Nebraska Parkinson's Disease Registry
Legal Requirements

Under the law, physicians are required to report patients to the Nebraska Department of Health and Human Services (DHHS) within sixty days of diagnosis of Parkinson's disease. The law also requires that pharmacists report patients prescribed any medication on the 'Reportable List of Drugs' to the (DHHS). Individuals may also self-report to the registry.

Since this is a state-mandated registry, it is exempt from HIPAA disclosure issues; patient consent is not needed to send us the information requested.

Please see the Parkinson’s Disease Registry Act and the Rules and Regulations beginning on the following page:

PARKINSON'S DISEASE REGISTRY ACT

81-697
Act, how cited.

Sections 81-697 to 81-6,110 shall be known and may be cited as the Parkinson's Disease Registry Act.

Source:
Laws 2001, LB 152, § 5.

81-698
Purpose of registry.

The purpose of the Parkinson's Disease Registry is to provide a central data bank of accurate, historical and current information for research purposes. The Parkinson's Disease Registry Act will provide for screening and collecting patient and family data that may be useful in detecting the incidence of and possible risk factors concerning Parkinson's disease and related movement disorders. The act will also aid in planning for health care requirements and education needs.

Source:
Laws 2001, LB 152, § 6.

81-699
Terms, defined.

For purposes of the Parkinson's Disease Registry Act:
(1) Approved researcher means an individual or entity who is approved by the department in accordance with section 81-666 to obtain access to data contained in the Parkinson's Disease Registry to assist in scientific or medical research for the prevention, cure, or control of Parkinson's disease;
(2) Department means the Department of Health and Human Services;
(3) Parkinson's disease means a chronic, progressive disorder in which there is a lack of the chemical dopamine in the brain as a direct result of the destruction of the dopamine-producing cells in the portion of the brain called the substantia nigra. Clinical features of the disease include tremor at rest, slow movements, rigidity, and unsteady or shuffling gait and may be indicated by improvement after using medications used for Parkinson's disease; and
(4) Related movement disorder means a disorder that resembles Parkinson's disease in some way, such as another kind of tremor.

Source:
Laws 2001, LB 152, § 7; Laws 2007, LB 296 §750.

81-6,100
Parkinson's Disease Registry; contents.

The department shall establish and maintain the Parkinson's Disease Registry. The registry shall consist of a compilation of the reports of cases of Parkinson's disease and related movement disorders occurring among residents of this state which are with the department. The registry shall include information the department deems necessary and appropriate for the statistical identification and planning for treatment and education of health care providers and persons diagnosed with Parkinson's disease and related movement disorders.

Source:
Laws 2001, LB 152, § 8.

81-6,101
Department; duties.

The department shall:
(1) Adopt and promulgate rules and regulations, including a uniform system of classification of Parkinson's disease which is consistent with medically and clinically accepted standards and definitions for use in reporting by medical personnel treating the disease;
(2) Execute any contracts that the department deems necessary to carry out the Parkinson's Disease Registry Act;
(3) Receive and record the data obtained from reports filed under sections 81-6,102 and 81-6,103; and
(4) Comply with all necessary requirements to obtain funds or grants.

Source:
Laws 2001, LB 152, § 9; Laws 2005, LB 301, § 67.

81-6,102
Diagnosis; report; contents.

(1) If a resident of this state is diagnosed with Parkinson's disease or a related movement disorder within this state in the office of a physician licensed under the Uniform Credentialing Act, the physician shall file a report of the diagnosis and pertinent information with the department within sixty days after the diagnosis.
(2) An individual resident of this state who has been diagnosed with Parkinson's disease or a related movement disorder by a licensed physician may file a report with the department providing relevant information. The department shall provide for validation of individual reports.
(3) A report filed under this section shall contain the following information about the person diagnosed with Parkinson's disease or a related movement disorder:

(a) Name;
(b) Social security number;
(c) Date of birth;
(d) Gender;
(e) Address at time of diagnosis;
(f) Current address;
(g) Date of diagnosis;
(h) Physician;
(i) Identification of reporting source; and
(j) Any additional information the department demonstrates is reasonable to implement the Parkinson's Disease Registry Act.

