INITIAL STATEMENT OF REASONS

Summary of the Proposed Regulations

The California Department of Public Health (hereafter "Department") proposes to adopt Subchapter 17 (sections 7201–7265) of Division 1, Chapter 4, Title 17 of the California Code of Regulations to establish standards and technical requirements for submitting case reports containing patient health data to the California Parkinson's Disease Registry (hereafter "Parkinson's Registry") and the California Neurodegenerative Disease Registry (hereafter "Neurodegenerative Registry"). The Department also proposes requirements for research institutions and government agencies to request access to confidential information gathered by the Parkinson's Registry and Neurodegenerative Registry (hereafter collectively called "registries"). The Department also proposes procedures for individual patients to access their own personal information, to limit their participation in research by joining a Do Not Contact List, and to request destruction of erroneous data reported to the registries. These proposed regulations will implement, interpret, and make specific the provisions in the Health and Safety Code that established the registries to provide clarity to the regulated community regarding how to report cases to the Department and how to request data from the registries.

Policy Statement Overview:

Problem Statement:

The Department requires regulations to establish the standards and technical requirements for mandatory reporters who must submit cases of Parkinson's disease and neurodegenerative disease to the registries. The Department further requires regulations to establish procedures for research institutions and government agencies to request access to confidential information contained in the registries. The Department requires regulations to establish procedures for individual patients seeking to access their personal information, to limit patient participation in research by enabling patients

to join a Do Not Contact List, and to request destruction of erroneous data reported to the registries. Finally, the Department requires regulations to establish the reporting schedule for each neurodegenerative disease.

Objectives (Goals): The broad objectives of this proposed regulatory action are:

- Establish the administrative framework of the Parkinson's Registry and Neurodegenerative Registry.
- Establish submission standards for mandatory reporters to transmit case reports containing patient health data to the registries.
- Establish the technical requirements for mandatory reporters to interface securely with the Department's reporting environment where case reports are collected.
- Establish the list of neurodegenerative diseases subject to reporting mandates.
- Establish the schedule for when each reporting mandate takes effect.

Benefits:

- Increased efficiency and consistency for the Department program administering the registries.
- Increased efficiency and consistency for mandatory reporters submitting case reports to the registries.
- Improved patient experiences for individuals whose data is reported to the registries.
- Improved reliability for research institutions and government agencies accessing data contained in the registries.

Authority and Reference

The Department may promulgate the proposed regulation sections under the Department's regulatory authority provided by Health and Safety Code sections 131050, 131051, 131052, 131200, 103870, 103870.1, 103871, 103871.1, and 103871.2. The regulation sections implement, interpret, and make specific Health and Safety Code sections 103870, 103870.1, 103871, 103871.1, and 103871.2.

Please note that parallel statutes found at Health and Safety Code sections 103860 and 103865 also provide additional authority to regulate; however, the Department is not relying on those laws because they are conditioned upon the availability of funding from federal and private sources. The Parkinson's Registry is solely funded by the State of California at this time.

Background

The California Parkinson's Disease Registry and the California Neurodegenerative Disease Registry are modeled after the California Cancer Registry. After it was fully implemented in 1988, the California Cancer Registry quickly grew into one of the leading cancer registries in the world due to the size and diversity of the state's population and became a cornerstone for medical research worldwide. California lawmakers have since adapted this successful disease registry model to confront the public health challenges of Parkinson's disease and neurodegenerative disease.

In 2004, Health and Safety Code sections 103860 and 103865 were enacted to establish the California Parkinson's Disease Registry.

In 2017, Health and Safety Code sections 103870, 103870.1, and 103870.2 were enacted to establish the Richard Paul Hemann Parkinson's Disease Program with an original sunset date of January 1, 2020. The sunset date was amended in 2019 to extend the Richard Paul Hemann Parkinson's Disease Program to January 1, 2021.

In 2021, Health and Safety Code section 103870.2 was repealed to extend the Richard Paul Hemann Parkinson's Disease Program indefinitely and sections 103871, 103871.1, and 103871.2 were enacted to establish the California Neurodegenerative Disease Registry. Section 103871 was amended in 2023 to include amyotrophic lateral sclerosis (ALS), also known as Lou Gehrig's disease.

Collectively, these provisions of the Health and Safety Code require the Department to conduct a program of epidemiological assessments, and to establish a statewide system for the collection of information for determining the incidence and prevalence of

Parkinson's disease and neurodegenerative disease within the state. The Health and Safety Code further requires a hospital, facility, physician and surgeon, or other health care provider (collectively called "mandatory reporters") to report cases of Parkinson's disease and specified neurodegenerative diseases to the Department. The Department's proposed regulations would clarify how the Department will implement, interpret, and make specific the provisions of the Health and Safety Code and administer the Parkinson's Registry and Neurodegenerative Registry.

Engagement with Partners and Stakeholders

In development of these regulations the Department has engaged Parkinson's disease and neurodegenerative disease stakeholders, including data providers, mandatory reporter facilities, researchers, and advocacy organizations, starting in 2018 and most recently in September 2024. The Department developed an implementation guide for the Parkinson's registry in 2018 to operationalize the collection of health data, and then the guide was updated in 2023 to cover the neurodegenerative registry. Also in 2018, stakeholders were invited to provide feedback on the implementation guide, including guidance on which data categories and data fields would be required for mandatory reporters to complete before submitting a case report. In 2023, the Department updated the implementation guide to include a case definition for multiple sclerosis and sought a new round of stakeholder feedback. The Department also hosted two public virtual listening sessions to inform stakeholders, mandatory reporters, and researchers about plans to expand coverage to include multiple sclerosis starting in July 2023 and Alzheimer's disease starting in July 2025. After the virtual listening sessions, the Department invited additional feedback from stakeholders and shared the listening session videos on the Department's Chronic Disease Surveillance and Research Branch website. In September 2024, the Department hosted two additional public virtual listening sessions to inform stakeholders, mandatory reporters, and researchers about plans to expand coverage to include amyotrophic lateral sclerosis starting in July 2026. Like the previous virtual listening sessions, the Department invited additional feedback

from stakeholders and shared the listening session videos on the Department's Chronic Disease Surveillance and Research Branch website.

Consideration of Reasonable Alternatives to the Regulations

The Department has determined that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which this action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

Evaluation as to Whether the Proposed Regulation is Inconsistent or Incompatible with Existing State and Federal Regulations

The Department has reviewed existing state and federal regulations and concludes that the proposed regulations are compatible with existing state and federal regulations.

Detailed Discussion of Each Regulation

The Department proposes to adopt the following articles and sections to implement the regulations needed to address the new reporting process for the Parkinson's Registry and the Neurodegenerative Registry, as follows:

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

Adopt Article 1. General

Adopt Section 7201. Definitions

Proposed section 7201 is necessary to establish the definitions of terms used in the requirements for the reporting process for the Parkinson's Registry and the Neurodegenerative Registry under this subchapter. Each of the definitions is discussed below:

Adopt the term "authorized user" to mean an employee or contractor who has been registered with the Parkinson's Registry or Neurodegenerative Registry to transmit case reports on behalf of the mandatory reporter to the Department. This definition is necessary to specify which people are responsible for submitting required case reports to the Department on behalf of the mandatory reporter.

Adopt the term "California Neurodegenerative Disease Registry" or "Neurodegenerative Registry" to specify one of two programs within the Department authorized to maintain the system of data reported under this subchapter. This definition is necessary to distinguish the two registries (the Parkinson's Registry and the Neurodegenerative Registry) covered under this subchapter. The two registries are administered by the same center within the Department and will use identical submission standards but will continue to operate as separate and parallel programs as designated by the California Legislature in the Health and Safety Code.

Adopt the term "California Parkinson's Disease Registry" or "Parkinson's Registry" to specify the second of two programs within the Department authorized to maintain the system of data reported under this subchapter. This definition is necessary to distinguish the two registries (the Parkinson's Registry and the Neurodegenerative Registry) covered under this subchapter. The two registries are administered by the same center within the Department and will use identical submission standards but will continue to operate as separate and parallel programs as designated by the California Legislature in the Health and Safety Code.

Adopt the term "case report" or "report" to specify the health data required to be submitted quarterly to either the Parkinson's Registry or the Neurodegenerative Registry or both pursuant to this subchapter. This definition is necessary to specify that when the regulations refer to a case report, the individual components of a case report do not constitute a case report on their own.

Adopt the term "confidential information" to mean any information, including case reports, collected by the Department for both the Parkinson's Registry and the

Neurodegenerative Registry in accordance with their respective statutes. This is necessary to specify that the term applies to the broadest category of data contained in both registries, increasing the Department's ability to protect the confidential information provided in the required case reports.

Adopt the term "data category" to specify that case reports contain discrete types of information which the Department has designated as reportable under the requirements of this subchapter.

Adopt the term "data field" to specify that a case report submitted to the Department includes specific values within data categories that are designated as reportable under this subchapter.

Adopt the term "data recovery measures" to specify the steps the Department takes to obtain the required data from a mandatory reporter facility or individual that fails to comply with the requirements of the Health and Safety Code and this subchapter.

Adopt the term "data validation" to specify the steps the Department takes to audit data submitted by mandatory reporters to ensure that each registry has high-quality data for recipient institutions to use in their research projects. Data validation measures may also include prescriptive steps issued by the Department after a data quality audit to improve the quality of future case reports.

Adopt the term "Department" to specify CDPH and not any other state department. This definition is necessary because many state agencies are referred to as "departments" and mandatory reporters need to understand that the term as used in these regulations refers to CDPH, not any other department or state agency in California.

Adopt the term "encounter" to specify what types of patient-provider interactions constitute an "encounter" for the purposes of gathering and reporting encounter data within the case reports required under this subchapter. Patients with Parkinson's disease and other neurodegenerative diseases interact with their healthcare providers

frequently, but not every patient-provider interaction constitutes an “encounter” that results in reportable data that must be submitted in a case report.

Adopt the term “neurodegenerative disease” to specify the types of medical conditions that are subject to the requirements of this subchapter. This definition is necessary to establish what conditions are subject to mandatory reporting under this subchapter.

Adopt the term “personal information” to specify the types of information that are subject to the requirements of this subchapter. This definition is necessary to clarify that personal information includes a wide variety of data that can be used to identify a person directly or indirectly.

Adopt the term “recipient institution” to specify that once an agency or institution has completed the data disclosure application process under Article 4, and the Department has granted authorization to access confidential information, the agency or institution becomes a “recipient institution” for the purposes of this subchapter. Each recipient institution has been granted authorization to access confidential information from the Parkinson’s Registry or the Neurodegenerative Registry or both for the purpose of conducting scientific research.

