California Neurodegenerative Disease Registry Implementation Guide

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1. Introduction

California State Senate Assembly Bill (AB) 133, signed by Governor Gavin Newson on July 27, 2021, established the California Neurodegenerative Disease registry (CNDR). As a result of this bill, the existing California Parkinson's Disease Registry (CPDR) will expand to collect additional disease conditions. "Neurodegenerative disease" may include, but is not limited to, Alzheimer's disease, multiple sclerosis (MS), Huntington's disease, and amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease. California Department of Public Health (CDPH) will decide what specific neurodegenerative disease will be reportable. Health care providers diagnosing or providing treatment for a patient with a neurodegenerative disease will be required to report each case of a neurodegenerative disease to the CDPH via the CNDR.

CNDR conducted two virtual listening sessions, held a public comment period, and conducted key informant interviews with stakeholders, providers, and subject matter experts. Based on the feedback and input from stakeholders, clinicians, and subject matter experts about which conditions to add to the CNDR, CNDR will collect data for diagnosis or treatment of MS occurring on or after July 1, 2023, and is considering designating Alzheimer's disease as a reportable disease on July 1, 2025".

Please read and become familiar with the information provide within this implementation guide to meet the new reporting mandate. ***Please note that providers already reporting Parkinson's Disease data to CDPH do not need to significantly alter their current process as this guide has been updated to include the case definition for MS.***

2. Purpose

This implementation guide describes who is required to report, the reporting criteria, and the timing of reporting to the CNDR. The guide also defines the methods for reporting, including the supported methods for data transmission, and provides the necessary specifications for automated electronic reporting of data. In addition, the guide defines the specific data elements to be included in the neurodegenerative disease case reports; describes how to create the appropriate, valid electronic message for transmission; and details how to transmit the reports to CNDR over a secure electronic transmission mechanism.

3. CNDR Reporting Requirements

3.1. Who is Required to Report?

Licensed independent practitioners[1] (LIPs) holding the following credentials, who diagnose or treat neurodegenerative disease patients, **are required** to report: Doctor of Medicine (MD), Doctor of Osteopathy (DO), Physician's Assistant (PA), and Nurse Practitioner (NP). Other LIPs, including advanced practice registered nurses, home care nurses, physical/occupational/speech therapists, chiropractors, podiatrists, acupuncturists, and optometrists **are not required** to report. If LIPs work in a group practice, have a formalized relationship within the practice, or are part of a hospital or facility medical staff, the encounter reporting can be performed by the hospital or facility. A single report may constitute encounter data from multiple LIPs.

3.2. Determination of Reportability

Patient encounters for diagnosis or treatment of a neurodegenerative disease[2] occurring on or after July 1, 2023, are reportable within the parameters described below, but historical backload is **not required**. The International Classification of Diseases, Tenth Revision (ICD-10) codes will be used to identify reportable cases. Any California resident patient encounter for the diagnosis or treatment of a neurodegenerative encounter (see ICD-10 codes in Table 1) may be reportable, but only when the code is documented as an *Encounter Diagnosis*.

Table 1. Reportable ICD-10 Codes and Their Clinical Descriptions

ICD-10 Code	Description
G20	Parkinson's Disease/ Parkinsonism
G90.3	Parkinsonism with neurogenic orthostatic hypotension, Multiple System Atrophy (MSA), MSA-Parkinson (MSA-P), MSA-Cerebella (MSA-C)
G35	Multiple Sclerosis

