase to $79 billion; and

Whereas, it is estimated that more than 110,000 military veterans, live with Parkinson’s and costs an estimated $58 billion each year in medical and nonmedical expenses, half of which is paid by the federal government; and

Whereas, the combined direct and indirect costs of Parkinson’s, including treatment and lost income, is estimated to be nearly $52 billion per year in the United States alone. Medications alone cost an average of $2,500 a year and therapeutic surgery can cost upwards of $100,000 per person; and

Whereas, the importance of states to collect critical research data is the first step to better understand who develops Parkinson’s and why; and

Whereas, the Medical University of South Carolina agrees to participate in this important research and supports passage of this legislation; and

Whereas, this legislation will expand our understanding of Parkinson’s disease to ultimately improve the lives of those affected, determine incidence and prevalence of Parkinson’s disease more accurately by state, and improve our understanding of the link between Parkinson’s and military service since a larger portion of the veteran’s community has Parkinson’s disease compared to the general population. Now, therefore,

Be it enacted by the General Assembly of the State of South Carolina:

SECTION 1. This act may be cited and known as “The South Carolina Parkinson’s Disease Research Collection Act”.

SECTION 2. Article 25, Chapter 7, Title 44 of the 1976 Code is amended by adding:

“Section 44‑7‑3240. (A)(1) The Medical University of South Carolina shall collect data on the incidence of Parkinson’s disease in South Carolina and other epidemiological data as defined in this section.

(2) For the purposes of this section:

(a) ‘Parkinson’s disease’ means a chronic and progressive neurologic disorder resulting from deficiency of the neurotransmitter dopamine as the consequence of specific degenerative changes in the area of the brain called the basal ganglia. It is characterized by tremor at rest, slow movements, muscle rigidity, stooped posture, and unsteady or shuffling gait. (b) ‘Parkinsonism’ means one or more related conditions that cause a combination of the movement abnormalities seen in Parkinson’s disease, such as tremor at rest, slow movement, muscle rigidity, impaired speech or muscle stiffness, which often overlap with and can evolve from what appears to be Parkinson’s disease. Examples of parkinsonism of particular interest include, but are not exclusive to, the following: Multiple System Atrophy (MSA), Dementia with Lewy Bodies (DLB), Corticobasal Degeneration (CBD), and Progressive Supranuclear Palsy (PSP).

(3) The database and system of collection and dissemination of information must be under the direction of the chief executive officer of MUSC, who may enter into contracts, grants, or other agreements as are necessary for the conduct of the program.

(B)(1) Every patient diagnosed with Parkinson’s disease or a related parkinsonism must be notified about the database and the opportunity to participate as provided in this subsection, but no patient may be forced to participate.

(2) A physician who diagnoses a patient with Parkinson’s disease or related parkinsonism, as advised by the advisory committee established pursuant to item (3), shall notify the patient orally and in writing about the database and the opportunity to participate by allowing for the collection of information and patient data on Parkinson’s disease. If a patient does not wish to participate, the physician shall certify in writing that the patient has been notified of the opportunity, and has been provided information about the operation of the database and afforded the opportunity to ask questions, but has declined.

(3) MUSC shall establish a Parkinson’s Disease Database Advisory Committee to assist in the development and implementation of the database; determine what data must be collected; and generally, advise MUSC. Membership of the committee must include at least one general neurologist, one movement disorder specialist, one primary care physician, one physician who practices clinical informatics, Parkinson’s patients, public health staff, population health researchers familiar with such databases, Parkinson’s disease researchers, and anyone else MUSC deems necessary.

(C) MUSC shall establish a system for the collection and dissemination of information determining the incidence and prevalence of Parkinson’s disease and related parkinsonism, as advised by the advisory committee. MUSC shall designate Parkinson’s disease and related parkinsonism as advised by the advisory committee as diseases required to be reported in the State or any part of the State. All cases of Parkinson’s disease diagnosed or treated in South Carolina must be reported to MUSC. However, the mere incidence of a patient with Parkinson’s is the sole required information for this database for any patient who chooses not to participate. For the subset of patients who choose not to participate, no further data may be reported to the database. MUSC may create, review, and revise a list of data points required as part of mandated Parkinson’s disease reporting pursuant to this section. This list must include, but not be limited to, necessary triggering diagnostic conditions, consistent with the latest International Statistical Classification of Diseases and Related Health Problems, and resulting case data including, but not limited to, diagnosis, treatment, and survival. MUSC may implement and administer this subsection through a bulletin, or similar instruction, to providers without taking regulatory action.

(D) MUSC shall provide notification of the mandatory reporting of Parkinson’s disease and parkinsonism on its website and also shall provide that information to associations representing physicians and hospitals and directly to the Board of Medical Examiners at least one hundred eighty days prior to requiring information be reported.

(E) A hospital, facility, physician, surgeon, physician assistant, nurse practitioner, or other health care provider deemed necessary by MUSC diagnosing or providing treatment to Parkinson’s disease or parkinsonism patients shall report each case of Parkinson’s disease and parkinsonism to MUSC in a format prescribed by MUSC. MUSC is authorized to enter into data sharing contracts with data reporting entities and their associated electronic medical record systems vendors to securely and confidentially receive information related to Parkinson’s disease testing, diagnosis, and treatment.

(F) MUSC may enter into agreements to furnish data collected in this database to other states’ Parkinson’s disease registries, federal Parkinson’s disease control agencies, local health officers, or health researchers for the study of Parkinson’s disease. Before confidential information is disclosed to those agencies, officers, researchers, or out‑of‑state registries, the requesting entity shall agree in writing to maintain the confidentiality of the information, and in the case of researchers, also shall do both of the following:

(1) obtain approval of the respective committee for the protection of human subjects established in accordance with 45 C.F.R. 46.101; and

(2) provide documentation to MUSC that demonstrates to MUSC’s satisfaction that the entity has established the procedures and ability to maintain the confidentiality of the information.

(G) Except as otherwise provided in this section, all information collected pursuant to this section is confidential. For purposes of this section, this information must be referred to as confidential information. To ensure privacy, MUSC shall promulgate a coding system that removes any identifying information about the patient.

(H) Notwithstanding another provision of law, a disclosure authorized by this section may include only the information necessary for the stated purpose of the requested disclosure, used for the approved purpose, and not be further disclosed.

(I) Provided the security of confidentiality has been documented, the furnishing of confidential information to MUSC or its authorized representative in accordance with this section does not expose any person, agency, or entity furnishing information to liability, and may not be considered a waiver of any privilege or a violation of a confidential relationship.

(J) MUSC shall maintain an accurate record of all persons who are given access to confidential information. The record must include:

(1) the name of the person authorizing access;

(2) name, title, address, and organizational affiliation of persons given access;

(3) dates of access; and

(4) the specific purpose for which information is to be used. The record of access must be open to public inspection during normal operating hours of MUSC.

(K)(1) Notwithstanding another provision of law, the confidential information may not be disclosed, is not discoverable, and may not be compelled to be produced in any civil, criminal, administrative, or other proceeding. The confidential information is not admissible as evidence in any civil, criminal, administrative, or other tribunal or court for any reason.

(2) This subsection does not prohibit the publication by MUSC of reports and statistical compilations that do not in any way identify individual cases or individual sources of information.

(3) Notwithstanding the restrictions in this subsection, the individual to whom the information pertains has access to his own information.

(L) This section does not preempt the authority of facilities or individuals providing diagnostic or treatment services to patients with Parkinson’s disease to maintain their own facility‑based Parkinson’s disease databases or registries.”

SECTION 3. This act takes effect twelve months after approval by the Governor.

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