Adopt the term “reporting environment” to specify that mandatory reporters transmit case reports to a designated online portal using secure data transfer methods.

Adopt the term “reporting process” to specify that any mention of the reporting process only refers to the steps required for reporting to the Department under this subchapter and not to any other steps or processes that a healthcare provider may follow pursuant to federal or state mandates beyond the scope of this subchapter. Healthcare providers are subject to numerous overlapping reporting requirements and information sharing processes under federal and state law, but for the purposes of this subchapter the term “reporting process” only refers to the steps that must be followed to submit data to the Parkinson’s Registry and the Neurodegenerative Registry.

Adopt the term "willful noncompliance" to specify that mandatory reporters who deliberately fail or who refuse to comply with the reporting process under this subchapter will be subject to sanctions by the Department. This definition is modeled after the "willful misconduct" degree of culpability as distinguished from negligence, which can be found in the *California Jurisprudence 3d* encyclopedia (46 Cal.Jur.3d § 103), to ensure that the regulated community and courts interpret and apply this term consistently with principles of California law.

Adopt the term "written notification of corrective action" or "corrective action notice" to specify the 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. This notice is necessary to alert mandatory reporters or recipient institutions that the Department requires the notified party to take additional steps to correct the noncompliance or they may face sanctions under this subchapter.

Adopt the term "written notification of proposed sanctions" to specify the document sent by the Department to a mandatory reporter or a recipient institution with an explanation of proposed sanctions for failure to address each instance of noncompliance specified in a corrective action notice. This notice is necessary to alert mandatory reporters or recipient institutions that the Department intends to pursue sanctions based on instances of noncompliance identified in the corrective action notice.

Adopt the term "written statement of data destruction" to specify the 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. This written statement is necessary for the Department to document when a recipient institution has completed the necessary steps to destroy the confidential information provided by the registries either upon the completion of a research project or upon the revocation of

authorization to access confidential information following sanctions for failure to comply with the requirements of this subchapter.

Adopt Section 7203. Purpose of the Parkinson's Registry and Neurodegenerative Registry

This proposed section is necessary to clarify to the regulated community why the Department has established the Parkinson's Registry and Neurodegenerative Registry. Proposed section 7203 summarizes the purpose of the Parkinson's Registry and Neurodegenerative Registry, and the broad goals of the Department in promulgating the requirements under this subchapter. Both registries exist to determine the incidence and prevalence of their respective diseases. Through the requirements of this subchapter, the Department will gather health information from mandatory reporters submitted in quarterly case reports. That confidential information will populate the databases that will be shared with qualified researchers and approved research institutions to further the scientific study of Parkinson's disease and neurodegenerative disease.

Adopt Section 7205. Applicability of the Parkinson's Registry and Neurodegenerative Registry

This proposed section is necessary to establish the schedule for reporting on the neurodegenerative diseases covered by this subchapter. The Department intends for each covered disease to be phased in sequentially based on the anticipated capacity of the program to process the health data submitted by mandatory reporters. The Department selected July 1 as the effective date for each covered disease to coincide with the start of the state's fiscal year. The Department selected a phased-in schedule to allow the program administering the Parkinson's Registry and Neurodegenerative Registry sufficient time and resources to scale up the program gradually, while still ensuring that at least two calendar quarters of data will be collected before the statutory sunset date for the Neurodegenerative Registry. The phased-in schedule will allow mandatory reporters sufficient time to adapt to the reporting process and prepare for expanding the requirements to each covered disease over time. Subsection (a)(1)

through (a)(4) lists each covered neurodegenerative disease in the order of the phased-in schedule.

The Department considered applying the reporting requirements simultaneously across all the covered diseases but determined that that approach would impose greater implementation costs and administrative burdens on the regulated community and on the program administering the Parkinson's Registry and Neurodegenerative Registry. Implementing the requirements under the phased-in schedule in conjunction with the voluntary reporting option for encounter data gathered prior to each effective date will result in a higher quantity and quality of data for each registry. Subsection (b) specifies that these medical conditions are subject to the mandatory reporting process under this subchapter on or after July 1 of the specified year. Subsection (b) specifies that mandatory reporters may submit case reports on a voluntary basis (and therefore exempt from sanctions) prior to the effective date, which will encourage additional reporting of high-quality data.

Adopt Section 7207. Petition for Designation of Additional Neurodegenerative Diseases

This proposed section is necessary to establish that the public may pursue the normal petition process under the Administrative Procedure Act (APA) to request the Department to designate additional diseases for the Neurodegenerative Registry. Adding a new disease to the Neurodegenerative Registry would require a regular rulemaking process under the APA. This adoption clarifies that there is an existing petition process the public can use to expand the scope of these regulations.

Adopt Article 2. Reporting Requirements

Adopt Section 7209. Mandatory Reporters

This proposed section is necessary to clarify that the reporting requirements of this subchapter apply jointly to the institutions and individual licensees who share mandatory reporting responsibilities. The proposed regulations would apply to any institution or

individual licensee responsible with providing diagnostic, therapeutic, or treatment services to a patient with Parkinson's disease or a neurodegenerative disease covered by this subchapter. The California Neurodegenerative Disease Registry Program requires reporting by "a hospital, facility, physician and surgeon, or other health care provider diagnosing or providing treatment for a patient with a neurodegenerative disease." (Health & Saf. Code, § 103871(d)). The categories of institutions and individual licensees listed under subsection (a)(1) and (a)(2) are necessary to make specific what qualifies as an "other healthcare provider."

A patient with Parkinson's disease or a neurodegenerative disease covered by this subchapter will have numerous encounters with a variety of healthcare providers over the course of their lifetime, but the Department needs only to define a "mandatory reporter" as those institutions and individual licensees in the best position to gather reliable encounter data and compile case reports in a format prescribed by the Department. Imposing the reporting requirements on a larger group of mandatory reporters would place an unnecessary burden on healthcare providers, and risk flooding the Department with a larger volume of less reliable encounter data.

The requirements under subsection (a)(1) are necessary to make clear that only institutions and facilities licensed or regulated by the Department will be responsible for submitting case reports. The requirements under subsection (a)(2) are necessary to make clear that only five categories of individual licensees (medical doctors, osteopathic doctors, physician assistants, nurse practitioners, and pharmacists) will be treated as jointly responsible for filing accurate, complete, and timely case reports. The categories of institutions and individuals listed under this section will share joint responsibility for filing case reports because they interact closely with patients and are in the best position to provide reliable encounter data to the Parkinson's Registry and Neurodegenerative Registry.

Subsection (b) is necessary to establish that the mandatory reporter institutions and individual licensees may collaborate to satisfy their joint responsibility to submit required

case reports. By specifying that a mandatory reporter may submit a case report on behalf of the institution and its employees and contractors jointly, this proposed section would ensure that the mandatory reporter institutions and individual licensees are able to collaborate and comply with the requirements in an efficient manner.

Subsection (c) is necessary to establish that the mandatory reporter will be held responsible for the actions and omissions of their agents, employees, authorized users, and independent contractors. This requirement ensures that mandatory reporters will supervise the conduct of the individuals who work on their behalf and guarantee that those individuals uphold the requirements of the Health and Safety Code and this subchapter.

Adopt Section 7211. Encounters Subject to Reporting Requirements

This proposed section is necessary to specify when encounter data must be reported to the Department and further specifies that all the following conditions must be present to trigger this reporting requirement for the reasons explained below. The conditions in this section were selected by the Department as necessary to capture the greatest amount of high-quality research data balanced against the risk of over collecting unnecessary and duplicate data, which would place undue burdens on the Department and on the regulated community of mandatory reporters.

Subsection (a)(1) specifies that encounter data is subject to the reporting requirements of this subchapter when a patient has a diagnosis of Parkinson's disease or one of the covered neurodegenerative diseases based on the International Classification of Diseases, Tenth Revision (ICD-10) codes applied to the patient's health record. Subsection (a)(2) specifies that encounter data must be reported only when it is related to the diagnostic, therapeutic or treatment services to the patient for their Parkinson's diseases or other neurodegenerative diseases covered by this subchapter on or after the effective date under Section 7205. Subsection (a)(3) specifies that the encounter data is only subject to reporting requirements when it has not been previously reported by the mandatory reporter. This third requirement balances the Department's interest in

collecting a broad spectrum of high-quality research data against collecting unnecessary and duplicative data, which would burden the mandatory reporters during the reporting process and the Department during the data deduplication process. Eliminating duplicate encounter data would assist the Department in validating case reports over the lifetime of the patient.

Establishing a broad reporting mandate to cover a wide spectrum of encounter types with a direct connection to the diagnosis, therapy, or treatment of Parkinson's disease or a covered neurodegenerative disease furthers the Department's goal of gathering more data to determine the incidence and prevalence of these diseases. Subsection (b) specifies that the term "diagnosis" refers to the application of a set of designated ICD-10 codes listed under section 7221 of this subchapter.

Adopt Section 7113. Types of Encounter Data for Case Report

This proposed section is necessary to establish which types of encounter data will be required for a case report. This section focuses the mandatory reporter's reporting obligations on the encounters most likely to provide meaningful data for scientific research of the covered diseases. The Department determined the six categories of encounters in subsections (a) through (f) as the most valuable sources of health data for future research. The Department considered but declined to require "all encounters" or a similarly expansive requirement because the result would likely be burdensome for mandatory reporters to implement. Additionally, the "all encounters" approach would likely result in a large amount of low-value data, placing additional deduplication and data validation burdens on the Department. Accordingly, the Department elected to exclude the less valuable sources of health data and focus on the six categories of encounters that are most likely to provide meaningful information and high-quality research data that can be interpreted and analyzed by researchers.

Adopt Section 7215. Schedule for Regular Reporting

This proposed section is necessary to establish the schedule for submitting a case report to the Department. This section would establish that the calendar quarter for organizing and compiling encounter data in a case report conforms to the traditional calendar quarter system, with each quarter ending on the last day of the third month of each quarter (March 31, June 30, September 30, and December 31 respectively). This proposed section is necessary to make clear to the regulated community that a mandatory reporter has one calendar quarter to prepare and submit each case report after the end of the previous calendar quarter. This reporting structure ensures that the mandatory reporter has more than enough time (three months) to compile and report encounter data to the Department. This structure also guarantees that the Department receives regular updates four times per year for each patient listed in the Parkinson's Registry and Neurodegenerative Registry. Requiring a mandatory report on a more frequent schedule (e.g., monthly reports) would pose an unnecessary burden on mandatory reporters with little benefit to the Department, and a less frequent schedule (e.g., annual reports) would result in unnecessary delays that might frustrate the purpose and mission of the Parkinson's Registry and Neurodegenerative Registry.