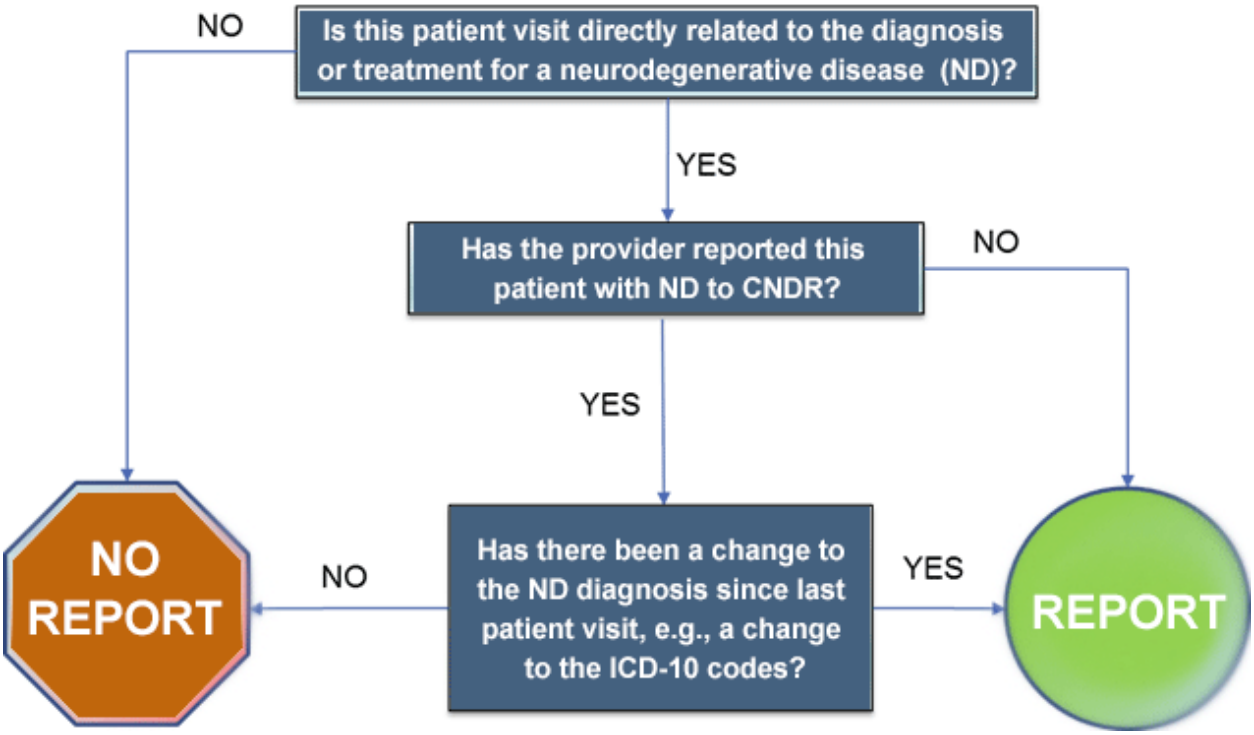
[1] As per the Joint Commission, licensed independent practitioner is defined as an individual permitted by California law and regulation, and by the organization, to provide care and services without direction or supervision within the scope of the individual's license and consistent with the privileges granted by the organization.

[2] "Neurodegenerative disease" may include, but is not limited to, Alzheimer's disease, multiple sclerosis (MS), Huntington's disease, and amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease. CDPH will decide what specific neurodegenerative disease will be reportable.

ICD-10 Code	Description
G37.3	Acute transverse myelitis in demyelinating disease of central nervous system
G37.8	Other specified demyelinating diseases of central nervous system
G37.9	Demyelinating disease of central nervous system, unspecified
Please Note: Case definitions for Alzheimer's are still under development.	

Any encounter type can trigger the requirement for reporting, including ambulatory visits, emergency department visits, inpatient hospital stays, non-acute institutional stays, and other outpatient visits. However, encounters are only reportable when (a) the patient has not been previously reported to the CNDR or (b) the triggering reportable diagnosis resulted in a change to the medical record (either entering an initial diagnosis or change in diagnosis) during the encounter. Please note, encounters are not reportable if the qualifying diagnosis is noted on the Problem List but is not applied to the encounter itself. Reportable encounters include face-to-face visit as well as certain non-face-to-face visits (telemedicine, telephone, online/e-visits) that include the specific diagnoses addressed. Ancillary encounters (e.g., lab, imaging, cardio-pulmonary, and therapies), are excluded from the triggering encounter list. Inpatient encounters can rely on diagnostic coding done for hospital billing purposes to trigger reportability.

Figure 1. Flow chart of Reportable Neurodegenerative Disease Cases



As shown in Figure 1, ND patients not previously reported are reportable regardless of the encounter outcome. Subsequent encounters for a previously reported patient are only reportable if their visit results in a change in diagnosis that is recorded in their medical record (e.g., a change from ICD10 code G20 to G90.3).

3.3. What is Reportable?

Reportable data elements are identified in *Appendix 1. Table of Data Elements for Manual Reporting to the CNDR* and *Appendix 2. Table of Data Elements for Electronic Reporting to the CNDR.*

3.4. Timing of Reporting

Regardless of the reporting modality (i.e., manual entry via web portal or submission via electronic interface) timing of reporting is based on the calendar quarter during which the encounter occurred. For the first quarter of the mandate (i.e., patient encounters occurring between July 1 and September 30) encounters must be reported within 180 days following the end of the quarter

(i.e., March 31, 2024, for reporting between July 1, 2023, and September 2023). Beginning October 1st, the deadline for data submission is 90 days following the end of the quarter. Frequency of data submission may be determined by the reporting physician or facility, but all data must be received by the deadlines outlined below (See Table 2). For inpatient encounters, the discharge date may be used as the date of the encounter.

