## 214.375 Definitions -- Kentucky Parkinson's Disease Research Registry -- Kentucky Parkinson's Disease Research Registry Advisory Committee -- Duties of the cabinet -- Provider reporting requirements -- Data collection -- Reports.

(1) As used in this section:

- (a) "Advisory committee" means the Kentucky Parkinson's Disease Research Registry Advisory Committee established under subsection (3) of this section;
- (b) "Cabinet" means the Cabinet for Health and Family Services;
- (c) "Movement disorder center" means a health facility licensed under KRS Chapter 216B that operates outpatient clinics or ambulatory care facilities that employ movement disorder health care providers;
- (d) "Movement disorder health care provider" means a licensed physician or osteopath licensed under KRS Chapter 311 that is fellowship trained in movement disorders as specified by either the American Academy of Neurology's Movement Disorders Section or the Movement Disorder Society's Pan American Section;
- (e) "Parkinson's disease" means a chronic and progressive neurologic disorder resulting from a deficiency of the neurotransmitter dopamine as a consequence of specific degenerative changes in the area of the brain called the basal ganglia characterized by tremor at rest, slow movements, muscle rigidity, stooped posture, and unsteady or shuffling gait;
- (f) "Parkinsonisms":
  - 1. Means Parkinson's disease-related conditions that cause a combination of movement abnormalities such as tremor at rest, slow movement, muscle rigidity, impaired speech, and muscle stiffness, which often overlap with and can evolve from what appears to be Parkinson's disease; and
  - 2. Includes multiple system atrophy, dementia with Lewy bodies, corticobasal degeneration, and progressive supranuclear palsy;
- (g) "Registry" means the Kentucky Parkinson's Disease Research Registry established in subsection (2) of this section; and
- (h) "Secretary" means the secretary of the cabinet.

(2) The Kentucky Parkinson's Disease Research Registry is hereby established within the cabinet under the direction of the secretary, who may enter into contracts, grants, or other agreements as necessary to administer the registry in accordance with this section.

(3) (a) The secretary shall establish the Kentucky Parkinson's Disease Research Registry Advisory Committee to assist in the development and implementation of the registry, determine what data will be collected, and advise the cabinet.

- (b) The advisory committee shall be appointed by the secretary and include at least one (1):
  - 1. Neurologist;

2. Movement disorder specialist;
3. Primary care provider;
4. Physician informaticist;
5. Patient living with Parkinson's disease;
6. Public health professional;
7. Population health researcher familiar with health data registries;
8. Parkinson's disease researcher;
9. Representative from the University of Kentucky College of Medicine with specific expertise in Parkinson's disease; and
10. Representative from the University of Louisville School of Medicine with specific expertise in Parkinson's disease.

The secretary may appoint additional members to the advisory committee as he or she deems necessary.

(4) The cabinet shall:

(a) Promulgate administrative regulations in consultation with the advisory committee and in accordance with KRS Chapter 13A to:

1. Designate Parkinson's disease and identified Parkinsonisms as diseases that are required to be reported to the cabinet;
2. Establish a system of collection and dissemination of information on the incidence and prevalence of Parkinson's disease and Parkinsonisms in Kentucky and related epidemiological data;
3. Identify specific data points to be collected based on the following four (4) core categories of data:
   a. Patient demographics;
   b. Geography;
   c. Diagnosis; and
   d. Sufficient information to allow for deduplication of patient records in the registry;
4. Periodically review and revise data points to be collected to ensure data and data collection procedures adapt to new knowledge and technology;
5. Establish a coding system that removes a patient's name, address, Social Security number, fingerprints, photograph, and any other information by which the identity of a patient can be determined with reasonable accuracy; and
6. Develop guidelines and procedures for reviewing and approving requests to use registry data for valid scientific research;

(b) Receive and collect data for the registry on the incidence and prevalence of Parkinson's disease and Parkinsonisms in Kentucky and related epidemiological data, and may enter into data-sharing contracts with data-reporting entities and their associated medical record system vendors to securely and confidentially receive information related to Parkinson's disease testing, diagnosis, and treatment; and

(c) Be responsible for any costs incurred in administering the registry and implementing this section.

(5) (a) Beginning January 1, 2026, each movement disorder center that treats a patient with Parkinson's disease and each movement disorder health care provider who treats or diagnoses Parkinson's disease or Parkinsonisms for a patient not otherwise reported shall submit a Parkinson's disease report to the cabinet in a format required or approved by the cabinet.

(b) 1. Movement disorder centers and movement disorder health care providers shall provide each patient diagnosed with Parkinson's disease or Parkinsonisms with a notice regarding the reporting and collection of information and patient data on Parkinson's disease.