Adopt Section 7217. Voluntary Reporting

This section is necessary to clarify to the regulated community that the Parkinson's Registry and the Neurodegenerative Registry would accept additional encounter data outside the reporting requirements of this subchapter if the encounter occurred before the effective date of these regulations. This is necessary to encourage mandatory reporters to voluntarily report previously gathered encounter data to bolster the registries with additional high-quality data.

Subsection (a)(1) is necessary to narrow the scope of voluntary reporting to the types of encounter data that would be required under this subchapter for regular reporting. Subsection (a)(2) is necessary to narrow the scope of voluntary reporting to the subset of encounter data that has not already been submitted to the Department, to discourage

unnecessary duplicate reporting, and to save the Department unnecessary costs related to deduplication during the data validation process. Subsection (a)(3) is necessary to narrow the scope of voluntary reporting to encounter data gathered by the mandatory reporter prior to the effective date of the requirements under section 7205. Subsection (a)(4) is necessary to establish that voluntary reporting must still conform to the Department's formatting requirements to ensure that the data is reported consistently, and to reduce the need for data validation audits.

Subsection (b) is necessary to clarify that the encounter data or diagnosis codes under section 7221(b) that are reported to the Department on a voluntary basis will not be subject to the sanctions under Article 5. This is necessary to comport with principles of notice and fairness, and to remove potential disincentives to reporting valuable encounter data outside the boundaries of the reporting requirements of this subchapter.

Adopt Section 7219. Coding of Reportable Encounters – Unknown Values

This section is necessary to clarify how mandatory reporters should format a case report when the encounter data includes fields with unknown values. The requirements of this section are necessary to ensure that the Department can receive and record encounter data where some values may be unknown. This approach ensures that data reported to the registry is as accurate as possible.

Subsection (a) is necessary to establish that a mandatory reporter must provide a value for every data field marked "required" or "required if data are available."

Subsection (b) is necessary because excluding empty, missing, or null values from case reports will conserve Department resources during the data verification process, and will ensure accurate data is reported for determining incidence and prevalence of neurodegenerative diseases.

Subsection (c) is necessary to establish that "unknown" is the preferred value to enter instead of an empty, blank, or null value when that response is appropriate. The requirements of subsections (b) and (c), when implemented together, ensure that the

recipient institutions who receive confidential data from the Parkinson's Registry or Neurodegenerative Registry can rely on the accuracy of data from the registries.

Adopt Section 7221. Diagnosis Codes to Trigger Reporting

This proposed section is necessary to establish which International Classification of Disease Tenth Revision (ICD-10) codes will trigger the reporting requirements of this subchapter. From the thousands of possible ICD-10 codes, only the ten codes described in the table are typically applied to a patient's medical record once they receive a diagnosis of Parkinson's disease or a neurodegenerative disease covered under this subchapter. Subsection (a) is necessary to establish which ICD-10 codes in Table 1 trigger mandatory reportability under this section. The ICD-10 codes correspond to the diagnoses that would typically be applied to a patient's medical record when they have a covered disease.

Subsection (b) is necessary to establish which ICD-10 codes trigger voluntary reportability under this section. The Department determined that these ICD-10 codes in Table 2 should be subject to voluntary rather than mandatory reporting because in some cases these ICD-10 codes may exceed the authority granted under the Health and Safety Code. The ICD-10 codes in this voluntary reporting list were selected because they are frequently assigned to a patient whose symptoms eventually develop into Alzheimer's disease and other covered neurodegenerative diseases, but those diagnoses can only be confirmed postmortem. Encouraging voluntary reporting of these ICD-10 codes strikes a necessary balance between the Department's desire to collect as much high-quality data for the registries without exceeding its authority to require mandatory reporting.

Subsection (c) is necessary to establish that mandatory reporters may use the same diagnostic coding for hospital billing purposes to trigger reportability under this section to eliminate any additional administrative burden on the regulated community from complying with this section.

Adopt Section 7223. Additional Time for New Reporting Mandates

This proposed section is necessary to establish that when a new reporting mandate takes effect, mandatory reporters have an additional calendar quarter (until March 31 rather than December 31) to submit the required encounter data the first time they comply with that new reporting mandate. This additional three-month grace period allows the Department and the mandatory reporters more time to reconfigure their reporting systems to meet the new requirements, and places less of an economic burden on mandatory reporters who must comply with this subchapter. This proposal also gives the Department additional time to prepare for receiving additional encounter data.

Adopt Section 7225. Determination of Date for Patient Encounter Data

This proposed section is necessary to establish how mandatory reporters must determine the date of a patient's encounter when coding encounter data. Subsection (a) is necessary to make clear that an outpatient visit, which typically lasts less than one day, should be coded based on the date of the visit. Subsection (b) is necessary to make clear that an inpatient stay, which can last more than one day, must be coded based on the discharge date rather than the admission date. These requirements are necessary to ensure that encounter data is coded with uniform conventions for the dates of a patient's visit and eliminate the risk of variable approaches to encounter date coding.

Adopt Section 7227. Requirements to Request an Extension

This proposed section is necessary to establish that mandatory reporters may request an extension to submit case reports after the established due date if certain conditions are met.

The Department estimates that hundreds of mandatory reporters handling thousands of case reports may occasionally need additional time to submit encounter data. This

section would provide an automatic extension mechanism for mandatory reporters who notify the Department that some case reports will be submitted after the due date.

Subsection (a) establishes the conditions that the mandatory reporter must meet to receive an automatic extension. Subsection (a)(1) requires that the request must be received by the Department at least ten (10) calendar days prior to the normal due date. This is necessary to give the Department adequate time to process the requests. Subsection (a)(2) requires that the mandatory reporter's request include the number of all patients covered by the extension. Subsection (a)(3) requires that the mandatory reporter provides the routine contact information (name, phone number, and email address) for the individuals responsible for submitting the case reports on or before the extended due date. Providing this contact information facilitates the Department's ability to review extension requests and follow up as needed.

Subsection (b) provides that, if the mandatory reporter meets the requirements in subsection (a), the new extended due date for the affected case reporters will be the last day of the next calendar quarter. Tying the extension due dates to the regular calendar quarter reporting ensures that the mandatory reporter will be able to maintain the normal reporting schedule with minimal disruption should the need for an extension arise. This extension structure also provides the Department with additional certainty and predictability in processing new data, while affording mandatory reporters adequate time to handle unforeseen delays.

Subsection (c) provides that if the mandatory reporter needs an extension but is not able to comply with the requirements of subsection (a), they may still submit a request to the Department. This is intended to give the mandatory reporter an opportunity to notify the Department of the "factors outside the control of the mandatory reporter" as provided in section 7265. This subsection requires that the mandatory reporter must provide everything under subsection (a) as well as an "explanation for the failure to file the case reports within the required timeframe." This explanation of facts will be evaluated by the Department as the basis for either granting the extension on a

discretionary basis or pursuing other remedies, including the data retrieval process wherein the mandatory reporter bears the actual costs of the Department's intervention. If a discretionary extension is granted under subsection (c), the extended due date will be the last day of the next calendar quarter in order to preserve the normal reporting structure.

Subsection (d) incentivizes mandatory reporters to submit extension requests in accordance with subsections (a), (b), and (c) by providing the potential for sanctions in accordance with the final article of this subchapter. This subsection further specifies that the failure to request an extension will be used as evidence of willful noncompliance in the event that the Department pursues sanctions under Article 5. This potential sanction for noncompliance is necessary to help the Department distinguish mandatory reporters encountering minor delays during the ordinary course of business from mandatory reporters engaging in conduct that rises to the level of willful noncompliance.

Adopt Article 3. Technical Requirements

Adopt Section 7229. Methods for Submitting Reports – Required Electronic Format Standards

This section is necessary to establish that mandatory reporters must submit case reports in an electronic format. This is a common industry practice and is necessary because submitting paper records to the Department via physical mail or fax would be burdensome for all parties involved. Subsection (a) is necessary to establish that mandatory reporters have two acceptable methods for submitting the required case reports to the Department: either as an automatic upload via a designated interface, or manually through a website designated by the Department. Both are standard industry practices for data collection and represent the least burdensome method for mandatory reporters to report data to the Department.

Subsection (a)(1) is necessary to establish that mandatory reporters must comply with the Health Level Seven International (HL7) format standards of data exchange

designated by the Department. The HL7 format standards are established by a not-for-profit Standards Developing Organization which has been accredited by the American National Standards Institute and have been broadly adopted across the healthcare industry for exchanging electronic health record data in a fast and safe manner. This subsection further specifies that the case reports must be transmitted via one of two methods: either the Secure File Transfer Protocol (SFTP) or the Simple Object Access Protocol (SOAP). These are the two methods of secure data transfer that have been approved by the Department.

Subsection (a)(2) is necessary to establish that mandatory reporters may manually enter and submit the same electronic health record information to the Department through the Direct Data Entry Web Portal.

Subsection (a)(3) is necessary to establish that the mandatory reporter must guarantee that each authorized user has registered a unique login to submit case reports to the Department, and to ensure that the mandatory reporter complies with the registration and onboarding process for new users. This is necessary to protect confidential information and to comply with the Department's security standards.

Subsection (b) is necessary to establish that the failure to comply with these requirements will be used as evidence of willful noncompliance in the event that the Department pursues sanctions under Article 5.

Adopt Section 7231. Methods for Correcting Erroneous Reports

This proposed section is necessary to establish that a mandatory reporter has the option to provide updated and corrected information to the Department. The proposed section would afford the regulated community one calendar quarter to contact the Department and correct erroneous information contained in a previously submitted case report. This section is necessary based on stakeholder feedback requesting a mechanism for self-correction of inaccuracies. The option to contact the Department to correct erroneous data discovered within required case reports gives the mandatory

reporter flexibility to voluntarily provide corrections ahead of the data validation process if any such errors are discovered.

Subsection (a) is necessary to establish that mandatory reporters may contact the Department to provide notice of any erroneous information in a case report. It further provides that the mandatory reporter may contact the Department within one calendar quarter to correct the error to ensure that each registry is updated on a regular basis with the most accurate data available.

