

NEBRASKA DEPARTMENT OF HEALTH AND HUMAN SERVICES
NOTICE OF PUBLIC HEARING

October 8, 2019
10:00 a.m. Central Time
Nebraska State Office Building – Lower Level B
301 Centennial Mall South, Lincoln, Nebraska

The purpose of this hearing is to receive comments on proposed changes to Title 186, Chapter 4 of the Nebraska Administrative Code (NAC) – *Parkinson's Disease Registry*. The proposed changes remove duplicative statutory language from the regulations; add additional data elements to be collected; and update formatting.

Authority for these regulations is found in Neb. Rev. Stat. § 81-3117(7).

Interested persons may attend the hearing and provide verbal or written comments or mail, fax or email written comments, no later than the day of the hearing to: DHHS Legal Services, PO Box 95026, Lincoln, NE 68509-5026, (402) 742-2382 or dhhs.regulations@nebraska.gov, respectively.

A copy of the proposed changes is available online at <http://www.sos.ne.gov>, or by contacting DHHS at the mailing address or email above, or by phone at (402) 471-8417. The fiscal impact statement for these proposed changes may be obtained at the office of the Secretary of State, Regulations Division, 1201 N Street, Suite 120, Lincoln, NE 68508, or by calling (402) 471-2385.

Auxiliary aids or reasonable accommodations needed to participate in a hearing can be requested by calling (402) 471-8417. Individuals with hearing impairments may call DHHS at (402) 471-9570 (voice and TDD) or the Nebraska Relay System at 711 or (800) 833-7352 TDD at least 2 weeks prior to the hearing.

FISCAL IMPACT STATEMENT

Agency: Department of Health and Human Services	
Title: 186	Prepared by: Jill Krause
Chapter: 4	Date prepared: July 3, 2019
Subject: NE Parkinson's Disease Registry	Telephone: 402-471-8582

Type of Fiscal Impact:

	State Agency	Political Sub.	Regulated Public
No Fiscal Impact	(<input checked="" type="checkbox"/>)	(<input checked="" type="checkbox"/>)	(<input type="checkbox"/>)
Increased Costs	(<input type="checkbox"/>)	(<input type="checkbox"/>)	(<input type="checkbox"/>)
Decreased Costs	(<input type="checkbox"/>)	(<input type="checkbox"/>)	(<input type="checkbox"/>)
Increased Revenue	(<input type="checkbox"/>)	(<input type="checkbox"/>)	(<input type="checkbox"/>)
Decreased Revenue	(<input type="checkbox"/>)	(<input type="checkbox"/>)	(<input type="checkbox"/>)
Indeterminable	(<input type="checkbox"/>)	(<input type="checkbox"/>)	(<input checked="" type="checkbox"/>)

Provide an Estimated Cost & Description of Impact:

State Agency:

Political Subdivision:

Regulated Public: **Indeterminable**

If indeterminable, explain why:

The time to report data varies for this ONE time reporting based upon the provider case load and existence of electronic medical records versus manual data reporting. Not all providers must submit this information; only those that newly diagnose a patient with Parkinson's Disease (one time).

There will be NO system upgrades or system purchases required to report this data. Providers already have processes to submit their data. Providers will not be the sole source of this data; existing electronic medical record systems are able to submit the data without manual processing.

The State has streamlined the process as much as possible. The State is working to ease the data reporting burden by creating electronic data submission capabilities. Since receiving Medicaid HITECH 90/10 funding in 2017, the State has developed an electronic system to be able to house and analyze this data.

To reduce the reporting burden on individual providers, our first data exchange partner will be the Nebraska Health Information Initiative (NeHII) which is already receiving a large percentage of the data to be reported. Data exchange will then be pursued with neurology and other clinics in the state not participating with NEHII to capture all possible Parkinson's cases.

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.~~

EFFECTIVE
JANUARY 1, 2014

NEBRASKA DEPARTMENT OF
HEALTH AND HUMAN SERVICES

186 NAC 4
ATTACHMENT 1

REPORTABLE LIST OF DRUGS
Effective January 1, 2014

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!**

TITLE 186 HEALTH REGISTRIES AND RELEASE OF INFORMATION

CHAPTER 4 PARKINSON'S DISEASE REGISTRY

001. SCOPE AND AUTHORITY. These regulations implement the establishment and maintenance of a registry pursuant to Nebraska Revised Statutes (Neb. Rev. Stats.) §§ 81-697 to 81-6,110 and 81-663 to 81-675.

002. DEFINITIONS. Definitions set out in Neb. Rev. Stat. §§ 81-697 to 81-6,110 and 81-663 to 81-875 apply to this chapter.

003. PHYSICIAN REPORTING REQUIREMENTS. Reports filed by physicians shall include the information identified in Neb. Rev. Stat. § 81-6,102 and the following:

- (A) Race;
- (B) Ethnicity;
- (C) Education level;
- (D) Marital Status;
- (E) Occupation;
- (F) Type of dementia, if any;
- (G) Bradykinesia diagnosis, if any;
- (H) Gait difficulty diagnosis, if any;
- (I) All Parkinson's disease-related medications – name, dose, frequency; and
- (J) All Parkinson's disease-related procedures provided.

003.01 REPORTING IN LIEU OF PHYSICIANS. If a licensed healthcare facility or the Nebraska Health Information Exchange Initiative, or its successor, submits the required information to the Department, the physician is not required to make the report to the Department. Physicians remain obligated to report when such report is not made by either a licensed healthcare facility or the Nebraska Health Information Exchange Initiative, or its successor, or a report does not contain all of the required information.

004. INDIVIDUAL REPORTING. An individual may file a report as provided in Neb. Rev. Stat. § 81-6,102 with the information set out in 186 Nebraska Administrative Code (NAC) 4-003 and the name of the treating physician.

005. PHARMACIST REPORTING REQUIREMENTS. Reports filed by pharmacist shall include the information identified in Neb. Rev. Stat. § 81-6,103. The report for the months of January through June must be filed on or before the following July 31st, and the report for the months of July through December must be filed on or before January 31st of the following year.

006. AVAILABILITY OF MEDICAL RECORDS. For purposes of validation of reports made by individuals 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. 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.

007. CONFIDENTIALITY AND RELEASE OF INFORMATION. Data can only be released as provided by statute and Title 186 NAC. Any de-identified 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.