Source:
Laws 2001, LB 152, § 10; Laws 2007, LB463, §1313.

Cross Reference:
Uniform Credentialing Act, see section 38-101.

81-6,103
Pharmacist; report; department; duty.

The pharmacist in charge of each pharmacy located within the state or doing business in the state shall file a semiannual report with the department listing persons to whom the pharmacist has dispensed drugs on the list of drugs required to be reported under this section for Parkinson's disease. The report shall include the name, address, and social security number of the person for whom the drugs were prescribed and the name and address

of the prescribing physician. The department shall issue a list of drugs used for the treatment of Parkinson's disease to be reported under this section, shall review and revise the list annually, and shall distribute the list to each pharmacy located within the state or doing business in the state.

Source:
Laws 2001, LB 152, § 11.

81-6,104
Release of data; other sections applicable.

All data and information developed or collected pursuant to the Parkinson's Disease Registry Act and the receipt and release of data from the Parkinson's Disease Registry is subject to and shall comply with sections 81-663 to 81-675. For purposes of the Parkinson's Disease Registry, data may be released as Class I data, Class II data, Class III data, or Class IV data as classified in section 81-667.

Source:
Laws 2001, LB 152, § 12.

81-6,105
Patient and patient's family; privacy rights.

Nothing in the Parkinson's Disease Registry Act shall be deemed to compel any individual to submit to any medical examination or supervision by the department, any of its authorized representatives, or an approved researcher. No person who seeks information or obtains registry data pursuant to the act shall contact a patient on the registry or such patient's family unless the registry has first obtained the permission of such patient or patient's family. The registry shall coordinate its activities with the person desiring such contact and may authorize the person desiring such contact to perform these contacts under the direction of the registry.

Source:
Laws 2001, LB 152, § 13; Laws 2002, LB 1021, § 108.

81-6,106
Refusal to provide information; effect.

Nothing in the Parkinson's Disease Registry Act requires a physician or pharmacist to deny medical treatment or services to an individual who refuses to provide the information necessary to make complete reports required under section 81-6,102 or 81-6,103.

Source:
Laws 2001, LB 152, § 14.

81-6,107
Immunity from liability.

Any physician or pharmacist required to make reports under section 81-6,102 or 81-6,103 is immune from liability, civil, criminal, or otherwise, for filing an incomplete report as a result of the failure of an individual to provide the information necessary to make such report.

Source:
Laws 2001, LB 152, § 15; Laws 2003, LB 667, § 23.

81-6,108
Repealed. Laws 2003, LB 667, §26.

81-6,109
Transition from prior law.

(1) On and after May 26, 2001, for purposes of the Parkinson's Disease Registry Act:

(a) Any rules, regulations, and orders of the Department of Health and Human Services Regulation and Licensure adopted pursuant to the former Parkinson's Disease Registry Act, as such act existed prior to February 14, 2001, and in effect on February 13, 2001, shall be revived and continue in effect until revised, amended, repealed, or nullified pursuant to law;

(b) Any contracts entered into by the department prior to February 14, 2001, and in effect on February 13, 2001, in connection with the duties and functions of the former act are recognized and may be revived upon the agreement of all contract parties. If revived, the department shall succeed to all rights and obligations under such contracts;

(c) Any cash funds, custodial funds, gifts, trusts, grants, and appropriations of funds which were available for use by the department for purposes of the former act shall continue to be available for use by the department if such funds continue to exist; and

(d) Any documents created, information compiled, or property used by the department under the former act shall continue to be available to and may be used by the department.

(2) For purposes of this section, former act means the Parkinson's Disease Registry Act, as such act existed prior to February 14, 2001, which act was outright repealed in Laws 2001, LB 209.

Source:
Laws 2001, LB 152, § 17.

81-6,110
Costs; how paid; termination of registry; when.

Costs associated with administration of the Parkinson's Disease Registry Act shall be paid from cash funds, contract receipts, gifts, and grants. No general funds shall be used to pay such costs. Funds received by the department for the payment of such costs shall be remitted to the State Treasurer for credit to the Department of Health and Human Services Cash Fund. Notwithstanding any other provision of the act, the Parkinson's Disease Registry and all duties related to the administration of such registry and such act shall cease as of June 30 of any year in which the department has insufficient funds on hand to perform its duties under the act for the next fiscal year, after providing thirty days' written notice to each approved researcher who has contracted with the department under section 81-6,101 in the current biennium.