Subsection (b) is necessary to establish that a patient has the option of contacting the mandatory reporter who submitted erroneous information to the Parkinson's Registry or Neurodegenerative Registry, and the mandatory reporter has an obligation to notify the Department in writing that the correction was requested by the patient.

Subsection (c) is necessary to establish that the failure to comply with these requirements will be used as evidence of willful noncompliance in the event that the Department pursues sanctions under Article 5.

Adopt Section 7233. Required Data

This proposed section is necessary to establish the required data that must be reported to the Department by mandatory reporters in the quarterly case reports. Subsection (a) is necessary to establish that the case reports must contain valid values as provided under section 7219 in every data field marked as "required" to be accepted as complete. Subsection (b) is necessary to establish that the data fields within each data category are marked as either "required" or "required if available" according to Table 1. Table 1 is necessary to specify which data is required for the Parkinson's Registry and the Neurodegenerative Registry. These specific data categories and data fields are necessary so to further the scientific study of these diseases by providing the most useful data possible. The data categories and data fields in Table 3 were selected with input from stakeholder engagement sessions.

Adopt Section 7235. Registration and Onboarding Requirements for Mandatory Reporters

This proposed section is necessary to establish that the mandatory reporter must follow the authorized user registration, onboarding, and data validation process required by the Department. The Department understands that each mandatory reporter must delegate responsibility for transmitting case reports to one or more employees or independent contractors. Because the Parkinson's Registry and Neurodegenerative Registry handle sensitive patient health data, this section would require the mandatory reporter to guarantee that any person responsible for transmitting case reports to the Department has established unique login credentials before they submit data. The Department considered allowing each mandatory reporter to share a single login credential with multiple people, but that approach is inconsistent with the Department's obligations to protect patient health data and to verify that only authorized users submit case reports to the Parkinson's Registry and Neurodegenerative Registry. Overall, the registration and onboarding requirements are designed to protect the confidential information and patient data stored by the registries.

Subsection (a) establishes that a mandatory reporter must follow the Department-prescribed processes for registering and onboarding authorized users and for validating data. This provision is necessary to create a consistent registration, onboarding, and data validation process.

Subsection (b) specifies that the registration, onboarding, and data validation processes 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. This is necessary to ensure that the Department has an accurate record of who is accessing the reporting environment, so that the Department can identify any problematic users or reporting issues during its data validation process.

Subsection (c) requires that each mandatory reporter have at least one active authorized user in each calendar quarter to guarantee continuity in the reporting

process. This is necessary because mandatory reporters cannot comply with the requirements of this subchapter without continuous access to the reporting environment.

Subsection (d) provides that each mandatory reporter may designate additional authorized users or deactivate authorized users as needed to guarantee continuity in the reporting process.

Subsection (e) requires that the mandatory reporter must guarantee that any authorized user who separates from the employment or contractor relationship will be deactivated within one calendar quarter. This is necessary to ensure that only authorized users who are employed or contracted by the mandatory reporter have access to the Parkinson's Registry and Neurodegenerative Registry reporting environment, and to the confidential information contained therein.

Subsection (f) is necessary to establish a mandatory reporter's duty to designate a point of contact and maintain current contact information with the Department. The primary problem this requirement solves is that sometimes the Department needs to correspond with a mandatory reporter about routine compliance matters, but the contact information for the mandatory reporter is incomplete or out of date. This proposed requirement ensures that mandatory reporters are easy to reach in a timely manner by designating an individual point of contact with their name, title, email address, mailing address, and telephone number. Subsection (f)(1) is necessary to establish that the designated point of contact is responsible for corresponding with the Department for matters relating to user registration, onboarding, data validation, and all other matters relating to compliance with this subchapter. Subsection (f)(2) is necessary to establish that the mandatory reporter has a duty to provide the Department with updates to any changes to the identity or contact information of the designated point of contact within one calendar quarter. An additional benefit to adhering to this requirement is that it decreases the likelihood that a mandatory reporter will fall out of compliance with the other requirements of this subchapter and risk potential sanctions under Article 5

because the designated point of contact will correspond with the Department and resolve any minor compliance issues long before the corrective action notice process begins.

Subsection (g) is necessary to establish that the Department will conduct correspondence with the designated point of contact electronically via email. This affords both the Department and the mandatory reporter the opportunity to conduct correspondence in the quickest and most efficient manner to address any issues that arise. For any instances of noncompliance that may result in sanctions, the Department will use all available methods of correspondence to comport with principles of notice and due process owed to mandatory reporters.

Subsection (h) is necessary to establish that the failure to comply with these requirements will be used as evidence of willful noncompliance in the event that the Department pursues sanctions under Article 5.

Adopt Section 7237. Data Validation

This proposed section is necessary to establish that the Department will conduct ongoing data validation for both the Parkinson's Registry and the Neurodegenerative Registry. The requirement for hospitals and facilities to reimburse the Department for its data validation costs is a statutory requirement, and this section is designed to encourage compliance.

Subsection (a) is necessary to establish that a mandatory reporter has thirty (30) days to respond to any request for data validation and must follow any steps prescribed by the Department to improve data quality.

Subsection (b) is necessary to establish that if any mandatory reporter fails to respond within the thirty (30) calendar day notice period for data validation, the Department may pursue the data recovery measures authorized under the statutes. Subsection (b) also establishes that if the Department pursues data recovery measures, the mandatory reporter must bear the actual costs associated with that process in addition to any

applicable sanctions under Article 5. This section encourages mandatory reporters to cooperate with the Department and respond to data validation requests in a timely fashion.

Subsection (c) is necessary to establish that the failure to comply with these requirements will be used as evidence of willful noncompliance in the event that the Department pursues sanctions under Article 5.

Adopt Section 7239. Department Access to Data

This proposed section is necessary to establish that the Department has a statutory right to access information subject to the reporting requirements of this subchapter, and that the mandatory reporter must submit case reports and respond to requests for data validation in a timely manner. Subsection (a) establishes that when the Department pursues data recovery measures, the mandatory reporter must bear the actual costs and reimburse the Department for any travel or staff required to access and report the information in addition to any applicable sanctions under Article 5. The Department considered establishing a fixed daily cost for each instance of data recovery but declined that approach because it might result in situations where some mandatory reporters overpay or underpay for the costs of the intervention. Charging the mandatory reporter only for actual costs of the data recovery measures will provide sufficient incentive for mandatory reporters to comply with the requirements of this subchapter.

Subsection (b) is necessary to establish that mandatory reporters have the option of avoiding payment for the Department’s actual costs if they respond to a corrective action notice and resolve the cited instances of noncompliance within the prescribed time period. This subsection serves as an explicit reminder to the mandatory reporter that compliance will be less costly than noncompliance to incentivize their cooperation with the Department’s data validation requests.

Adopt Article 4. Data Disclosure

Adopt Section 7241. Authorized Access to Confidential Information

This proposed section is necessary to establish the application process for research institutions and government agencies to gain authorized access to confidential information in the registries.

Subsection (a) is necessary to establish who can apply to access the confidential information contained in the Parkinson's Registry and the Neurodegenerative Registry, or both. The requirements of this subdivision are provided by Health and Safety Code sections, 103870.1 and 103871.1, which are intended to prevent unauthorized users from gaining access to confidential information.

Subsection (b) is necessary to identify the applicant and whether they are applying on behalf of another agency or of a research institution. Applicants from research institutions will need to provide additional information and materials during the application process.

Subsection (c) is necessary to specify that any authorization to access confidential information is granted to the agency or research institution, and not to the individual. This is necessary to facilitate the Department's ability to administer the program and to clarify that, if any individual named in an application relocates or changes affiliation to another agency or research institution, the previously granted authorization will remain with the applicant agency or institution and will not follow the individual person to their new agency or institution.

Subsection (d) is necessary to clarify to the regulated community that, under the Health and Safety Code, that authorization to access confidential information contained in either the Parkinson's Registry or Neurodegenerative Registry is conditioned upon a written agreement to maintain confidentiality. This subsection is necessary to establish that recipient institutions will be subject to additional contract requirements once authorized access to confidential information is granted by the Department.

Subsection (e) is necessary to establish that when an applicant has completed the application process, the recipient institution will be held responsible for the actions and omissions of their agents, employees, authorized users, and independent contractors.

Adopt Section 7243. Required Information for Application

This section is necessary to establish the information and documentation required from an applicant before the Department will grant authorization to access confidential information from either the Parkinson's Registry or the Neurodegenerative Registry.

Subsections (a)(1)(A) through (a)(1)(C) are necessary to identify the key individuals involved and their institutional affiliations, as well as the purpose of the study and how they intend to use the confidential information once access is granted.

Subsection (a)(2) requires the applicant to provide documentation that summarizes the study protocol of the project. This is an industry standard requirement for scientific research.

Subsection (a)(3) requires the applicant to provide documentation that summarizes the peer review of the scientific merit of the project. The applicant has three options to satisfy this requirement: (1) documentation from a funding agency award; (2) a dissertation committee approval; or (3) an application review committee report issued by the Department, depending on the applicant's project and institutional procedures to demonstrate scientific merit.

Subsection (a)(4) is necessary for the applicant to clarify to the Department what items of data they seek once authorization is granted and the intended use of the data.

Subsection (a)(5) is necessary to establish that the applicant will agree in writing to maintain the confidentiality of the information and data provided by the Department. The agreement must be signed by the principal investigator and at least one authorized representative identified under subsection (a).

Subsection (a)(6) is necessary to establish that the confidentiality agreement must include contact information for the key individuals that the Department may contact in the event of a security incident, which must include the Principal Investigator, Privacy Officer, Information Security Officer, and Information Technology Service Desk. These are industry standard roles for research institutions handling confidential information for health science research. This subsection also requires the name, title, and contact information (mailing address, telephone number, fax number, and email address) for each required individual listed in the confidentiality agreement so that the Department may promptly and efficiently communicate with those key individuals in the event of a security incident.

Subsection (a)(7) is necessary to prove that the research institution has taken the steps to review and approve the proposed study in a manner consistent with a valid scientific study. The Department requires approval by both the research institution's Institutional Review Board and the Committee for the Protection of Human Subjects for the California Health and Human Services Agency. Approval from both entities is necessary to ensure that authorized access to the confidential information provided by the registries will only be granted to research projects with the appropriate controls and security procedures in place.

Subsection (b) is necessary to make clear to the regulated community that whenever a study involves the affiliation or collaboration of multiple research institutions, each research institution is required to comply with the requirements of this article and provide the required information and documentation of subsections (a)(5) through (a)(7).

