Title 17. Public Health

Division 1. State Department of Health Services (Refs & Annos)

Chapter 4. Preventive Medical Service (Refs & Annos)

Adopt Subchapter 17 to read as follows:

Subchapter 17. California Parkinson's Disease Registry and California Neurodegenerative Disease Registry

Article 1. General

§ 7101. Definitions

For the purposes of this subchapter the following definitions apply:

"Authorized user" means an employee or contractor who has completed the registration, onboarding, and data validation process with the Parkinson's Registry or Neurodegenerative Registry that allows them to transmit case reports on behalf of the mandatory reporter to the Department.

"California Neurodegenerative Disease Registry" or "Neurodegenerative Registry" means the program authorized to receive, collect, and share the neurodegenerative disease related data required to be reported under this subchapter, and to maintain the system by which the data is reported to the Department.

"California Parkinson's Disease Registry" or "Parkinson's Registry" means the program authorized to receive, collect, and share the Parkinson's disease related data required to be reported under this subchapter, and to maintain the system by which the data is reported to the Department.

"Case report" means the health data and patient information required to be submitted quarterly to either the Parkinson's Registry or the Neurodegenerative Registry or both pursuant to the Health and Safety Code and this subchapter.

“Confidential information” means any information collected by the Department for the Parkinson’s Registry and Neurodegenerative Registry pursuant to Health and Safety Code sections 103870(g) and 103871(g), including data submitted in case reports.

“Data category” means a basic unit of standardized information which contains one or more data fields pertaining to a case report.

“Data field” means a specific variable for data inputs such as the patient’s name, date of birth, symptom onset, or other information pertaining to a case report.

“Data recovery measures” means any steps the Department takes to obtain required data from a mandatory reporter that fails to comply with the requirements of the Health and Safety Code and this subchapter.

“Data validation” means the process by which the Department audits the quality of data submitted by mandatory reporters for accuracy and prescribes measures for improving the quality of future case reports.

“Department” means the California Department of Public Health.

“Encounter” means an interaction between a patient and a hospital, facility, physician and surgeon, or other health care provider of diagnostic, treatment or therapeutic services for Parkinson’s disease or a neurodegenerative disease, rendered for the purpose of providing healthcare services or assessing the health status of the patient, and conducted either in person or electronically via telemedicine, telephone call, online chat, video call, or another technology platform.

“Neurodegenerative disease” means a medical condition relating to or marked by the degeneration of nervous tissue including Alzheimer's disease, multiple sclerosis (MS), Huntington's disease, amyotrophic lateral sclerosis (ALS, also known as “Lou Gehrig’s disease”), and other diseases designated as reportable by the Department under section 7205 of this subchapter.

“Personal information” means the same information defined under Civil Code section 1798.3 as well as any other identifying particular assigned to a person, including the

person's name, date of birth, California driver's license or identification number, medical record number, Social Security Number, physical description, home address, mailing address, electronic mail (email) address, telephone number, medical history, employment history, or any record of information, including data or metadata collected, created, or stored in an electronic form, that identifies or describes a particular person.

"Recipient institution" means any applicant agency or institution that has completed the application process under Article 4 of this subchapter and has been granted authorization by the Department to access confidential information maintained by the Parkinson's Registry or the Neurodegenerative Registry or both.

"Reporting environment" means the location where case reports are transmitted to the Department by mandatory reporters using secure data transfer methods.

"Reporting process" means all the steps required to collect and transmit case reports to the Parkinson's Registry or the Neurodegenerative Registry under this subchapter.

"Willful noncompliance" means deliberate, intentional, or wanton conduct in doing or omitting to perform acts with knowledge or appreciation of the fact, on the part of a mandatory reporter, or their agent, employee, authorized user, or independent contractor, that noncompliance with the requirements of the Health and Safety Code or this subchapter is likely to result therefrom, or as otherwise specified in this subchapter.

"Written notification of corrective action" or "corrective action notice" means a document sent by the Department to a mandatory reporter or a recipient institution with an explanation of each instance of noncompliance with the requirements of the Health and Safety Code or this subchapter.

"Written notification of proposed sanctions" means a document sent by the Department to a mandatory reporter or a recipient institution with an explanation of each proposed sanction for failure to address each instance of noncompliance specified in a corrective action notice.

"Written statement of data destruction" means a document submitted by a recipient institution to the Department to confirm that any confidential information provided by the Department to the recipient institution under this subchapter has been destroyed and can no longer be accessed by any person.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103870.1, 103871, 103871.1, and 103871.2, Health and Safety Code. Reference: Sections 103870, 103870.1, 103871, and 103871.1, Health and Safety Code.

§ 7203. Purpose of the Parkinson's Registry and Neurodegenerative Registry

The Parkinson's Registry and the Neurodegenerative Registry collect information for the purpose of determining the incidence and prevalence of Parkinson's disease and neurodegenerative disease as required by law. The requirements of this subchapter facilitate the statutory requirement to gather health information in the form of case reports containing encounter data gathered by healthcare institutions and individual licensees providing diagnostic, therapeutic, and treatment services to patients with Parkinson's disease and neurodegenerative disease. The Department collects, analyzes, and shares data and information regarding the incidence and prevalence of Parkinson's disease and neurodegenerative disease to protect public health.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103870.1, 103871, 103871.1, and 103871.2, Health and Safety Code. Reference: Sections 103870, 103870.1, 103871, 103871.1, and 103871.2 Health and Safety Code.