Source:
Laws 2001, LB 152, § 18; Laws 2003, LB 667, § 24; Laws 2007, LB296, § 751.

TITLE 186 HEALTH REGISTRIES AND RELEASE OF INFORMATION

CHAPTER 4 PARKINSON'S DISEASE REGISTRY

4-001 SCOPE AND AUTHORITY: The purpose of the Parkinson's Disease Registry is to establish and maintain a compilation of cases of Parkinson's disease and related movement disorders occurring among residents of the state of Nebraska to achieve the goals of statistical identification for research, planning for health care requirements, and education of health care providers and persons with Parkinson's disease and related movement disorders.

186 NAC 4 applies to each physician licensed under the Uniform licensing law and the pharmacist in charge of each pharmacy located within the state or doing business in the state. 186 NAC 4 sets forth procedures for the reporting of such cases and information to the Department by physicians and pharmacists. 186 NAC 4 also provides procedures and standards that govern access to registry data pursuant to Neb. Rev. Stat. §§ 81-663 to 81-675.

4-002 DEFINITIONS:

Department means the Nebraska Department of Health and Human Services Regulation and Licensure.

Parkinson's disease means a chronic, progressive disorder in which there is a lack of the chemical dopamine in the brain as a direct result of the destruction of the dopamine-producing cells in the portion of the brain called the substantia nigra. Clinical features of the disease include tremor at rest, slow movements, rigidity, and unsteady or shuffling gait and may be indicated by improvement after using medications used for Parkinson's disease.

Related movement disorder means a disorder that resembles Parkinson's disease in some way, such as another kind of tremor.

4-003 LIST OF DRUGS REQUIRED TO BE REPORTED FOR PARKINSON'S DISEASE: The Department will issue a list of drugs used for the treatment of Parkinson's disease to be reported under this section. A copy of the list is provided in Attachment 1. This list will be reviewed and revised annually. The annual list will be revised before January 1 of each year. During January of each year, the Department will distribute the list to each pharmacy located within the state or doing business in the state. The list distributed in January will be used for all cases reported in that calendar year.

4-004 DATA REQUIREMENTS: Data to be reported to the Department for each individual resident of this state who is diagnosed with Parkinson's disease or related movement disorder as specified by reporting requirements set forth in 186 NAC 4-004.01 to 4-004.03.

4-004.01 Physician reporting requirements. Each physician licensed under the Uniform Licensing Law must report the diagnosis of Parkinson's disease or related movement disorder and required information for all Nebraska residents within 60 days after the diagnosis is made. The report must contain the following information about the person diagnosed with Parkinson's disease or related movement disorder:

1. Name;
2. Social security number;
3. Date of birth;
4. Gender;
5. Address at time of diagnosis;
6. Current address;
7. Date of diagnosis;
8. Physician;
9. Identification of reporting source; and
10. Any additional information the department demonstrates is reasonable to implement the Parkinson's Disease Registry Act.

4-004.02 Pharmacist reporting requirements. The pharmacist in charge of each pharmacy located within the state or doing business in the state must report dispensation of drugs that are included on the list of drugs to be reported for Parkinson's disease issued by the Department each January. The report will be filed on a semi-annual basis. The report for the months of January through June must be due on or before the following July 31st, and the report for the months of July through December must be due on or before January 31st of the following year. Data to be reported to the Department for each individual resident of this state to whom the pharmacist has dispensed drugs as specified on the list of drugs required to be reported for Parkinson's disease, as specified in 186 NAC 4-003 are as follows:

1. Name;
2. Address;
3. Social security number;
4. Name of the prescribing physician; and
5. Address of the prescribing physician.