Subsection (c) is necessary to establish that when an applicant representing a state, federal, or local health agency applies for authorization to access confidential information for the purpose of disease surveillance only, the applicant is exempt from the requirements of (a)(2), (a)(3), and (a)(7) of this section. These requirements are appropriate for exemption in those limited circumstances because it streamlines the process for the Department to grant access for its public health agency counterparts in

the critical purpose of conducting disease surveillance. Those exempted requirements are not necessary to facilitate the disease surveillance process by a public health agency. Subsections (a)(2), (a)(3), and (a)(7) are necessary components to evaluate the scientific merit of an application to conduct a research study, but amount to unnecessary paperwork in the public health agency disease surveillance context. The public health agency applicants must still comply with the other requirements of this section and this article when conducting disease surveillance.

Subsection (d) is necessary to establish that failure to comply with the application requirements under this section will result in the denial of authorization to access confidential information for each institution named in the application that fails to comply. If a research project has multiple applicant institutions, each institution will be evaluated separately and independently so that only the applicant institutions that fail to comply will be denied access.

Adopt Section 7245. Annual Reporting of Access to Disclosed Data

This proposed section is necessary to establish the recipient institution's annual reporting requirements, which are required under the Health and Safety Code. The Department selected June 30 as the due date for annual reports for the previous calendar year to give each authorized user six months to prepare the annual report before submission.

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

Subsection (b) specifies the information and documentation required in the annual report. Subsection (b)(1) requires the number of individuals who have accessed the confidential information during the previous calendar year. Subsections (b)(1)(A) through (b)(1)(D) are necessary to furnish the Department with accurate records of "all

persons who are given access to confidential information" in accordance with Health and Safety Code section 103870.1(e) and 103871.1(e).

Subsection (b)(2) requires that the applicant demonstrate that their research institution has approved the annual renewal of the study along with the appropriate documentation for the recipient institution's Institutional Review Board and the Committee for Protection of Human Subjects for the California Health and Human Services Agency. These are standard requirements for a valid scientific study using data provided by the Department.

Subsection (c) is necessary to establish the requirement that a recipient institution must file a final annual report once an approved study is complete, along with 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. This step is necessary to ensure that access to confidential information is limited to the duration of the research study. The written statement of data destruction includes the names and institutions of each Principal Investigator, the project name or title, the project approval date, and a signature and date attesting to a quoted statement certifying the destruction of the data provided in accordance with the National Institute of Standards and Technology (NIST) recommended destruction methods for physical and electronic documents. These steps summarize the industry standard practice for scientific research projects relying on health data provided by the Department. Subsection (c) is necessary to establish that compliance with the annual reporting requirements is necessary to maintain continued authorization to access confidential information from the Parkinson's Registry or the Neurodegenerative Registry or both.

Subsection (d) is necessary to establish that the failure to comply with the annual reporting requirements of this section will result in the suspension or revocation of the recipient institution's authorization to access confidential information from the registries.

If the authorization is revoked, the recipient institution must complete the written statement of data destruction to ensure that only authorized institutions have access to confidential information.

Adopt Section 7247. Mandatory Reporting of Breach of Confidentiality or Security Incident

This proposed section is necessary for the Department to maintain the integrity of confidential information and data provided to a recipient institution. Recipient institutions are subject to stringent data security requirements within the data usage agreements required by the Department to access confidential information. The requirements of this section provide the Department with additional security assurances in the event that a breach of confidentiality or security incident occurs in a gap between Data Usage Agreements with the Department.

Subsection (a) is necessary to establish that if a recipient institution discovers that their project or institution may have experienced a breach of confidentiality and/or security incident involving confidential information provided by the Department, the recipient institution must notify the Department within ten (10) calendar days. This ensures that the Department is provided with notice in a timely fashion so that the Department may contact the key individuals identified in the application to coordinate efforts.

Subsection (b) is necessary to establish that failure to submit a notice of breach will result in the suspension or revocation of the recipient institution’s authorization to access confidential information provided by the registries. The subsection further requires that if authorization is revoked, the recipient institution must complete the written statement of data destruction. These requirements are necessary to incentivize the timely reporting of breaches or security incidents so that the Department may take appropriate steps to protect the confidential information provided by the registries under this subchapter.

Adopt Section 7249. Individual Access to Personal Information

This proposed section is necessary to establish a process for individual patients to access their personal information after it has been entered into the Parkinson's Registry or the Neurodegenerative Registry. Subsection (a) is necessary to establish that patients must contact the Department's Privacy Office to request access. The Privacy Office is responsible for compliance with the Information Practices Act, the Health Insurance Portability and Accountability Act, and other laws that regulate how the Department handles sensitive information.

Subsection (b) is necessary to define the term "authorized representative" to include the patient's family, spouse, registered domestic partner, legal representative, or primary care provider. This is necessary so that the people who share responsibility for assisting a patient with Parkinson's disease or a neurodegenerative disease can be involved in the request if needed.

Subsection (c) is necessary to establish that the patient or their 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 in instances where the patient decides not to participate in scientific research studies. This requirement is based on feedback from stakeholders and strikes a balance between the interests of patients with Parkinson's disease and neurodegenerative disease who want to share their case report information to advance research into their diagnoses, and patients who prefer to protect their privacy.

Adopt Section 7251. Destruction of Erroneous Case Report Data

This proposed section is necessary to establish that a recipient institution has a duty to destroy erroneous case report data. The duty to destroy erroneous case report data is only triggered once the Department confirms the error and notifies the recipient institution.

Subsection (a) establishes the requirement that once the recipient institution has been notified of the erroneous case report data, the recipient institution must submit a written statement of data destruction for the erroneous data pertaining to that patient within one calendar quarter. This proposed section ensures that recipient institutions who receive confidential information from the Parkinson's Registry or Neurodegenerative Registry have a routine process to exclude unreliable and erroneous information from their scientific studies.

Subsection (b) establishes the requirement that the failure to submit a written statement of data destruction for the erroneous case report data will result in the suspension or revocation of the recipient institution's authorization to access confidential information from the registries. The section further establishes that if authorization is revoked, the recipient institution must complete the written statement of data destruction for any data they receive from the Department. This will incentivize recipient institutions to adhere to the requirement to destroy erroneous case report data in a timely fashion or else they risk losing access to all the data they receive from the registries.

Adopt Article 5. Penalties

Adopt Section 7253. Corrective Action Notices

This proposed section is necessary to establish the corrective action notices process that the Department will use to alert mandatory reporters and recipient institutions to any instances of noncompliance discovered during an inspection, audit, or review of documentation and case reports submitted under this subchapter. The corrective action notices process is necessary to comply with due process and standards of notice and fairness before subjecting a party to sanctions.

Subsection (a) is necessary to establish the minimum requirements of a corrective action notice sent by the Department to the party (either a mandatory reporter or recipient institution) found to be out of compliance. Subsection (a)(1) requires a description of each noncompliance. Subsection (a)(2) requires a citation to each

applicable section of the Health and Safety Code or California Code of Regulations corresponding to each noncompliance so that the party can understand which standards the Department seeks to enforce. Subsection (a)(3) requires a statement of the facts upon which the corrective action notice is based. Subsection (a)(4) requires the Department to specify any actions required to correct the noncompliance within the prescribed time period to give the party an opportunity to restore compliance. Subsection (a)(5) requires the Department to specify the due date by which the party 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. The Department selected thirty (30) calendar days as a sufficient amount of time to rebut or correct each instance of noncompliance because a shorter period of time would not be sufficient for the mandatory reporter or recipient institution to evaluate and prepare a response, whereas a longer period of time would add unnecessary delay to the reporting process. The Department estimates that the majority of noncompliance can be corrected in less than thirty (30) calendar days and the corrective action notices will represent the bulk of the Department's enforcement actions to maintain compliance.

Subsection (b) is necessary to establish that the Department will send a written notification of noncompliance resolution once the mandatory reporter or recipient institution has demonstrated in writing with supporting documentation that each noncompliance has been corrected within the time allotted under subsection (a). For example, if a mandatory reporter is required to submit case reports for 100 patients, but for some internal administrative reason only transmits 90 of them, then the Department will send a corrective action notice specifying that 10 case reports have not been received. The mandatory reporter would have thirty (30) calendar days to transmit the remaining 10 case reports or explain why they cannot be transmitted (which might occur for a patient who dies or relocates to another state). Once those 10 case reports are transmitted or explained by the mandatory reporter, then the Department would transmit a written notification of noncompliance resolution to confirm that the mandatory reporter

has restored compliance. Subsection (b) further establishes that 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. This is necessary to comport with principles of due process, notice and fairness while still ensuring that the Department receives the required case report data within the time limits established under this subchapter.

Adopt Section 7255. Notice of Proposed Sanctions for Mandatory Reporters

This proposed section is necessary to establish the process the Department will use to provide notice of proposed sanctions for mandatory reporters. While mandatory reporters and recipient institutions will be subject to an identical process for corrective action notices, the notice of proposed sanctions process must be bifurcated for mandatory reporters and recipient institutions because the California Legislature has enacted monetary sanctions for mandatory reporters for noncompliance. However, recipient institutions cannot be subject to monetary sanctions for noncompliance, but they risk loss of access to confidential information provided by the registries. As a result of the difference in potential sanctions for mandatory reporters and recipient institutions, the bifurcated notice of proposed sanctions process will be mostly the same, with some key differences in the potential penalties and the right to request a formal hearing pursuant to Health and Safety Code section 131071 for mandatory reporters but not for recipient institutions. Since mandatory reporters face the potential deprivation of property in the form of monetary penalties, they are entitled to more robust due process protections, while the recipient institutions would only risk loss of access to confidential information and would need to redo the application process to reestablish access. The Department determined that this bifurcation in process based on the differences in potential sanctions strikes a reasonable balance between the interests of the parties found to be out of compliance and the Department’s goals to efficiently administer the registries.

Subsection (a) is necessary to establish the minimum requirements for a notice of proposed sanctions for mandatory reporters. The notice of proposed sanctions may be sent separately or in combination with the corrective action notice, depending on whether the Department determines that the correction of noncompliance is not possible. The Department estimates that the combined corrective action notice and proposed sanctions notice will be used infrequently, based on the estimation that the corrective action notice process alone will resolve the majority of noncompliance instances, but nevertheless reserves the right to combine them when necessary. The notice of proposed sanctions will typically be sent out after the mandatory reporter has failed to resolve the noncompliance within the thirty (30) calendar days period prescribed under the corrective action notices process.