§ 7205. Applicability of the Parkinson's Registry and Neurodegenerative Registry

(a) The following medical conditions are subject to the reporting requirements of the Parkinson's Registry and the Neurodegenerative Registry on or after the effective date listed below:

(1) Parkinson's Disease, effective July 1, 2018.

(2) Multiple Sclerosis (MS), effective July 1, 2023.

(3) Alzheimer's Disease, effective July 1, 2025.

(4) Amyotrophic Lateral Sclerosis (ALS), effective July 1, 2026.

(5) Huntington's Disease, effective July 1, 2027.

(b) Case reports involving medical conditions listed in subsection (a) are subject to the reporting process under this subchapter on or after the effective date listed for each condition once this subchapter becomes effective.

(1) Case reports collecting data gathered prior to the effective date of this subchapter may be submitted to the Department on a voluntary basis.

(2) Case reports submitted under subsection (b)(1) are not subject to sanctions under Article 5 of this subchapter.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103870.1, 103871, 103871.1, and 103871.2, Health and Safety Code. Reference: Sections 103870, 103870.1, 103871, 103871.1 and 103871.2, Health and Safety Code.

§ 7207. Petition for Designation of Additional Neurodegenerative Diseases

Any member of the public may request that the Department designate additional neurodegenerative diseases as subject to the requirements of this subchapter by following the petition process under Government Code section 11340.6.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103870.1, 103871, 103871.1, and 103871.2, Health and Safety Code. Reference: Sections 103870, 103871, and 103871.2, Health and Safety Code; Section 11340.6, Government Code.

Article 2. Reporting Requirements

§ 7209. Mandatory Reporters

(a) The reporting requirements of this subchapter apply jointly to the institutions and individual licensees responsible for providing diagnostic, therapeutic, or treatment services to a patient with Parkinson's disease or a neurodegenerative disease listed under section 7205 of this subchapter. The institutions and individual licensees listed in this section are jointly responsible for submitting accurate and complete case reports to the Parkinson's Registry or the Neurodegenerative Registry as provided in this subchapter. The reporting requirements of this subchapter apply to the following mandatory reporters:

(1) Any hospital, outpatient clinic, agency, or other facility licensed or regulated by the Department.

(2) Any individual licensee practicing medicine or healing arts in the following fields:

(A) A person licensed as a medical doctor by the Medical Board of California.

(B) A person licensed as an osteopathic doctor by the Osteopathic Medical Board of California.

(C) A person licensed as a physician assistant by the Physician Assistant Board of California.

(D) A person licensed as a nurse practitioner by the California Board of Registered Nursing.

(E) A person licensed as a pharmacist by the California State Board of Pharmacy.

(b) Any institution under subsection (a)(1) may submit a case report to the Parkinson's Registry or the Neurodegenerative Registry on behalf of any individual licensees under subsection (a)(2) who work as employees or independent contractors to provide services to the patient. Once the case report is received by the Department, all of the institutions and individual licensees under subsection (a) will have satisfied the reporting requirements of this subchapter.

(c) The mandatory reporter is responsible for the actions and omissions of their agents, employees, authorized users, and independent contractors.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103871, and 103871.2, Health and Safety Code. Reference: Sections 103870 and 103871, Health and Safety Code.

§ 7211. Encounters Subject to Reporting Requirements

(a) The mandatory reporter must submit encounter data when all of the following conditions are present:

(1) The patient has a diagnosis of Parkinson's disease or a neurodegenerative disease listed under section 7205 of this subchapter.

(2) The encounter data is directly related to diagnostic, therapeutic, or treatment services provided on or after the applicable effective date to address the patient's Parkinson's disease or a neurodegenerative disease listed under section 7205 of this subchapter.

(3) The encounter data has not been submitted by the mandatory reporter to the Parkinson's Registry or the Neurodegenerative Registry in a prior case report.

(b) For the purposes of subsection (a), "diagnosis" refers to when one or more of the International Classification of Diseases, Tenth Revision (ICD-10) codes are applied to the patient's health record to include Parkinson's disease or a neurodegenerative disease listed under section 7221 of this subchapter.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103871, and 103871.2, Health and Safety Code. Reference: Sections 103870 and 103871, Health and Safety Code.

§ 7213. Types of Encounter Data for Case Report

The mandatory reporter must include in each case report any encounter data gathered during the calendar quarter for the following primary patient interactions:

(a) Inpatient hospital stays.

(b) Emergency department visits.

(c) Ambulatory visits.

(d) Nonacute institutional stays.

(e) Laboratory services.

(f) Outpatient visits.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103871, and 103871.2, Health and Safety Code. Reference: Sections 103870 and 103871, Health and Safety Code.

§ 7215. Schedule for Regular Reporting

(a) Each case report submitted to the Department by a mandatory reporter listed under section 7209 of this subchapter must contain all required encounter data gathered in one of the four calendar quarters according to the following schedule:

(1) First quarter case reports cover data gathered from January 1 through March 31.

(2) Second quarter case reports cover data gathered from April 1 through June 30.

(3) Third quarter case reports cover data gathered from July 1 through September 30.

(4) Fourth quarter case reports cover data gathered from October 1 through December 31.

(b) Case reports must be submitted to the Department on or before the last day of the calendar quarter after the data was gathered according to the following schedule:

(1) First quarter case reports must be submitted no later than June 30.

(2) Second quarter case reports must be submitted no later than September 30.

(3) Third quarter case reports must be submitted no later than December 31.

(4) Fourth quarter case reports must be submitted no later than March 31.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103871, and 103871.2, Health and Safety Code. Reference: Sections 103870 and 103871, Health and Safety Code.