4-004.03 Individual reporting. Any individual resident of this state who has been diagnosed with Parkinson's disease or a related movement disorder by a licensed physician may file a report with the Department providing the following information:

1. Name;
2. Social security number;
3. Date of birth;
4. Gender;
5. Address at time of diagnosis;
6. Current address;
7. Date of diagnosis;
8. Physician;
9. Identification of reporting source; and
10. Any additional information the department demonstrates is reasonable to implement the Parkinson's Disease Registry Act.

The Department must validate all individual reports as specified in 186 NAC 4-005.

4-005 VALIDATION OF INDIVIDUAL REPORTS: The Department must provide for validation of reports made by individuals who have been diagnosed with Parkinson's disease or related movement disorder. This validation will consist of finding a corroborating report within the information having been reported by physicians.

4-006 AVAILABILITY OF MEDICAL RECORDS: Each physician must make available medical records that document the diagnosis of individuals with Parkinson's disease or related movement disorders. Each pharmacist must make available patient drug profiles that document the prescribing of the reportable drugs. For the Department's purpose of recording and auditing specific data such medical records or patient drug profiles must be made available to the Department or its authorized representative in the offices of such physician or pharmacist during normal working hours. The Department or its authorized representative will present proper identification to the physician or pharmacist.

4-007 CONFIDENTIALITY AND RELEASE OF INFORMATION: All data and information obtained from records of individuals with Parkinson's disease or related movement disorders will be subject to and comply with Neb. Rev. Stat. §§ 81-663 to 81-675. For the purposes of the Parkinson's Disease Registry data may be released either as Class I, Class II, Class III, or Class IV data as described in Neb. Rev. Stat. §§ 81-667 and 186 NAC 5 Release of Medical Records and Health Information.

Any de-identified data (other than Class III data) asked for by and furnished to a researcher may not be intentionally re-identified in any manner. Should a recipient of de-identified information unintentionally or accidentally be able to identify any individual they must not use that information in any way. The recipient must also notify the Department of the means of accidental re-identification in order for the Department to consider additional procedures to safeguard against breaches in confidentiality.

4-008 RELEASE FROM LIABILITY: Any physician, pharmacist, or medical professional required to make reports under the Parkinson's Disease Registry Act and 186 NAC 4-004.01 and 4-004.02 is immune from liability, civil, criminal, or otherwise, that might result from divulging such information. Any physician, pharmacist or medical professional required to make reports is immune from liability, civil, criminal, or otherwise, for filing an incomplete report as a result of the failure of an individual to provide the information necessary to make such a report.

4-009 PENALTY FOR IMPROPER DISCLOSURE: Any private or public entity, individual, or approved researcher who wrongfully discloses confidential data obtained from the medical record and health information registry or uses such information with the intent to deceive will be guilty of a Class IV misdemeanor for each offense. Any person or entity that fails to make reports in good faith as provided by the Parkinson's Disease Registry Act will be guilty of a Class V misdemeanor for each offense.

REPORTABLE LIST OF DRUGS
Effective January 1, 2016

Nebraska Parkinson's Disease Registry
Nebraska Department of Health and Human Services

To fully implement the Nebraska Parkinson's Disease Registry, the following is a list of drugs, which if dispensed in any combination or in any generic form, require reporting of certain items to the Nebraska Department of Health and Human Services. These items are patient name and address, Social Security number and prescribing physician name and address.

Azilect
Carbidopa/levodopa (if prescribed for times other than evening or bedtime only)
Mirapex (if prescribed for times other than evening or bedtime only)
Neupro
Requip (if prescribed for times other than evening or bedtime only)
Selegiline (except Emsam)
Stalevo

PLEASE NOTE: **DO NOT** REPORT PATIENTS IF
THE PHYSICIAN INDICATES THAT THE DRUG IS PRESCRIBED FOR
RESTLESS LEG SYNDROME ONLY
OR IF THE DRUG IS PRESCRIBED FOR **EVENING OR BEDTIME USE ONLY**.

Please submit this information to:
Jill Krause
DHHS Public Health/Health Statistics
PO Box 95026
Lincoln NE 68509-5026

For more information, please send an email to jill.krause@nebraska.gov, call (402) 471-8582, or visit our website www.dhhs.ne.gov/parkinsons.

Thank you for your support of the Nebraska Parkinson's Disease Registry!