The notice of proposed sanctions must contain, at a minimum, five elements to be considered complete. Subsection (a)(1) requires a statement of the reasons for the proposed sanctions. Subsection (a)(2) requires a list of the proposed sanctions necessary to correct the noncompliance. Subsection (a)(3) requires a proposed effective date of the sanctions, which will be stayed pending an informal review conference, a formal hearing, and a final determination. Subsection (a)(4) requires a statement notifying the mandatory reporter of their 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. Subsection (a)(5) requires a statement notifying the mandatory reporter of their right to request a formal hearing pursuant to Health and Safety Code section 131071 to contest the determination of noncompliance and the proposed sanction. These five elements are necessary in the notice in order to adequately inform the mandatory reporter of their available options to resolve the noncompliance and the potential sanctions that would result. As mentioned above, the mandatory reporter risks potential deprivation of property in the form of monetary sanctions if noncompliance is established, and for that reason the Department

has determined that the formal hearing process pursuant to Health and Safety Code section 131071 must be available to protect their due process rights before the deprivation of property. However, a formal hearing process can be slow, costly, and cumbersome for both the Department and the mandatory reporter, which is why the Department also created an informal hearing conference to expeditiously resolve the noncompliance in a prompt and inexpensive manner. By informing the mandatory reporter of the five required elements under subsection (a)(1) through (a)(5), the Department is discharging its duty to properly notify the mandatory reporter of the noncompliance, the proposed sanctions, the effective date of the proposed sanctions, and the procedural options (both informal and formal) available to resolve the matter.

Subsection (b) is necessary to establish that if a mandatory reporter fails to comply with the requirements of this subchapter, they may be subject to monetary sanctions. The Department may seek data recover measures and reimbursement of the Department's actual costs under section 7139 or a civil penalty for willful noncompliance under section 7161 or this subchapter, or both. The notice of proposed sanctions element under subsection (a)(2) will alert the mandatory reporter whether the Department has determined which sanction is appropriate to correct the noncompliance.

Subsection (c) is necessary to establish that if the mandatory reporter provides the Department with written documentation within the prescribed time period demonstrating that all noncompliance has been corrected, the Department may withdraw the proposed sanctions. The Department estimates that this situation is more likely to occur in the rare instances where the corrective action notice and notice of proposed sanctions are combined into a single notice but reserves the right to withdraw the proposed sanctions where appropriate.

Subsection (d) is necessary to establish that for a mandatory reporter, any sanctions proposed by the Department will be stayed while the informal review conference and formal hearing processes are pending, if applicable. This is necessary to ensure that the mandatory reporter is not subject to sanctions until all procedural remedies have been

completed so that the mandatory reporter is incentivized to resolve the noncompliance promptly.

Adopt Section 7257. Notice of Proposed Sanctions for Recipient Institutions

This proposed section is necessary to establish the process the Department will use to provide notice of proposed sanctions for recipient institutions. As discussed above, while the mandatory reporters and recipient institutions will be subject to an identical process for corrective action notices, the notice of proposed sanctions process must be bifurcated for mandatory reporters and recipient institutions because the California Legislature has enacted monetary sanctions for mandatory reporters for noncompliance. However, recipient institutions cannot be subject to monetary sanctions for noncompliance, but they risk loss of access to confidential information provided by the registries. As a result of the difference in potential sanctions for mandatory reporters and recipient institutions, the bifurcated notice of proposed sanctions process will be mostly the same, with some key differences in the potential penalties and the right to request a formal hearing pursuant to Health and Safety Code section 131071 for mandatory reporters but not for recipient institutions. Since mandatory reporters face the potential deprivation of property in the form of monetary penalties, they are entitled to more robust due process protections, while the recipient institutions would only risk loss of access to confidential information and would need to redo the application process to reestablish access. The Department determined that this bifurcation in process based on the differences in potential sanctions strikes a reasonable balance between the interests of the parties found to be out of compliance and the Department's goals to efficiently administer the registries.

Subsection (a) is necessary to establish the minimum requirements for a notice of proposed sanctions for recipient institutions. The notice of proposed sanctions may be sent separately or in combination with the corrective action notice, depending on whether the Department determines that the correction of noncompliance is not possible. The Department estimates that the combined corrective action notice and

proposed sanctions notice will be used infrequently, based on the estimation that the corrective action notice process alone will resolve the majority of noncompliance instances, but nevertheless reserves the right to combine them when necessary. The notice of proposed sanctions will typically be sent out after the mandatory reporter has failed to resolve the noncompliance within the thirty (30) calendar days period prescribed under the corrective action notices process.

The notice of proposed sanctions must contain, at a minimum, four elements to be considered complete. Subsection (a)(1) requires a statement of the reasons for the proposed sanctions. Subsection (a)(2) requires a list of the proposed sanctions necessary to correct the noncompliance. Subsection (a)(3) requires a proposed effective date of the sanctions, which will be stayed pending an informal review conference, if applicable. Subsection (a)(4) requires a statement notifying the mandatory reporter of their right to request an informal review conference within thirty (30) calendar days to contest the determination of noncompliance and proposed sanctions and to negotiate a modified deadline to correct the noncompliance.

Subsection (b) is necessary to establish that if a recipient institution fails to comply with the requirements of this subchapter, they may be subject to non-monetary sanctions. A recipient institution that fails to comply with this subchapter will be subject to denial, suspension, or revocation of authorization to access confidential information. This subsection further establishes that these sanctions are applicable to each recipient that fails to comply, which means that when a research project with two or more institutions applies for access, one may lose access for noncompliance, and the other recipient institution will remain unaffected. For example, in a joint application if one recipient institution is granted authorization to access confidential information and another is denied, the denied party must amend their application materials and resubmit them to the Department to gain authorization. In a situation where two recipient institutions are granted authorization and then later one recipient institution is suspended, the sanctioned recipient institution would need to follow the required steps under the corrective action notice to restore compliance and regain authorization. In a situation

where a recipient institution is suspended and fails to restore compliance under the corrective action notice process and the Department revokes authorization, the revoked party must undergo the application process anew. While all of these proposed sanctions are non-monetary, and therefore subject to fewer due process protections than a mandatory reporter facing monetary sanctions, they are necessary conditions to ensure that the Department is properly safeguarding the confidential information protected by the registries by only granting authorization to access to recipient institutions in compliance with the requirements of this subchapter. The California Legislature entrusted the Department with the authority to mandate collection of sensitive personal identifying information and personal health information, and the requirements of this section and this subchapter strike the appropriate balance to protect that information in the registries.

Subsection (c) is necessary to establish that if the recipient institution provides the Department with written documentation within the prescribed time period demonstrating that all noncompliance has been corrected, the Department may withdraw the proposed sanctions and reinstate authorization to access confidential information. The Department estimates that this situation is more likely to occur in the rare instances where the corrective action notice and notice of proposed sanctions are combined into a single notice but reserves the right to withdraw the proposed sanctions where appropriate.

Subsection (d) is necessary to establish that if a recipient institution’s authorization is suspended, the recipient institution may provide the Department with written documentation demonstrating that all noncompliance has been corrected and request reinstatement of authorization. The Department estimates that this situation is more likely to occur in the instances where the corrective action notice and notice of proposed sanctions are not combined into a single notice, and the recipient institution has taken the prescribed corrective actions within the allotted time period. This subsection further establishes that for any recipient institution subject to revocation sanctions, the recipient institution must also complete the data destruction process under section 7151 for any

date they received from the Department. This is necessary to ensure that revocation sanctions bear meaningful consequences for the recipient institution that fails to comply with the requirements of this subchapter. If the Department permitted a recipient institution subject to revocation sanctions to retain access to the data provided during the period of time when it was complying, there would not be sufficiently strong disincentives to motivate recipient institutions to follow the requirements of this subchapter after they obtain the confidential information from the registries.

Subsection (e) is necessary to establish that if a recipient institution is subject to denial or revocation sanctions under this section, they may submit a new application and obtain a new authorization under this subchapter. While this does not amount to a monetary sanction or deprivation of property (in the form of civil penalties or paying the Department's actual costs, like mandatory reporters might face for noncompliance), it does require the recipient institution to expend additional resources to undergo the application process multiple times until it properly complies with the requirements of this subchapter. Taken as a whole, subsections (a) through (e) are necessary to establish a system of incentives and disincentives to ensure that recipient institutions are careful to follow the requirements of this subchapter and properly safeguard the confidential information granted by the Department. This strikes the proper balance between the Department's interest in safeguarding the confidential information held within the registries and the public's interest in providing high-quality research data to recipient institutions capable of analyzing and synthesizing the patient health data to provide additional treatments and potential cures for patients diagnosed with Parkinson's disease and the covered neurodegenerative diseases.

Adopt Section 7259. Willful Noncompliance for Mandatory Reporters

This proposed section is necessary to establish the conditions that would subject a mandatory reporter to sanctions for willful noncompliance. The California Legislature granted the Department with authority to sanction mandatory reporters with a monetary

penalty under Health and Safety Code section 103865(e) for the Parkinson's registry and section 103871(e) for the neurodegenerative registry. Those sections both state:

"Willful failure to grant access to those records shall be punishable by a civil penalty of up to five hundred dollars ($500) each day access is refused."

To implement, interpret, and make specific these twin provisions for each registry, the Department has determined that the "willful failure to grant access" element should be jointly defined as "willful noncompliance" under the definitions section of this subchapter. As stated above, the Department proposes to adopt the term "willful noncompliance" to mean "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." This definition is modeled after the "willful misconduct" degree of culpability as distinguished from negligence, which can be found in the *California Jurisprudence 3d* encyclopedia (46 Cal.Jur.3d § 103), to ensure that the regulated community and courts interpret and apply this term consistently with principles of California law. Accordingly, this proposed section is necessary to establish when a mandatory reporter's conduct rises to the level of "willful" sufficient to subject it to the civil penalty of up to five hundred dollars ($500) for each day the noncompliance results in a refusal to access records. The Department has determined that most mandatory reporters are able to comply with the reporting requirements of the Health and Safety Code most of the time, and to date the program administering the registries has not yet encountered any instances of noncompliance egregious enough to amount to "willful noncompliance." However, even without any past misconduct to guide the Department, it must implement, interpret, and make specific that statutory provision in this subchapter in a way that provides mandatory reporters with clarity on how the requirements will be enforced against mandatory reporters.