§ 7217. Voluntary Reporting

(a) The mandatory reporter may submit any additional encounter data on a voluntary basis if all of the following conditions are met:

(1) The additional encounter data is directly related to providing diagnostic, therapeutic, or treatment services to a patient with Parkinson's disease or a neurodegenerative disease listed under section 7205 of this subchapter;

(2) The additional encounter data was not previously submitted by the mandatory reporter to the Parkinson's Registry or Neurodegenerative Registry in a prior case report;

(3) The additional encounter data was collected prior to the applicable effective date for mandatory reporting under section 7205 of this subchapter; and

(4) The additional encounter data conforms to the formatting requirements of this subchapter.

(b) Any additional encounter data or diagnosis codes under section 7221(b) reported on a voluntary basis is not subject to sanctions under Article 5 of this subchapter.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103871, and 103871.2, Health and Safety Code. Reference: Sections 103870 and 103871, Health and Safety Code.

§ 7219. Coding of Reportable Encounters – Unknown Values

(a) A case report will be accepted as complete if it includes a valid value for every data field marked “required” or “required if data are available.”

(b) Any empty, blank, or null value will be treated as invalid and incomplete.

(c) Any data field marked “required” or “required if data are available” may include a value of “unknown” when that response is appropriate.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103871, and 103871.2, Health and Safety Code. Reference: Sections 103870 and 103871, Health and Safety Code.

§ 7221. Diagnosis Codes to Trigger Reporting

(a) The mandatory reporting requirements of this subchapter are triggered when a patient receives a diagnosis and any of the following International Classification of Disease Tenth Revision (ICD-10) codes are applied to their medical record:

Table 1

ICD-10 Code	Description
Parkinson’s Disease	
G20.A1	Parkinson's disease without dyskinesia, without mention of fluctuations
G20.A2	Parkinson’s disease without dyskinesia, with fluctuations
G20.B1	Parkinson's disease with dyskinesia, without mention of fluctuations
G20.B2	Parkinson’s disease with dyskinesia, with fluctuations
G20.C	Parkinsonism, unspecified
Multiple Sclerosis	
G35.A	Relapsing-remitting multiple sclerosis
G35.B0	Primary progressive multiple sclerosis, unspecified
G35.B1	Active primary progressive multiple sclerosis

G35.B2	Non-active primary progressive multiple sclerosis
G35.C0	Secondary progressive multiple sclerosis, unspecified
G35.C1	Active secondary progressive multiple sclerosis
G35.C2	Non-active secondary progressive multiple sclerosis
G35.D	Multiple sclerosis, unspecified
G37.3	Acute transverse myelitis in demyelinating disease of central nervous system
G37.89	Other specified demyelinating diseases of central nervous system
G37.9	Demyelinating disease of central nervous system, unspecified
Alzheimer's Disease	
G30.0	Alzheimer's disease with early onset
G30.1	Alzheimer's disease with late onset
G30.8	Other Alzheimer's disease
G30.9	Alzheimer's disease, unspecified
F03.90	Unspecified dementia, unspecified severity, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F03.911	Unspecified dementia, unspecified severity, with agitation
F03.918	Unspecified dementia, unspecified severity, with other behavioral disturbance
Amyotrophic Lateral Sclerosis	
G12.20	Motor neuron disease, unspecified
G12.21	Amyotrophic lateral sclerosis
G12.29	Other motor neuron disease

(b) The voluntary reporting requirements of this subchapter are triggered when a patient receives a diagnosis of Parkinson's disease or a neurodegenerative disease listed

under section 7105 and the following International Classification of Disease Tenth Revision (ICD-10) code is applied to their medical record:

Table 2

Parkinson's Disease	
G31.83	Neurocognitive disorder with Lewy bodies
G90.3	Multi-system degenerative of the autonomic nervous system
Alzheimer's Disease	
F01.50	Vascular dementia, unspecified severity, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F01.A0	Vascular dementia, mild, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F01.B0	Vascular dementia, moderate, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F01.C0	Vascular dementia, severe, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F02.A0	Dementia in other diseases classified elsewhere, mild, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F02.B0	Dementia in other diseases classified elsewhere, moderate, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F02.C0	Dementia in other diseases classified elsewhere, severe, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety

F02.80	Dementia in conditions classified elsewhere without behavioral disturbance Dementia in other diseases classified elsewhere, unspecified severity, without behavioral disturbance, psychotic disturbance, mood disturbance, and anxiety
F02.811	Dementia in other diseases classified elsewhere, unspecified severity, with agitation
F02.818	Dementia in other diseases classified elsewhere, unspecified severity, with other behavioral disturbance
G31.83	Neurocognitive disorder with Lewy bodies
G31.09	Other frontotemporal neurocognitive disorder
Amyotrophic Lateral Sclerosis	
G12.22	Progressive bulbar palsy
G12.23	Primary lateral sclerosis
G12.24	Familial motor neuron disease
G12.25	Progressive spinal muscle atrophy

If the ICD-10 code in subsection (b) is applied to a patient's medical record in conjunction with one or more of the mandatory reporting trigger codes in subsection (a), the code in subsection (b) may be reported on a voluntary basis.

(c) The mandatory reporter may use the corresponding diagnostic coding used for hospital billing purposes to trigger reportability under this section.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103871, and 103871.2, Health and Safety Code. Reference: Sections 103870 and 103871, Health and Safety Code.

§ 7223. Additional Time for New Reporting Mandates

When a new reporting requirement takes effect on July 1 of a given year under section 7205 of this subchapter, the encounter data gathered during the third and fourth quarters of that year must be submitted to the Department on or before the following March 31.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103871, and 103871.2, Health and Safety Code. Reference: Sections 103870 and 103871, Health and Safety Code.

