The California Parkinson's Disease Registry

Implementation Guide

California Department of Public Health
Version 3.0
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Table of Contents

1. Introduction

California State Senate Bill (SB) 97, signed by Governor Jerry Brown in July 2017, established the Richard Paul Hemann Parkinson's Disease Program, updating the California Health and Safety Code (HSC) [103870-103870.2] regarding the reporting of Parkinson's disease. Beginning July 1, 2018, health care providers diagnosing and/or providing treatment to Parkinson's disease patients will be required to report each case of Parkinson's disease to the California Department of Public Health (CDPH). This implementation guide provides the information needed to meet this reporting mandate.

2. Purpose

This implementation guide describes who is required to report, the reporting criteria, and the timing of reporting to the California Parkinson's Disease Registry (CPDR). 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 Parkinson's Disease case reports; describes how to create an appropriate, valid electronic message for transmission; and details how to transmit reports to CPDR over a secure electronic transmission mechanism.

3. CPDR Reporting Requirements

3.1. Who is Required to Report?

Providers holding the following credentials who diagnose and/or treat Parkinson's Disease patients are required to report: Doctor of Medicine (MD), Doctor of Osteopathy (DO), Physician's Assistant (PA), and Nurse Practitioner (NP) (each a "Reporting Provider"). Advanced practice registered nurses, home care nurses, physical/occupational/speech therapists, chiropractors, podiatrists, acupuncturists, psychotherapists and optometrists are not required to report.

If Reporting Providers work in a group practice, have a formalized relationship within the practice, or are part of a hospital or facility medical staff, the reporting can be performed by the practice, hospital or facility ("Reporting Entity"). A single report may include encounter data from multiple Reporting Providers.

3.2. Parkinson's Disease Surveillance Case Definition

Any California resident seen and treated between July 1, 2018 and December 31, 2019, by a medical doctor (MD), Doctor of Osteopathy (DO), Nurse Practitioner (NP), or Physician's Assistant (PA) at a patient visit with a coded diagnosis[1] of Parkinson's Disease or Parkinsonism (ICD-10 G-20 or G-90.3, see Table 1 below) represents a case.

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)

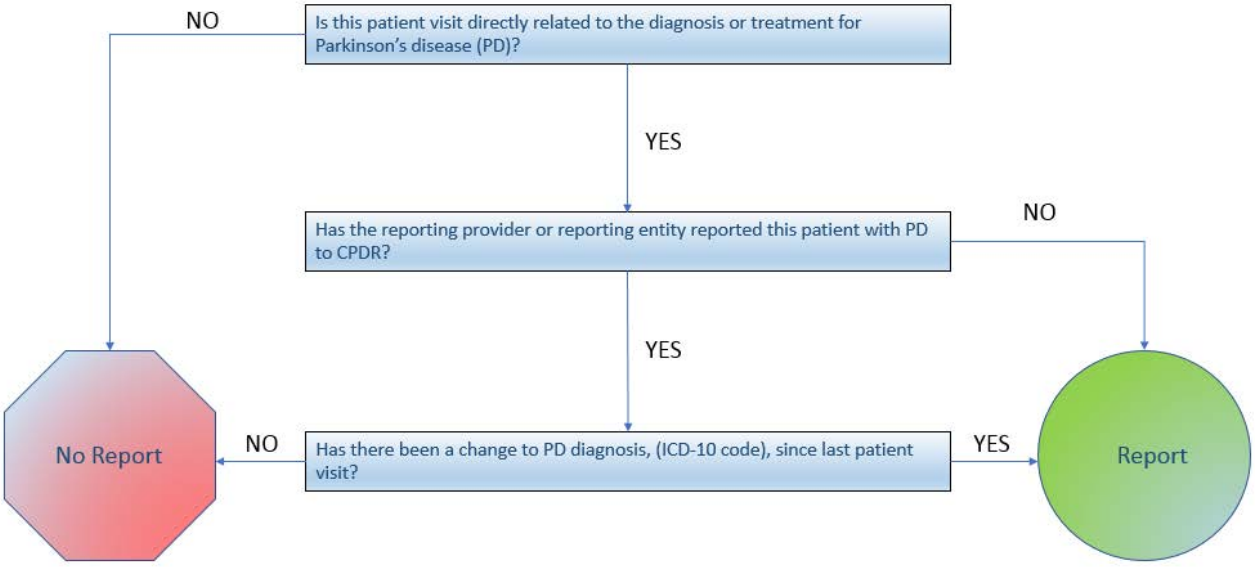
3.3. Criteria for Reporting

Reporting Providers are responsible for reporting cases when one or both of the following criteria apply:

1. The Reporting Provider or their Reporting Entity (per section 3.1) has not previously reported the patient to the California Parkinson's Disease Registry.
2. The patient medical encounter resulted in a new diagnosis of or change to the Parkinson's diagnosis (ICD 10 code) since the last report to the California Parkinson's Disease Registry.

Flow chart (Figure 1) illustrates these criteria.