Subsection (a) is necessary to establish that “willful noncompliance” by a mandatory reporter includes failure to respond to a corrective action notice sent by the Department within the prescribed time period. This requirement is necessary to ensure that mandatory reporters take every opportunity afforded under the corrective action notice process to resolve instances of noncompliance. This subsection further establishes that 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. This requirement is necessary to ensure that any Department enforcement action for willful noncompliance does not unfairly punish mandatory reporters making a good faith effort to adhere to the corrective action notice process or the data recovery process.

Subsection (b) is necessary to establish the list of factors that the Department will consider when determining whether noncompliance is willful. Subsection (b)(1) establishes that the Department will consider the number of instances of noncompliance cited in the corrective action notice. The Department has determined that a mandatory reporter engaged in “willful noncompliance” is likely to present a large number of instances of noncompliance, whereas negligent noncompliance is likely to present a small number of instances of noncompliance.

Subsection (b)(2) establishes that the failure to respond to a corrective action notice within the prescribed time period will be considered one factor in evaluating whether the noncompliance is willful. This factor will not be dispositive on its own because negligent noncompliance may also result in the failure to respond to a corrective action notice, but this factor also incentivizes mandatory reporters to respond to the corrective action notice promptly to eliminate any doubt as to whether the noncompliance is willful.

Subsection (b)(3) establishes that receiving two or more corrective action notices within a calendar year will be considered one factor in evaluating whether noncompliance is willful. The Department determined that negligent mandatory reporters may occasionally receive a single corrective action notice, but by following the steps prescribed by the

Department the mandatory reporter will resolve any internal processes that caused the noncompliance to occur. However, a mandatory reporter that receives two or more corrective action notices is more likely to be engaged in the “deliberate, intentional, or wanton conduct” that rises to a higher degree of culpability consistent with California jurisprudence.

Subsection (b)(4) establishes that if a mandatory reporter sends communications to the Department indicating intentional or deliberate refusal to comply with the requirements of this subchapter, the Department will consider that a factor to establish willful noncompliance. This factor is necessary to establish a factor that covers the rare situation where a mandatory reporter receives a corrective action notice and explicitly refuses to comply. The Department estimates that most of the noncompliance will be resolved through the corrective action notice process, and the remaining cases will be resolved through the informal review conference process. However, in a case where a mandatory reporter explicitly communicates a deliberate intent to refuse compliance, the matter will need to be resolved through a formal hearing process. In this hypothetical case of willful noncompliance, the Department would treat any written communication by a mandatory reporter explicitly refusing to comply as the strongest available evidence of willful noncompliance. As stated above, such an extreme situation has never happened to date in the seven years of administering the Parkinson’s registry, but the Department reserves the right to treat communications indicating intentional or deliberate refusal to comply with the requirements of this subchapter as highly probative evidence in the formal hearing process before issuing monetary sanctions.

Subsection (b)(5) establishes that the Department will consider any other factors applicable to the specific circumstances surrounding the noncompliance, as identified by the Department, will be used to determine whether noncompliance is willful. This catch-all provision is necessary to afford the Department the ability to document any additional facts or circumstances that may be probative for an administrative law judge when evaluating whether noncompliance rises to a willful degree of culpability. The Department acknowledges that mandatory reporters hire agents, employees, and

contractors with a wide variety of experiences, temperaments, and dispositions, and accordingly, not every statement by an agent, employee, or contractor can be fully attributed to the hospital or clinic where they work. However, in order to effectively and efficiently administer the registries and ensure compliance with the requirements of this subchapter, the Department will thoroughly document the words and actions and omissions of each instance of noncompliance through the corrective action notice process and the informal review conference process and also will reserve the right to use that documentation to support any allegations of willful noncompliance as necessary.

Subsection (c) establishes that when the Department proposes sanctions for willful noncompliance, the mandatory reporter may request either procedure as it deems fit to resolve the matter. Subsection (c)(1) establishes that the mandatory reporter may request only the formal hearing process pursuant to Health and Safety Code section 131071. Subsection (c)(2) establishes that the mandatory reporter may request an informal review conference under section 7263 of this subchapter, followed by a formal hearing under section 7263(c) of this subchapter. Taken as a whole, this subsection is necessary to provide the mandatory reporter with the widest degree of flexibility in resolving a proposed sanction for willful noncompliance.

Subsection (d) is necessary to establish that the request for either process under subsection (c) must be submitted to the Department in writing within thirty (30) calendar dates of the date of the written notice of proposed sanctions are issued. The Department determined that thirty (30) calendar days was sufficient time for a mandatory reporter to evaluate its options and select for its preferred process to resolve the matter. Providing less time would be insufficient and unfair to the mandatory reporter and providing more time would delay the Department’s ability to enforce the requirements of this subchapter and ensure that the registries capture high-quality data in a timely fashion.

Adopt Section 7261. Sanctions for Willful Noncompliance

This proposed section is necessary to establish the sanctions for willful noncompliance by a mandatory reporter. Subsection (a) is necessary to establish that 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 or both, where the Department deems such remedies appropriate to correct the noncompliance. The Department reserves the right to exercise its full authority to obtain required data from a mandatory reporter. In order to ensure that the Department has timely access to the required data to populate the registries, the Department may need to pursue either the data recovery process or the civil penalty remedy or both. This subsection is necessary to notify mandatory reporters that either or both remedies may be pursued by the Department in order to correct the noncompliance.

Subsection (b) is necessary to establish that if willful noncompliance by a mandatory reporter results in the failure to grant access to records as required under the Health and Safety Code and this subchapter, the mandatory reporter will be subject to the five hundred dollars ($500) civil penalty for each calendar day that access is refused. Subsection (b)(1) is necessary to establish that in determining 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. This is necessary to incentivize prompt compliance with the corrective action notice and disincentivize mandatory reporters from delaying their cooperation with the Department. Subsection (b)(2) is necessary to establish that 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. This is necessary to incentivize mandatory reporters to promptly address the issues raised in the corrective action notice process and minimize the number of days they are out of compliance.

Adopt Section 7263. Informal Review Conference

This proposed section is necessary to establish the informal review conference process, which will be available to both mandatory reporters and recipient institutions. The Department estimates that the corrective action notice process will resolve the majority of instances of noncompliance, and the informal review conference process will resolve most of the remaining instances that are not successfully resolved by the corrective action notice process. The goal of the informal review conference is to establish steady communication between the Department and the mandatory reporter or recipient institution so that the parties can work through any lingering issues and restore compliance as promptly as possible. As stated above, a small number of mandatory reporters may also resort to a formal hearing process under Health and Safety Code section 131071 if the informal review conference does not successfully resolve the noncompliance. Meanwhile, a small number of recipient institutions that fail to resolve noncompliance through the informal review conference may need to restart the application process to gain authorization to access confidential information after the Department has denied, suspended, or revoked authorization.

Subsection (a) is necessary to establish the framework for the Department to provide a helpful, efficient, and accurate process to resolve any remaining instances of noncompliance through the informal review conference process. Subsection (a)(1) is necessary to establish that a mandatory reporter or recipient institution shall have the right to be represented by legal counsel, or a person of their choosing, to present oral or written information on their behalf, and to explain any mitigating circumstances. This requirement affords the mandatory reporter or recipient institution the flexibility to choose the best person to represent their interests and point of view, regardless of whether that person is a licensed attorney or a subject matter expert familiar with the reporting process or a person with some other professional skillset that can help resolve the noncompliance.

Subsection (a)(2) is necessary to establish that 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. In most cases, the Department representatives will be a mix of subject matter experts who work on the program that administers the registries and attorneys from the Department's Office of Legal Services. The Department will have the same flexibility in choosing their representatives that the mandatory reporter or recipient institution will have in order to ensure that the informal review conference is attended by people with the skills necessary to resolve the noncompliance.

Subsection (a)(3) is necessary to establish that the informal review conference shall be an informal proceeding. The subsection further specifies that the informal review conference shall not be conducted in the manner of a judicial hearing or administrative hearing and need not be conducted according to the technical rules relating to evidence and witnesses. These requirements are necessary to clarify to the mandatory reporters and recipient institutions that the informal review conference should not be treated as a slightly expedited formal hearing, but rather an informal conference to review the facts, corrective actions, and proposed sanctions together. The choice of who represents each party and the requirement that the informal review conference not be treated as a judicial hearing or administrative hearing is necessary to clarify to the regulated community that the informal review conference is a more flexible forum to resolve any instances of noncompliance.

Subsection (a)(4) is necessary to establish that neither the Department nor the mandatory reporter or recipient institution shall have the right to subpoena any witness to attend the conference, to record testimony, nor to formally cross-examine any person testifying at the conference. The subsection further establishes that the parties may present any witness on their behalf at the conference. This subsection reinforces the informal nature of this conference and clarifies to the mandatory reporters and recipient institutions that this process should not resemble formal litigation. The lack of subpoena power and cross-examination will reduce the chances of an unnecessarily

confrontational meeting of the parties and will further the goal of ensuring they reach a prompt, efficient resolution of the noncompliance.

Subsection (a)(5) is necessary to establish that the mandatory reporter or recipient institution may negotiate a modified due date to correct the noncompliance. This is necessary to incentivize the mandatory reporter or recipient institution to correct the noncompliance by affording them the opportunity to negotiate for an appropriate amount of time to resolve the matter. The Department's primary goal with the informal review conference is to restore compliance in a prompt, efficient manner in a way that ensures the mandatory reporter or recipient institution can continue without further corrective action notices. The Department estimates that a substantial number of noncompliance matters will be resolved by clarifying the expectations under this subchapter and granting the noncompliant party additional time to handle any internal procedures and train agents, employees, and contractors on how to comply with the requirements going forward.

Substantial (a)(6) is necessary to establish that 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. This subsection is necessary to afford the Department the widest latitude necessary to reach a negotiated resolution with the mandatory reporter or recipient institution. The parties may present the Department with additional information not discoverable during the normal reporting and data auditing processes. Mandatory reporters and recipient institutions may experience a broad spectrum of frictions and inconveniences common to large institutions with numerous employees, agents, and contractors responsible for maintaining compliance. For example, a party may experience: a temporary staff shortage, a disgruntled employee engaging in willful misconduct that should not be attributed to the institution, a technological problem with IT infrastructure, a gap in training for responsible staff, or any other mundane business process failure that results in brief periods of noncompliance. The informal review conference is the best opportunity for a mandatory reporter or recipient institution to share information and

suggest strategies to restore compliance with the requirements of this subchapter. Only under a nonconfrontational meeting can the Department ask questions and listen to better understand the unique situation that has resulted in the mandatory reporter or recipient institution falling out of compliance. An informal review conference will succeed when the Department has the appropriate staff and an array of potential remedies available to address those unique circumstances in a manner that results in sustainable, long-term compliance with the requirements. For those reasons, the informal review conference will be the fallback option to resolve any instances of noncompliance that could not be addressed through the corrective action notice process.