§ 7225. Determination of Date for Patient Encounter Data

(a) When encounter data is gathered in a single outpatient visit on one date, the encounter data must be coded based on the date of the visit. Multiple outpatient visits must be coded as separate encounters and may not be coded as a single encounter.

(b) When encounter data is gathered during an inpatient stay across one or more dates, the encounter data must be coded based on the discharge date and may not be coded based on the admission date.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103871, and 103871.2, Health and Safety Code. Reference: Sections 103870 and 103871, Health and Safety Code.

§ 7227. Requirements to Request an Extension

(a) A mandatory reporter may submit a written request for an extension of up to one calendar quarter for the late filing of one or more case reports. The written request must:

(1) Be received by the Department at least ten (10) calendar days prior to the due date of the case report.

(2) Identify the number of patients for which the case report will be filed late; and

(3) Include the name, telephone number, and email address of the individual(s) responsible for submitting the case reports on or before the extended due date.

(b) If the conditions in subsection (a) are met, the Department will automatically grant an extension of up to one calendar quarter to file the case reports covered by the written request. The extended due date will be the last day of the next calendar quarter.

(c) If the conditions in subsection (a) are not met, the mandatory reporter may submit a written request for an extension of up to one calendar quarter for late filing of one or more case reports.

(1) The written request must include all of the information required in subsection (a) and an explanation for the failure to file the case reports within the required timeframe.

(2) The Department may grant an extension on a case-by-case basis of up to one calendar quarter to file the case reports listed in the written request. The extended due date will be the last day of the next calendar quarter.

(d) If a mandatory reporter fails to comply with this section, the Department will seek sanctions as provided under Article 5 of this subchapter. Failure to request an extension under this section will be used as evidence of willful noncompliance.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103871, and 103871.2, Health and Safety Code. Reference: Sections 103870 and 103871, Health and Safety Code.

Article 3. Technical Requirements

§ 7229. Methods for Submitting Case Reports – Required Electronic Format Standards

(a) A mandatory reporter must submit the case report in an electronic format to the Department's reporting environment as either an automatic upload to the designated interface or manually entered and submitted through the website designated by the Department as follows:

(1) For the automatic upload of files, the case report must be submitted using the Health Level Seven International (HL7) format standards of data exchange and must be transmitted via technology approved by the Department, including Secure File Transfer Protocol (SFTP) or Simple Object Access Protocol (SOAP).

(2) For the manual entry of data and direct submission to the Department, the mandatory reporter must use the Direct Data Entry Web Portal.

(3) The mandatory reporter must register and onboard new users, complete data testing and data validation, and must guarantee that each authorized user has registered a unique login to submit case reports to the Department.

(b) Failure to comply with the requirements of this section will be used as evidence of willful noncompliance.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103871, and 103871.2, Health and Safety Code. Reference: Sections 103870 and 103871, Health and Safety Code.

§ 7231. Methods for Correcting Erroneous Case Reports

(a) If a mandatory reporter discovers that a case report was submitted to the Parkinson's Registry or Neurodegenerative Registry with erroneous information, they may contact the Department in writing within one calendar quarter after the error was discovered and provide updated information to correct the error.

(b) If a patient discovers that a case report was submitted to the Parkinson's Registry or the Neurodegenerative Registry with erroneous information, the patient or their authorized representative may contact the mandatory reporter to request that the mandatory reporter notify the Department of the error as provided in subsection (a). The mandatory reporter must notify the Department in writing that the correction of the erroneous case report was requested by the patient.

(c) Failure to comply with the requirements of this section will be used as evidence of willful noncompliance.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103870.1, 103871, 103871.1 and 103871.2, Health and Safety Code. Reference: Sections 103870, 103870.1, 103871, and 103871.1, Health and Safety Code.

§ 7233. Required Data

(a) To be accepted as complete, all case reports submitted to the Department must contain valid values as provided in section 7219 of this subchapter in every data field marked as "required" under subsection (b).

(b) The data fields within every data category are marked as "required" ("R") or "required if available" ("RE") according to the following table:

Table 3.

Data Category	Requirement Optionality	Data Fields
Patient ID	R	Name (Last, First, Middle Initial)
	R	Date of Birth
	R	Sex (Gender)
	R	Patient Street Address (Street & Number)
	R	Patient Address City

Data Category	Requirement Optionality	Data Fields
	R	Patient Address State
	R	Patient Address ZIP (Postal) Code
	RE	Social Security Number
	R	Medical Record Number (MRN)
Patient Demographics	R	Race
	R	Ethnicity
	RE	Date of last Contact/Death
	RE	Sexual Orientation
	RE	Gender Identity
Patient Visit Information	RE	Attending Doctor
	RE	Consulting Doctor
	RE	Hospital Service
	RE	Admission Reason
Physician Identifiers (Primary)	R	Physician Name (Last, First)
	R	Author National Provider Identifier (NPI)- Physician ID
	R	Physician Specialty
	R	Physician Address (Street & Number)
	R	Physician Address State
	R	Physician Address ZIP (Postal) Code
	R	Physician Email
	R	Physician License Number

Data Category	Requirement Optionality	Data Fields
Primary Diagnosis	R	ICD-10 Codes/Diagnostic Term (International Classification of Disease, Tenth Reversion, Clinical Modification Diagnosis Codes (ICD-10)
	R	Month and/or Year of Diagnosis
Disease Onset	RE	Onset Date, Onset of Symptoms if known.
	RE	Symptoms at Onset
	RE	Comment
Facility ID	R	Reporting Facility Name
	R	Reporting Facility ID
	R	Facility Address
	R	Facility Phone Number
	R	Sending Facility Application
	R	Date/Time of Message
	R	Facility Type
Software ID	R	Software Vendor Organization
	R	Software Version or Release Number
	R	Software Product Name
	R	Software Binary ID

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103871, and 103871.2, Health and Safety Code. Reference: Sections 103870 and 103871, Health and Safety Code.