Figure 1. Flow Chart of Reportable Parkinson's Disease Case Criteria



As shown in Figure 1, if the patient was not previously reported to CPDR, the encounter is reportable regardless of the encounter outcome. Subsequent encounters for a previously reported patient are only required to be reported if they result in a change in Parkinson's diagnosis (ICD10 code).

Multiple types of encounters can trigger the requirement for reporting, including ambulatory visits, emergency department visits, inpatient hospital stays, non-acute institutional stays, and other outpatient visits. Reportable encounters include face-to-face visits as well as certain non-face- to-face visits (i.e. telemedicine, telephone, online/e-visits) that include the coding of a specific triggering diagnosis. Ancillary encounters (e.g., lab, imaging, cardio-pulmonary, and therapies), are excluded from the triggering encounter list. Inpatient encounters can rely on the diagnostic codes used for hospital billing purposes to determine reportability.

3.4. How to Report: Reporting Modalities and Reportable Data Fields

As detailed below (Section 4. Technical Implementation), CPDR will accept electronic case reports through two methods: (1) manual data entry via Direct Data Entry Web Portal (secure web page accessible only to registered Reporting Providers and Reporting Entities); and (2) automated electronic transfer of case files from the Reporting Provider's or Reporting Entity's electronic medical record system. Reportable data elements for method (1) are identified in *Appendix 1. Data Elements for Manual Reporting to the California Parkinson's Disease Registry* while reportable data elements for method (2) are found in *Appendix 2. Data Elements for Automated Electronic Reporting to the California Parkinson's Disease Registry.* Providers reporting manually should ONLY report data elements found in Appendix 1.

3.5. Timing of Reporting

Regardless of the reporting modality (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, 2018) encounters must be reported within 180 days following the end of the quarter (i.e., by March 29, 2019). Beginning with encounters occurring on October 1, 2018, the deadline for data submissions is 90 days following the end of the calendar quarter. Frequency of data submission is at the discretion of the reporting provider or facility, but all data must be received by the deadlines specified 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
July 1 – September 30, 2018	March 29, 2019
October 1 – December 31, 2018	March 29, 2019
January 1 – March 31, 2019	June 29, 2019
April 1 – June 30, 2019	September 27, 2019
July 1 – September 30, 2019	December 27, 2019
October 1 – December 31, 2019	March 30, 2020

* For inpatient settings, the discharge date may be used as the date of the patient encounter.

4. Technical Implementation

4.1. Methods for Reporting

CPDR will accept electronic case reports through two 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 delivered via Secure File Transfer Protocol (SFTP).

Manual Data Entry (via Direct Data Entry Web Portal)

A Direct Data Entry Web Portal is available for providers, facilities, and hospitals which do not have the ability to generate and send an electronic message to CPDR. The Direct Data Entry Web Portal will require manual input of data in multiple fields for each patient and may not be the most efficient solution for physicians or facilities that diagnose and treat a significant volume of patients with Parkinson's Disease.

Automated Electronic Transfer of Case Files (via Electronic Interface)

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

CPDR will support two established HL7 standards:

1. HL7 CDA R2 Implementation Guide: Public Health Case Report, Release 2 STU 1.1 – US Realm
2. HL7 2.5.1 ORU_R01 based specification standard. [See *California Parkinson's Disease Registry, Electronic Reporting of Parkinson's Disease* (http://www.cdph.ca.gov/parkinsons)].

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

All data elements listed in the respective Appendix (Appendix 1 for manual data entry via the web portal or Appendix 2 for automated electronic reporting) are reportable. The appendices list the fields that are required as part of a case report and those that may be reported 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. If a required data element has an allowable code for "unknown", then that code should be transmitted for that element instead of an empty value.

NOTE: Those reporting manually through the web portal should ONLY report data elements found in Appendix 1 as these are the only fields collected by the CPDR.

4.3. Transmission Methods

As previously noted, CPDR will accept Parkinson's Disease case reports through two methods of transfer: manual data entry via Direct Data Entry Web Portal and automated electronic transfer of case files in HL7 v2.5.1 or HL7 CDA. The following methods of secure 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

Reporting Provider and Reporting Entity Registration

For either method of reporting, Reporting Providers or the Reporting Entity can establish their intent to report by registering their provider information on the CDPH Health Information Exchange (HIE) Gateway, beginning in June 8, 2018 (https://hie.cdph.ca.gov/). The reporting requirement falls on the entity that will complete the reporting. Thus, if an individual Reporting Provider will report their own cases, the individual should register. However, if a Reporting Entity will report for their affiliated Reporting Providers, only the Reporting Entity should register. Registering on the HIE Gateway is voluntary for those submitting through the interface; however, registration will assist in management of the onboarding process and document intent to report.

For manual data entry, registration on the CDPH HIE Gateway is required to establish an account on the Direct Data Entry Web Portal. Reporting Providers and Reporting Entities will receive an email confirmation from the CPDR within approximately 2-4 weeks of their registration which explains the process. The Direct Data Entry Web Portal is a secured website conforming to state information security requirements for the data entry of confidential patient information to CPDR.