2. A patient who does not wish to participate in the collection of data for the purposes of research in the registry may affirmatively opt out in writing after an opportunity to review the documents and ask questions.

3. If a patient has chosen not to participate and has opted out under subparagraph 2. of this paragraph, the movement disorder center and the movement disorder health care provider shall only report that a Parkinson's disease case exists and no further data shall be reported to the cabinet for the purposes of the registry.

4. If a patient has been diagnosed with Parkinson's disease or Parkinsonsisms in error, the movement disorder center and the movement disorder health care provider shall notify the cabinet and the cabinet shall remove the patient from the registry.

(c) To ensure compliance with the reporting and notification requirements of this subsection, the secretary or his or her agent may, upon reasonable notice, inspect a representative sample of the medical records of patients admitted, diagnosed, or treated for Parkinson's disease or Parkinsonisms at a movement disorder center.

(d) A movement disorder center or movement disorder health care provider who in good faith submits a report in accordance with paragraph (a) of this subsection is not liable in any cause of action arising from the submission of the report.

(e) A movement disorder center or movement disorder health care provider may use automated reporting methods supplied by the cabinet or the Kentucky Health Information Exchange to meet the requirements of this subsection.

(6) The cabinet shall make data from the registry, with or without identifiers, available to researchers that have the approval of an institutional review board in accordance with requirements of the Federal Policy for the Protection of Human Subjects, 45 C.F.R. pt. 46, and, as applicable, 21 C.F.R. pt. 56, 45 C.F.R. pt. 164, KRS 216.2920 to 216.2929, 900 KAR 7:030 and 7:040, and any other relevant federal or state requirements.

(7) (a) The cabinet may enter into agreements to furnish data collected in the registry to other states' Parkinson's disease registries, federal Parkinson's disease control agencies, local health officers, or health researchers not described in

subsection (6) of this section for the study of Parkinson's disease.

(b) Before confidential information is disclosed pursuant to paragraph (a) of this subsection, the out-of-state registry, agency, officer, or researcher shall agree in writing to maintain the confidentiality of the information. A researcher shall also:

1. Obtain approval of the researcher's respective committee for the protection of human subjects under 45 C.F.R. pt. 46; and
2. Provide documentation to the cabinet that demonstrates to the cabinet's satisfaction that the researcher has established the procedures and ability to maintain the confidentiality of the information.

(8) (a) Except as specifically provided in this section, all information collected pursuant to this section shall be confidential.

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

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

(d) The cabinet shall maintain an accurate record of all persons who are given access to information collected by the cabinet pursuant to this section, which shall 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 accessed information is to be used.

The record of access shall be open to public inspection during normal operating hours of the cabinet.

(e) Notwithstanding any other provision of law, information collected by the cabinet pursuant to this section shall not be:

1. Available for subpoena or disclosed, discoverable, or compelled to be produced in any civil, criminal, administrative, or other proceeding; or
2. Deemed admissible as evidence in any civil, criminal, administrative, or other proceeding for any reason.

(9) This section does not:

(a) Prohibit the publication by the cabinet of reports and statistical compilations that do not in any way identify individual patients, cases, or sources of information;

(b) Restrict in any way a patient's access to his or her own information; or

(c) Prohibit movement disorder center or movement disorder health care providers from maintaining their own facility-based Parkinson's disease registries.

(10) (a) Nothing in this section shall be deemed to compel any individual to submit to any medical examination or supervision by the cabinet, any of its authorized representatives, or an approved researcher.

(b) A person who seeks information or obtains registry data pursuant to this section shall not contact a patient on the registry or the patient's family unless the cabinet has first obtained permission for the contact from the patient or the patient's family.

(11) The cabinet shall provide notice of the mandatory reporting of Parkinson's disease and Parkinsonisms required under this section on its website and to professional associations representing movement disorder center and movement disorder health care providers.

(12) (a) By October 1, 2027, and October 1 of each year thereafter, the cabinet shall submit to the Legislative Research Commission for referral to the Interim Joint Committee on Health Services a yearly program summary update that includes:

1. The incidence and prevalence of Parkinson's disease and Parkinsonisms in the state by county;
2. The number of records that have been reported to the cabinet and included in the registry; and
3. Demographic information, including but not limited to patients' age, gender, and race.

(b) In consultation with the advisory committee, the cabinet may include recommendations on necessary changes to the registry in the yearly program summary update.

(c) The cabinet shall publish the yearly program summary update in a downloadable format on the website created under subsection (13) of this section.

(13) By October 1, 2027, the cabinet shall create, and update annually thereafter, the Kentucky Parkinson's Disease Research Registry website where the public can find information related to the Parkinson's disease and the registry, the yearly program summary update, and any other information deemed relevant by the advisory committee.

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