§ 7235. Registration and Onboarding Requirements for Mandatory Reporters

(a) Each mandatory reporter must follow the authorized user registration, onboarding, and data validation processes prescribed by the Department.

(b) The registration, onboarding, and data validation process must include the verification of contact information and identification of each authorized user granted permission to transmit case reports on behalf of the mandatory reporter to the Department.

(c) Each mandatory reporter must have at least one active authorized user in each calendar quarter to maintain continuous access to the reporting environment.

(d) The mandatory reporter may register additional authorized users or deactivate authorized users as needed to comply with the requirements of this subchapter.

(e) The mandatory reporter must deactivate an authorized user within one calendar quarter if the authorized user separates from the employment or contractor relationship with the mandatory reporter.

(f) The mandatory reporter must designate an individual as their point of contact and provide that individual's current contact information to the Department, including their name, title, email address, mailing address, and telephone number.

(1) This designated point of contact must correspond with the Department on behalf of the mandatory reporter regarding user registration, onboarding, data validation, and all other matters relating to compliance with this subchapter.

(2) The mandatory reporter must maintain current contact information for the designated point of contact and must provide the Department with updates to any changes to the identity or contact information of the designated point of contact within one calendar quarter.

(g) Correspondence and other notifications between the Department and the mandatory reporter will be conducted electronically via email to the mandatory reporter's point of contact designated under this section.

(h) Failure to comply with the requirements of this section will be used as evidence of willful noncompliance.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103871, and 103871.2, Health and Safety Code. Reference: Sections 103870 and 103871, Health and Safety Code.

§ 7237. Data Validation

The Department will conduct ongoing data validation for the Parkinson's Registry and Neurodegenerative Registry by contacting mandatory reporters.

(a) The mandatory reporter must respond to any request for data validation within thirty (30) calendar days and must follow steps prescribed by the Department in a corrective action notice to improve data quality.

(b) If the mandatory reporter fails to respond to a request for data validation within thirty (30) calendar days, the mandatory reporter will be subject to data recovery measures pursuant to section 7239 of this subchapter. The mandatory reporter will bear actual costs associated with any data recovery measures prescribed by the Department in addition to any applicable sanctions under Article 5.

(c) Failure to comply with the requirements of this section will be used as evidence of willful noncompliance.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103871, and 103871.2, Health and Safety Code. Reference: Sections 103870 and 103871, Health and Safety Code.

§ 7239. Department Access to Data

(a) If the mandatory reporter fails to submit case reports or fails to respond to a data validation request according to the requirements of this subchapter, the Department will

issue a corrective action notice and will pursue data recovery measures to access the information. When the Department pursues data recovery measures, the mandatory reporter will bear the actual costs and must reimburse the Department for any travel costs, software costs, staff time, or contractor costs required to access and report the information in addition to any applicable sanctions under Article 5.

(b) The mandatory reporter may avoid data recovery measures and pay the Department's actual costs by responding to a corrective action notice and resolving any noncompliance within the prescribed time period.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103871, and 103871.2, Health and Safety Code. Reference: Sections 103870 and 103871, Health and Safety Code.

Article 4. Data Disclosure

§ 7241. Authorized Access to Confidential Information

(a) An applicant with an approved scientific interest who is engaged in demographic, epidemiological, or other studies related to health may apply for authorization on behalf of an entity under subsection (b) to access confidential information maintained by the Parkinson's Registry or the Neurodegenerative Registry or both.

(b) Each applicant seeking authorization to access confidential information must identify whether they are applying for access on behalf of either:

(1) A state, federal, or local health agency, or

(2) A research institution engaged in the study of Parkinson's disease or a neurodegenerative disease.

(c) For the purposes of this article, any authorization to access confidential information is granted to the applicant's agency or institution identified in subsection (b) and not to any individual person named in the application.

(d) A recipient institution granted authorization to access confidential information must agree in writing to maintain confidentiality of all information and data provided under the Health and Safety Code and this subchapter.

(e) The recipient institution will be held responsible for the actions and omissions of their agents, employees, authorized users, and independent contractors.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103870.1, 103871, 103871.1, and 103871.2, Health and Safety Code. Reference: Sections 103870, 103870.1, 103871, 103871.1 and 103871.2, Health and Safety Code.

§ 7243. Required Information for Application

(a) To initiate the application process, an applicant seeking authorization to access confidential information must submit the following to the Department:

(1) An application summary that includes:

(A) The name of the individual designated as the principal investigator and the names of any additional authorized representatives participating in the study.

(B) The institutional affiliations of the principal investigator and each additional authorized representative.

(C) A description of the intended use of the confidential information in the study.

(2) Documentation summarizing the study protocol of the project.

(3) Documentation summarizing the peer review of the scientific merit of the project, such as a funding agency award, dissertation committee approval, or an application review committee report issued by the Department.

(4) A list of requested data items with justifications for their use in the study.

(5) A confidentiality agreement from the Department signed by the principal investigator and at least one authorized representative identified under subsection (a) of this section.