Table 2. Data Collection Timeframe and Case Submission Deadlines

Date of Patient Encounter*	Submission Deadline (Is the last day of each month)
July – September	December **
October – December	March
January – March	June
April – June	September

* For inpatient settings, the discharge date may be used as the date of the patient encounter.
The first reporting period (July-September 2023) **has a six-month deadline (i.e., data is due to the CNDR by 3/31/2024); All subsequent reporting periods have **three-month deadlines**.

4. Technical Implementation

4.1. Methods for Reporting

CNDR will accept electronic case reports through two primary methods of reporting: (1) manual data entry via Direct Data Entry Web Portal (secure web page accessible only to registered providers, facilities, and hospitals) and (2) automated electronic transfer of case files from the provider's electronic medical record system.

1. Manual Data Entry (via Direct Data Entry Web Portal)

A Direct Data Entry Web Portal will be provided to physicians, facilities, and hospitals who do not have the ability to output and send an electronic message to CNDR. The Direct Data Entry Web Portal will support the manual entry of 'required' and 'required if available' data fields. Registrants for the CNDR are only required to fill out fields highlighted in red. Fields for phone numbers, emails, and marital status are to be left blank. Information for these fields is not

collected by CNDR. The Direct Data Entry Web Portal will require manual input of data fields for each patient and may not be the most efficient solution for physicians or facilities that diagnose and treat a moderate to high volume of patients.

2. Automated Electronic Transfer of Case Files (via Electronic Interface)

CNDR is also establishing a secure system that healthcare providers can use to automate neurodegenerative disease case reporting. With the advancement of health information technology, patient data can be exchanged efficiently between reporting entities (providers, hospitals, and other facilities) and the CNDR using Health Level Seven (HL7) format standards. Using this method, information from the patient's electronic medical record is transmitted to the CNDR without the reporting entity needing to manually enter data into a web portal.

CNDR will support two versions of HL7:

1. HL7 CDA R2 Implementation Guide: Public Health Case Report, Release 2 STU 1.1 – US Realm
    a. See Neurodegenerative Disease Registry HL7 CDA eICR Data Elements
2. HL7 2.5.1 ORU_R01 based specification standard. [See *CNDR, Electronic Reporting of Neurodegenerative Disease*
    a. See California Neurodegenerative Disease Registry HL7 251 Constraints v1

The reporting system is secured using state approved information security standards and will ease the burden of reporting for those providers and facilities willing and able to leverage the technology.

4.2. Data Elements

For either method of reporting, all data elements listed in Appendix 1 and Appendix 2 are required or required if available. If a data element is required it must be transmitted with a value other than empty, blank, or null, or the record will not be accepted. For a data element that is required if available it must be sent when a known value is available in the sending system. However, if a data element has an allowable code for "unknown" then that code should be transmitted for that element instead of an empty value.

4.3. Transmission Methods

As previously noted, CNDR will accept electronic case reports through the two methods of transmission: manual data entry via Direct Data Entry Web Portal or automated electronic transfer of case files. The following methods of transmission are supported for the automated electronic transfer of case files:

- Secure File Transfer Protocol (SFTP)
- Web Services – Simple Object Access Protocol (SOAP 1.2)

4.4. On-boarding

Provider Registration: For either method of reporting, reporting entities (providers, facilities, and hospitals) can establish their intent to report by emailing us at cdsrbhelp@cdph.ca.gov to start the registration process. The reporting requirement falls on the entity that will complete reporting. Thus, if an individual LIP will report their own cases, the LIP should register. However, if the facility or hospital will report for their affiliated LIPs, only the facility or hospital should register. Registering is voluntary for those submitting through the interface; however, registration will assist in management of the onboarding process and document intent to report.

Data Submission Testing/Validation: Providers wishing to use the electronic interface for reporting will work with CNDR in a data submission testing and validation phase to initiate connectivity, validate message structure, validate content, and perform user acceptance testing. Upon validation, data submission will transition to production reporting.

Step 1. Initiate Connectivity

- Work with CNDR staff to establish connectivity (using SOAP transport method or SFTP).