Upon successful registration for the automated electronic case submission process, SFTP login information and/or a SOAP 1.2 web interface implementation guide will be provided.

Data Submission Testing/Validation

Reporting Providers and Reporting Entities wishing to use the electronic interface for reporting will work with CPDR in a data submission testing and validation process to initiate connectivity, validate message structure and content, and perform user acceptance testing. Upon validation, data submission will transition to production reporting.

Step 1. Initiate Connectivity:

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

Step 2. Validate Message Structure:

- Implement logical filters to ensure that only Parkinson's disease cases are sent to CPDR.
- Ensure that the information system produces a message compliant with CPDR HL7 CDA R2 Implementation Guide: Public Health Case Report, Release 2 STU 1.1 – US Realm or CPDR 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 CPDR staff to ensure that message content is valid and logical filters are properly formatted and functioning to send complete case reports.

Step 4. Transition to Production:

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

Following the successful completion of the testing and validation phase, Reporting Providers and Reporting Entities will be required to consistently submit production data for the life of the CPDR program.

5. Ongoing Data Validation

After completing initial implementation validation, data quality will be continuously monitored by CPDR. If data quality changes after passing validation, CPDR will notify and work with Reporting Providers and Reporting Entities to remediate identified data quality issues for Parkinson's disease surveillance.

Appendix 1. Data Elements for Manual Reporting to the California Parkinson's Disease Registry

Data Content Area	Requirement Optionality	Field
Patient ID	Required	Name (Last, First, MI)
	Required	Date of Birth
	Required	Sex - (Gender)
	Required	Patient Street Address (Street & No)
	Required	Patient Address City
	Required	Patient Address State
	Required	Patient Address Zip (Postal) Code
	Optional	Social Security Number
	Required	Medical Record Number - MRN
Patient Demographics	Required	Race
	Required	Ethnicity
	Optional	Date Last Contact/Death
Physician Identifiers (Primary)	Required	Physician Name (Last, First)
	Required	Author NPI - Physician ID
Primary (Triggering) Diagnosis	Required	ICD-10/Diagnostic Term
	Required[1]	IF known, Month and/or Year of Diagnosis[1]
Disease Onset	Optional	Onset Date, Onset of Symptoms, if known

[1]Date of diagnosis is optional if the case was diagnosed before July 1, 2018, required when available if diagnosed after July 1, 2018; date that a triggering diagnosis was first documented within the patient's record per an encounter or on the patient's Problem List in the practitioner's electronic health record system (date of submission) is acceptable.

Appendix 2. Data Elements for Automated Electronic Reporting to the California Parkinson's Disease Registry (HL7 v2.5.1)

Data Content Area	Requirement Optionality	Field	HL7 Segment/Sequence
Facility ID	Required	Reporting Facility Name	MSH.3, ORC.21
	Required	Reporting Facility ID	MSH.4
	Required	Facility Address	ORC.22
	Required	Facility Phone Number	ORC.23
	Required	Sending Facility Application	MSH.3
	Required	Date/Time of Message	MSH.7
	Optional	Facility Type	PV1.10
Software ID – if using HL-7	Required	Software Vendor Organization	SFT.1
	Required	Software Version or Release Number	SFT.2
	Required	Software Product Name	SFT.3
	Required	Software Binary ID	SFT.4
Patient ID	Required	Name (Last, First, MI)	PID.5
	Required	Date of Birth	PID.7
	Required	Sex - (Gender)	PID.8
	Required	Patient Street Address (Street & No)	PID.11
	Required	Patient Address City	PID.11
	Required	Patient Address State	PID.11
	Required	Patient Address Zip (Postal) Code	PID.11
	Optional	Social Security Number	PID.19
	Required	Medical Record Number - MRN	PID.3
Patient Demographics	Required	Race	PID.10
	Required	Ethnicity	PID.22
	Optional	Date Last Contact/Death	PID.29
Patient Visit Information	Optional	Attending Doctor	PV1.7
	Optional	Consulting Doctor	PV1.9

Appendix 2. Data Elements for Automated Electronic Reporting to the California Parkinson's Disease Registry (HL7 v2.5.1)

Data Content Area	Requirement Optionality[1]	Field	HL7 Segment/Sequence
	Optional	Hospital Service	PV1.10
	Optional	Admission Reason	PV2.3
Physician Identifiers (Primary)	Required	Author NPI - Physician ID	OBR.16
	Required	Physician office phone number	OBR.17
Primary (Triggering) Diagnosis	Required	ICD-10/Diagnostic Term	OBX.5 following Diagnosis OBR
	Required[1]	Month and/or Year of Diagnosis[1]	OBX.14
Disease Onset	Optional	Onset Date, Onset of Symptoms, if known	OBX.5 following Diagnosis OBR

[1]Date of diagnosis is optional if the case was diagnosed before July 1, 2018, required when available if diagnosed after July 1, 2018; date that a triggering diagnosis was first documented within the patient's record per an encounter or on the patient's Problem List in the practitioner's electronic health record system (date of submission) is acceptable.