(6) The applicant must provide the Department with security incident contact information. This must include contact information for each person the recipient institution has designated as Principal Investigator, Privacy Officer, Information Security Officer, and Information Technology Service Desk. The attachment must provide the following information for each person listed:

(A) The full name and title of each person the Department may contact in the event of a breach.

(B) Mailing address.

(C) Telephone number.

(D) Fax number.

(E) Email address.

(7) Documentation that the research study has been reviewed and approved by the applicant's Institutional Review Board and by the Committee for Protection of Human Subjects for the California Health and Human Services Agency.

(b) If an applicant seeking authorization to access confidential information is applying on behalf of multiple research institutions for a single study, each affiliated research institution must comply with the requirements of this article and provide the required information and documentation under subsections (a)(5) through (a)(7).

(c) If an applicant is applying on behalf of a state, federal, or local health agency under Section 7241(b)(1) for the purpose of disease surveillance only, that applicant is exempt from the requirements of (a)(2), (a)(3), and (a)(7) of this section.

(d) Failure to comply with the requirements of this section will result in the denial of authorization to access confidential information for each research institution named in the application that fails to comply.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103870.1, 103871, 103871.1, and 103871.2, Health and Safety Code. Reference: Sections 103870, 103870.1, 103871, 103871.1 and 103871.2, Health and Safety Code.

§ 7245. Annual Reporting of Access to Disclosed Data

(a) Each recipient institution must submit an annual report to the Department for every calendar year that the research study is conducted.

(b) The annual report must be submitted by the recipient institution to the Department no later than June 30 for the previous calendar year and must contain the following information:

(1) The number of all individuals who have accessed the confidential information during the previous calendar year that contains the following information for each named individual:

(A) The name of the person at the recipient institution authorizing access;

(B) The name, title, address, and organizational affiliation of the persons who were granted access;

(C) The dates of access;

(D) The specific purpose for which the data was used.

(2) Documentation of annual renewal approval letters from the recipient institution's Institutional Review Board and the Committee for Protection of Human Subjects for the California Health and Human Services Agency for each research study named in the initial application.

(c) Once an approved study is complete, the recipient institution must submit a final annual report including a written statement of data destruction to confirm that the recipient institution has completed a data destruction process to confirm that the confidential information provided by the Department to the recipient institution under this article has been destroyed and can no longer be accessed by any person. The written statement of data destruction must include:

(1) The names of each Principal Investigator.

(2) The institutions of each Principal Investigator.

(3) The project name or title.

(4) The project approval date.

(5) The printed name and signature by the Principal Investigator to acknowledge the following statement:

"This is to certify that ALL California Parkinson's Disease Registry (CPDR) and/or California Neurodegenerative Disease Registry (CNDR) data in my possession, pertaining to this project, have been destroyed in accordance with National Institute of Standards and Technology (NIST) recommended destruction methods for physical and electronic documents. Destruction means physical destruction of files, documents and/or other records. De-identification of records shall not be considered destruction."

(6) The date when the written statement of data destruction was signed.

(d) Failure to submit an annual report under this section will result in the suspension or revocation of the recipient institution's authorization to access confidential information from the Parkinson's Registry or the Neurodegenerative Registry or both. If authorization is revoked, the recipient institution must complete the written statement of data destruction for any data they received from the Department.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103870.1, 103871, 103871.1, and 103871.2, Health and Safety Code. Reference: Sections 103870, 103870.1, 103871, 103871.1 and 103871.2, Health and Safety Code.

§ 7247. Mandatory Notice of Breach of Confidentiality or Security Incident

(a) If a recipient institution discovers that their project or institution may have experienced a breach of confidentiality and/or a security incident involving confidential information provided under this article, the recipient institution must notify the Department within ten (10) calendar days.

(b) Failure to submit a notice of breach under this section will result in the suspension or revocation of the recipient institution's authorization to access confidential information from the Parkinson's Registry or the Neurodegenerative Registry or both. If authorization is revoked, the recipient institution must complete the written statement of data destruction for any data they received from the Department.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103870.1, 103871, 103871.1, and 103871.2, Health and Safety Code. Reference: Sections 103870, 103870.1, 103871, 103871.1 and 103871.2, Health and Safety Code.

§ 7249. Individual Access to Personal Information

(a) An individual patient whose personal information has been entered into the Parkinson's Registry or the Neurodegenerative Registry may request access to their personal information on their own behalf or through an authorized representative. The requestor must contact the Department's Privacy Office in writing to request access.

(b) For the purposes of this section “authorized representative” may include the patient’s family member as defined under Health and Safety Code section 1796.12(f), legal representative, or primary care provider.

(c) A patient or authorized representative may contact the Department’s Privacy Office to request that the patient’s name be added to the Do Not Contact List for future research projects.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103870.1, 103871, 103871.1, and 103871.2, Health and Safety Code. Reference: Sections 1796.12, 103870, 103870.1, 103871, 103871.1 and 103871.2, Health and Safety Code.

§ 7251. Destruction of Erroneous Case Report Data

(a) If the Department notifies a recipient institution that a patient was erroneously included in the Parkinson’s Registry or Neurodegenerative Registry, the recipient institution must submit a written statement of data destruction within one calendar quarter to document and confirm that the erroneous data pertaining to that patient provided by the Department has been destroyed and can no longer be accessed by any person.

(b) Failure to submit a written statement of data destruction under this section will result in the suspension or revocation of the recipient institution’s authorization to access confidential information from the Parkinson’s Registry or the Neurodegenerative Registry or both. If authorization is revoked, the recipient institution must complete the written statement of data destruction for any data they received from the Department.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103870.1, 103871, 103871.1, and 103871.2, Health and Safety Code. Reference: Sections 103870, 103870.1, 103871, 103871.1 and 103871.2, Health and Safety Code.