Step 2. Validate Message Structure:

- Implement logical filters to ensure that only reportable neurodegenerative disease cases are sent to CNDR.

  Ensure that the information system produces a message compliant with CNDR HL7 CDA R2 Implementation Guide: Public Health Case Report, Release 2 STU 1.1 – US Realm or CNDR HL7 2.5.1 ORU_R01.

- Perform structural testing of messages without Protected Health Information (PHI)

Step 3. Validate Content and Acceptance Testing:

- Work with CNDR staff to ensure that message content is valid and logical filters are properly formatted and functioning to send complete reportable cases.

Step 4. Transition to Production:

- Upon successful completion of User Acceptance Testing (UAT), a submitter's CNDR feed will transition to production reporting. This marks the transition to CDPH and CNDR ongoing support.

Following the successful completion of the testing and validation phase, providers will be required to consistently submit production data.

5. Ongoing Data Validation

After completing initial implementation validation, data quality will continue to be monitored by CNDR. If data quality changes after passing validation CNDR will notify and work with facilities or providers to improve data quality for neurodegenerative disease surveillance.

6. Support

For questions regarding establishing connectivity with the registry, or for ongoing support. Please email us at cdsrbhelp@cdph.ca.gov.

Appendix 1. Table of Data Elements for Manual Reporting to the California Neurodegenerative Disease Registry

Data Content Area	Requirement Optionality[1]	Field
Patient ID	R	Name (Last, First, MI)
	R	Date of Birth
	R	Sex - (Gender)
	R	Patient Street Address (Street & No)
	R	Patient Address City
	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 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 NPI - Physician ID
	R	Physician Specialty
	R	Physician Address (Street & No)
	R	Physician Address State
	R	Physician Address Zip (Postal) Code
	R	Physician email
	R	Physician License Number

[1]R = Required, RE = Required if available

[2]Date of Diagnosis is RE if the case was diagnosed before July 1, 2018, R if diagnosed after 7/1/18; transmission of the date that a triggering diagnosis was first documented on the patient's Problem List in the practitioner's electronic health record system is acceptable.

Appendix 1. Table of Data Elements for Manual Reporting to the California Neurodegenerative Disease Registry

Data Content Area	Requirement Optionality[1]	Field
Primary Diagnosis	R	ICD-10/Diagnostic Term
	R	Month and/or Year of Diagnosis[2]
Disease Onset	RE	Onset Date, Onset of Symptoms, if known
	RE	Symptoms at Onset

[1]R = Required, RE = Required if available

[2]Date of Diagnosis is RE if the case was diagnosed before July 1, 2018, R if diagnosed after 7/1/18; transmission of the date that a triggering diagnosis was first documented on the patient's Problem List in the practitioner's electronic health record system is acceptable.

Appendix 2. Table of Data Elements for Electronic Reporting to the California Neurodegenerative Disease Registry

Data Content Area	Requirement Optionality[1]	Field
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
	RE	Facility Type
Software ID	R	Software Vendor Organization
	R	Software Version or Release Number
	R	Software Product Name
	R	Software Binary ID
Patient ID	R	Name (Last, First, MI)
	R	Date of Birth
	R	Sex - (Gender)
	R	Patient Street Address (Street & No)
	R	Patient Address City
	R	Patient Address State
	R	Patient Address Zip (Postal) Code
	RE	Social Security Number
	R	Medical Record Number - MRN

[1]R = Required, RE = Required if available

[2]Date of Diagnosis is RE if the case was diagnosed before July 1, 2018, R if diagnosed after 7/1/18; transmission of the date that a triggering diagnosis was first documented on the patient's Problem List in the practitioner's electronic health record system is acceptable.

Appendix 2. Table of Data Elements for Electronic Reporting to the California Neurodegenerative Disease Registry

Data Content Area	Requirement Optionality[1]	Field
Patient Demographics	R	Race
	R	Ethnicity
	RE	Date 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	Author NPI - Physician ID
	R	Physician office phone number
Primary Diagnosis	R	ICD-10/Diagnostic Term
	R	Month and/or Year of Diagnosis[2]
	RE	Comment
Disease Onset	RE	Onset Date, Onset of Symptoms, if known
	RE	Comment

[1]R = Required, RE = Required if available

[2]Date of Diagnosis is RE if the case was diagnosed before July 1, 2018, R if diagnosed after 7/1/18; transmission of the date that a triggering diagnosis was first documented on the patient's Problem List in the practitioner's electronic health record system is acceptable.