Article 5. Noncompliance and Sanctions

§ 7253. Corrective Action Notices

(a) When an inspection, audit, or review of a mandatory reporter or recipient institution by the Department reveals any noncompliance with the requirements of the Health and Safety Code or this subchapter, a written notification of corrective action will be sent to the mandatory reporter or recipient institution. The corrective action notice must state at a minimum:

(1) A description of each noncompliance;

(2) A citation of each applicable section of the Health and Safety Code or California Code of Regulations corresponding to each noncompliance;

(3) The facts upon which the notification of the noncompliance is based;

(4) Any actions that the mandatory reporter or recipient institution must take to correct the noncompliance within the prescribed time period; and

(5) The due date by which the mandatory reporter or recipient institution must rebut or correct each noncompliance and submit supporting documentation of each such correction when correction is possible. The due date will be thirty (30) calendar days after the date when the corrective action notice is issued.

(b) When a mandatory reporter or recipient institution demonstrates in writing with supporting documentation that each noncompliance has been corrected within the time allotted in subsection (a), the Department will send a written notification of noncompliance resolution to the mandatory reporter or recipient institution. The mandatory reporter or recipient institution will not be subject to sanctions for any instance of noncompliance that is corrected and resolved within the prescribed time period.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103870.1, 103871, 103871.1, and 103871.2, Health and Safety Code. Reference: Sections 103870, 103870.1, 103871, 103871.1 and 103871.2, Health and Safety Code.

§ 7255. Notice of Proposed Sanctions for Mandatory Reporters

(a) For a mandatory reporter, when the resolution is unsuccessful or the correction of the noncompliance is not completed within the time period prescribed in the corrective action notice, the Department will send a written notification of proposed sanctions. When the correction of noncompliance is not possible, the notification of noncompliance and the notification of proposed sanctions may be combined in one notification. The notification of proposed sanctions must state at a minimum:

(1) The reasons for the proposed sanctions;

(2) The proposed sanctions necessary to correct the noncompliance;

(3) The proposed effective date of the sanctions, which will be stayed pending an informal review conference, a formal hearing, and a final determination;

(4) The right to request an informal review conference with the Department within thirty (30) calendar days to contest the determination of noncompliance and proposed sanctions and to negotiate a modified deadline to correct the noncompliance, followed by a formal hearing if the informal review conference does not correct the noncompliance; and

(5) The right to request a formal hearing pursuant to Health and Safety Code section 131071 to contest the determination of noncompliance and the proposed sanction.

(b) Failure to comply with the requirements of this subchapter will result in the sanctions of data recovery measures and reimbursement of the Department's actual costs under section 7239 or a civil penalty for willful noncompliance under section 7261 of this subchapter or both.

(c) If the mandatory reporter provides the Department with written documentation within the prescribed time period demonstrating that all noncompliance has been corrected, the Department will withdraw the proposed sanctions.

(d) For a mandatory reporter, any sanctions proposed by the Department in the written notification of noncompliance will be stayed while the informal review conference and formal hearing processes are pending, if applicable.

Note: Authority cited: 131050, 131051, 131052, 131071, 131200, 103870, 103870.1, 103871, 103871.1, and 103871.2, Health and Safety Code. Reference: Sections 103870, 103870.1, 103871, 103871.1, 103871.2, and 131071, Health and Safety Code.

§ 7257. Notice of Proposed Sanctions for Recipient Institutions

(a) For a recipient institution, when the resolution is unsuccessful or the correction of the noncompliance is not completed within the time period prescribed in the corrective action notice, the Department will send a written notification of proposed sanctions. When the correction of noncompliance is not possible, the notification of noncompliance and the notification of proposed sanctions may be combined in one notification. The notification of proposed sanctions must state at a minimum:

(1) The reasons for the proposed sanctions;

(2) The proposed sanctions necessary to correct the noncompliance;

(3) The proposed effective date of the sanctions, which will be stayed pending an informal review conference, if applicable; and

(4) The right to request an informal review conference with the Department within thirty (30) calendar days to contest the applicability of sanctions and to negotiate a modified deadline to correct the noncompliance.

(b) Failure to comply with the requirements of Article 4 of this subchapter will result in the sanctions of denial, suspension, or revocation of authorization to access confidential information for each recipient institution that fails to comply.

(c) If the recipient institution provides the Department with written documentation within the prescribed time period demonstrating that all noncompliance has been corrected,

the Department will withdraw the proposed sanctions and reinstate authorization to access confidential information.

(d) If the recipient institution's authorization is suspended under this section, the recipient institution may submit written documentation that the noncompliance has been corrected and request reinstatement of authorization. If authorization is revoked, the recipient institution must complete the data destruction process under section 7251 for any data they received from the Department.

(e) If a recipient institution's authorization is denied or revoked under this section, the recipient institution may submit a new application and obtain a new authorization under this subchapter.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103870.1, 103871, 103871.1, and 103871.2, Health and Safety Code. Reference: Sections 103870, 103870.1, 103871, 103871.1 and 103871.2, Health and Safety Code.

§ 7259. Willful Noncompliance for Mandatory Reporters

(a) "Willful noncompliance" by a mandatory reporter includes failure to respond to a corrective action notice sent by the Department within the prescribed time period. A mandatory reporter will not be subject to sanctions for delays due to the normal course of responding to a corrective action notice to grant the Department access to conduct the data recovery process or to correct instances of noncompliance.

(b) To determine whether noncompliance is willful, the Department will consider the following factors:

(1) The number instances of noncompliance cited in the corrective action notice;

(2) Failure to respond to a corrective action notice within the prescribed time period;

(3) Receiving two or more corrective action notices within a calendar year; or

(4) Communications to the Department indicating intentional or deliberate refusal to comply with the requirements of this subchapter; or

(5) Any other factors applicable to the specific circumstances surrounding the noncompliance, as identified by the Department on a case-by-case basis.

(c) When the Department proposes sanctions for willful noncompliance, the mandatory reporter may request:

(1) a formal hearing pursuant to Health and Safety Code section 131071; or

(2) an informal review conference under section 7263 of this subchapter, followed by a formal hearing under section 7263(c) of this subchapter.

(d) The request under subsection (c) must be submitted to the Department in writing within thirty (30) calendar days of the date the written notice of proposed sanctions was issued.

Note: Authority cited: 131050, 131051, 131052, 131071, 131200, 103870, 103870.1, 103871, 103871.1, and 103871.2, Health and Safety Code. Reference: Sections 103870, 103870.1, 103871, 103871.1 and 103871.2, Health and Safety Code.

§ 7261. Sanctions for Willful Noncompliance

(a) For noncompliance by a mandatory reporter, the proposed sanctions will include either data recovery measures and reimbursement of the Department's actual costs pursuant to section 7239 or a civil penalty for willful refusal to grant access to records pursuant to section 7259 of this subchapter or both where the Department deems such remedies appropriate to correct the noncompliance.

(b) If willful noncompliance by a mandatory reporter results in the failure to grant access to records required under the Health and Safety Code or this subchapter, the mandatory reporter will be subject to a civil penalty of five hundred dollars ($500) for each calendar day that access is refused.

(1) To determine the number of calendar days subject to the civil penalty, the refusal of access period will include every calendar day after the due date on the corrective action notice.

(2) The period of refusal of access will terminate on the date when the Department receives notice from the mandatory reporter which demonstrates in writing with supporting documentation that each noncompliance has been resolved.

Note: Authority cited: 131050, 131051, 131052, 131071, 131200, 103870, 103870.1, 103871, 103871.1, and 103871.2, Health and Safety Code. Reference: Sections 103870, 103870.1, 103871, 103871.1 and 103871.2, Health and Safety Code.

§ 7263. Informal Review Conference

(a) At an informal review conference:

(1) The mandatory reporter or recipient institution shall have the right to be represented by legal counsel, or a person of the mandatory reporter or recipient institution's choosing, to present oral or written information on their behalf, and to explain any mitigating circumstances.

(2) The representatives of the Department who issued the corrective action notice should attend the conference and present information, oral or written, in substantiation of the alleged noncompliance.

(3) The conference shall be an informal proceeding. The conference shall not be conducted in the manner of a judicial hearing or as a hearing under the Administrative Procedure Act (Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of Title 2 of the Government Code) and need not be conducted according to the technical rules relating to evidence and witnesses.

(4) Neither the mandatory reporter or recipient institution nor the Department shall have the right to subpoena any witness to attend the conference, to record testimony, at the conferences, nor to formally cross-examine any person testifying at the conference. However, the mandatory reporter or recipient institution and the Department may present any witness on its behalf at the conference.

(5) The mandatory reporter or recipient institution may negotiate a modified due date to correct the noncompliance.

(6) After the informal review conference, the Department may affirm, modify, or dismiss the corrective action notice, the proposed sanctions, or the due date of correction for noncompliance based on the totality of the circumstances.

(b) After an informal review conference, the Department will send an informal review conference report to the mandatory reporter or recipient institution. The informal review conference report will confirm in writing any modifications to the corrective action notice, including a modified due date to correct the noncompliance or the applicable sanctions for failure to correct the noncompliance within the prescribed time period.

(c) If the mandatory reporter intends to contest the decision made at the informal review conference, the mandatory reporter may submit a written request for a formal hearing pursuant to Health and Safety Code section 131071. The written request for a formal hearing must be received by the Department within fifteen (15) calendar days after receipt of the informal review conference report.

(d) If the mandatory reporter fails to correct every noncompliance in the modified corrective action notice from the informal review conference report within the modified time period, the matter will proceed to a formal hearing if the mandatory reporter has requested one within the prescribed time period. Any proposed sanctions will be stayed pending a final determination after the formal hearing.

Note: Authority cited: 131050, 131051, 131052, 131071, 131200, 103870, 103870.1, 103871, 103871.1, and 103871.2, Health and Safety Code. Reference: Sections 103870, 103870.1, 103871, 103871.1 and 103871.2, Health and Safety Code.

§ 7265. Factors Outside the Control of the Mandatory Reporter or Recipient Institution

The mandatory reporter or recipient institution will not be subject to sanctions under this subchapter if factors outside of the control of the mandatory reporter or recipient institution impact the compliance process. “Factors outside the control of the mandatory reporter or recipient institution” means any circumstance not within the reasonable control of the mandatory reporter or recipient institution, including fires, explosions, natural disasters, severe weather events, war, invasion, civil unrest, acts or threats of terrorism, and utility or infrastructure failure. “Factors outside the control of the mandatory reporter or recipient institution” does not include the acts of the mandatory reporter or recipient institution, their business associates, or their respective workforce members.

Note: Authority cited: 131050, 131051, 131052, 131200, 103870, 103870.1, 103871, 103871.1, and 103871.2, Health and Safety Code. Reference: Sections 103870, 103870.1, 103871, 103871.1 and 103871.2, Health and Safety Code.