Adopt Section 7265. Factors Outside the Control of the Mandatory Reporter

This section is necessary to establish that the Department may grant relief to mandatory reporters impacted by force majeure-type events during the application process. California communities can endure wildfires, earthquakes, civil unrest, and other disruptions that cannot be anticipated. The Department does not intend to penalize mandatory reporters or recipient institutions impacted by extraordinary events beyond their control. “Factors outside the control of the applicant” is defined to clarify under what circumstances the Department will consider those factors outside the control of the mandatory reporter when determining whether relief from potential sanctions under Article 5 can be justified. The Department’s definition covers events that are truly outside the control of a mandatory reporter including natural disasters, severe weather, war, and civil unrest. These events are selected based upon basic force majeure provisions found commonly in contract law. Under the doctrine of non-delegable duties, parties are responsible for the actions of their workforce and their business associates. This section is necessary to clarify to mandatory reporters that the Department will not take action to pursue penalties if a force majeure situation arises during the reporting process.

Identification of Documents Upon Which Department is Relying

Alzheimer's Disease Citations:

1. Alzheimer's Association. Factsheet, Cognitive Assessment and Care Planning Services, <https://www.alz.org/careplanning/downloads/cms-consensus.pdf>.

2. Alzheimer's Prevention Registry. *Arizona Alzheimer's Consortium*, <https://azalz.org/alzheimers-prevention-registry/>.

3. American Psychiatric Association (APA). *Listing of DSM-5-TR Diagnoses and New ICD-10-CM-Codes*, <https://www.psychiatry.org/getmedia/de1bf4c9-c75e-4e89-add8-3dd6e9c29de9/APA-DSM5TR-ICD10CM-Code-Updates-092022.pdf>.

4. Banner Health, *Banner Health Provider ICD-10 Education Diseases of the Nervous System*, <https://www.bannerhealth.com/-/media/files/project/bh/for-physicians/icd10/bhicd10providercodingeducationneurology.ashx>.

5. CarePatron, *Alzheimer's Dementia ICD-10-CM Codes*, (2023) <https://www.carepatron.com/icd/alzheimers-dementia>.

6. Centers for Disease Control and Prevention (CDC) - *CDC Wonder Underlying Cause of Death*, 1999-2020 Request (cdc.gov), < https://wonder.cdc.gov/ucd-icd10.html>.

7. *Chronic Conditions Data Warehouse,* 30 CCW Chronic Conditions Algorithms: MBSF_CHRONIC_{YYYY} File*, 2024. <file://phtmsisilon00.tmspfile.cdphintra.ca.gov/PVDI-Redir/PROFILES-VDI/PMunoz/Documents/chr-chronic-condition-algorithms.pdf>.*

8. Duan, R., Chen, Z., Tong, J., et al. (2021). *Leverage real-world longitudinal data in large clinical research networks for Alzheimer's disease and related dementia*

(ADRD). AMIA Annu Symp Proc, 2020, 393-401. Published 2021 Jan 25. <https://pubmed.ncbi.nlm.nih.gov/33936412/>.

9. Estiri, H., Azhir, A., Blacker, D.L., Ritchie, C.S., Patel, C.J., & Murphy, S.N. (2023). *Temporal characterization of Alzheimer's Disease with sequences of clinical records*. EBioMedicine, 92, 104629. doi: <https://www.thelancet.com/journals/ebiom/article/PIIS2352-3964(23)00194-9/fulltext>.

10. Fujiyoshi, A., Jacobs, D. R. Jr., Alonso, A., Luchsinger, J. A., Rapp, S. R., & Duprez, D. A. (2017). *Validity of death certificate and hospital discharge ICD codes for dementia diagnosis: The Multi-Ethnic Study of Atherosclerosis.* Alzheimer Disease & Associated Disorders, 31:(2), 168-172. <https://journals.lww.com/alzheimerjournal/citation/2017/04000/validity_of_death_certificate_and_hospital.13.aspx>.

11. Georgia Department of Public Health**.** *GARDR Provider User Guide*. <https://dch.georgia.gov/provider-manual>.

12. Health Information Associates**.** *Defining and Coding Alzheimer's Disease*, <https://hiacode.com/blog/education/defining-coding-alzheimers-disease>.

13. Health and Safety Code section 103871, 103871.1, 103871.2, Chapter 1.7. 2021, Ch. 143, Sec. 20 California Neurodegenerative Disease Registry Program, *California Code, HSC 103871*, <https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=103871&lawCode=HSC>.

14. Lisa A. Cannon-Albright, PhD, Norman L. Foster, MD., et al. (2019). *Relative risk for Alzheimer disease based on complete family history*. Neurology, 2019; 92: e1745-e1753. <https://www.neurology.org/doi/10.1212/WNL.0000000000007231>.

15. Missouri Department of Health & Senior Services. *Chronic Disease Death MICA - ICD-10 Codes*. <https://health.mo.gov/data/documentation/chronic-death/chronic-death-icd10.php>.

16. National Center for Health Statistics. *Alzheimer's Disease*. <https://www.cdc.gov/nchs/fastats/alzheimers.htm>.

17. National Hospice and Palliative Care Organization (NHPCO). *Dementia ICD-10 Fact Sheet*, <https://www.nhpco.org/wp-content/uploads/Dementia_ICD10_Fact_Sheet.pdf>.

18. New York State Department of Health. *Alzheimer's Disease and Related Dementia*. <https://www.health.ny.gov/diseases/conditions/dementia/>

19. Park, J.H., Cho, H.E., Kim, J.H., et al. (2020). *Machine learning prediction of incidence of Alzheimer's disease using large-scale administrative health data*. NPJ Digit Med, 3, 46. Published 2020 Mar 26. doi: <https://www.nature.com/articles/s41746-020-0256-0>.

20. Ponjoan, A., Garre-Olmo, J., Blanch, J., Fages, E., Alves-Cabratosa, L., Martí-Lluch, R., Comas-Cufí, M., Parramon, D., García-Gil, M., & Ramos, R. (2019). *How well can electronic health records from primary care identify Alzheimer's disease cases?* Clin Epidemiol, 11, 509-518. <https://pubmed.ncbi.nlm.nih.gov/31456649/>.

21. United States Department of Health and Human Services, Office of Disease Prevention and Health Promotion, Healthy People 2030, *Increase the proportion of older adults with dementia, or their caregivers, who know they have it — Data Methodology and Measurement*. <https://odphp.health.gov/healthypeople/objectives-and-data/browse-objectives/dementias/increase-proportion-older-adults-dementia-or-their-caregivers-who-know-they-have-it-dia-01/data-methodology>.

22. University of South Carolina, *South Carolina Alzheimer's Disease Registry. 2022 Annual Report South Carolina Alzheimer's Disease Registry*, <https://sc.edu/study/colleges_schools/public_health/documents/alzheimers_registry_report.pd>.

23. Utah Department of Health & Human Services. *Utah's Public Health Data Resource - IBIS IBIS-PH - Complete Health Indicator Report - Alzheimer's Disease and Related Dementias*, (2021), <https://ibis.utah.gov/ibisph-view/indicator/complete_profile/AlzDea.html>.

24. West Virginia University (WVU). *West Virginia Alzheimer's Registry, Health Care Provider Reporting Form*, <https://wvadr.hsc.wvu.edu/media/2474/wvadrd_fillable_dataform.pdf0>.

25. World Health Organization (WHO). *International Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10)-WHO Version: 2019, Chapter V Mental and behavioral disorders*, < https://icd.who.int/browse10/2019/en#/F00>.

26. Zhang, L., Yang, W., Li, X., et al. (2023). *Association of life-course traumatic brain injury with dementia risk: A nationwide twin study.* Alzheimer's & Dementia, 19, 217–225. <https://doi.org/10.1002/alz.12671>.

Amyotrophic lateral sclerosis (ALS) Citations:

1. Agency for Toxic Substance and Disease Registry (ATSDR), *Diagnostic Coding continued ICD 10 codes (cdc.gov)*, *<https://www.atsdr.cdc.gov/emes/ALS/training/page1389.html >*.

2. American Speech-Language-Hearing Association (ASHA), *2025 ICD-10-CM Diagnosis Codes Related to Speech, Language, and Swallowing Disorders*, <https://www.asha.org/siteassets/uploadedfiles/icd-10-codes-slp.pdf>.

3. Brooks, B. R., Berry, J. D., Ciepielewska, M., Liu, Y., Zambrano, G. S., Zhang, J., & Hagan, M. (2022). *Intravenous edaravone treatment in ALS and survival: An exploratory, retrospective, administrative claims analysis*. e*ClinicalMedicine*, *52*, 101590, <https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(22)00320-0/fulltext>.

4. Canadian Institute for Health Information. ICD-10-CA Reference Guide. Ottawa, ON: CIHI; 2022. ICD-10-CA Reference Guide (cihi.ca), <https://www.cihi.ca/sites/default/files/document/icd-10-ca-reference-guide-manual-en.pdf>.

5. Centers for Disease Control and Prevention (CDC) - *CDC Wonder Underlying Cause of Death, 1999-2020 Request (cdc.gov)*, < https://wonder.cdc.gov/ucd-icd10.html>.

6. Centers for Medicare & Medicaid Services (CMS), Article, *Billing and Coding: Speech Language Pathology (SLP) Services: Communication Disorders*, (2024), <https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleID=54111>.

7. Centers for Medicare & Medicaid Services (CMS), *ICD-10-CM/PCS MS-DRG v35.0 Definitions Manual*, <https://www.cms.gov/icd10m/version35-fullcode-cms/fullcode_cms/P1281.html>.

8. Horrocks, S., Wilkinson, T., Schnier, C., Ly, A., Woodfield, R., Rannikmäe, K., Quinn, T. J., & Sudlow, C. L. (2017). *Accuracy of routinely collected healthcare data for identifying motor neurone disease cases: A systematic review*. PloS one, 12(2), e0172639. <https://doi.org/10.1371/journal.pone.0172639>.

9. Kupelian, V., Viscidi, E., Hall, S., Li, L., Eaton, S., Dilley, A., Currier, N., Ferguson, T., & Fanning, L. (2023). *Increased Risk of Venous Thromboembolism in Patients with Amyotrophic Lateral Sclerosis: Results From a US Insurance*

Claims Database Study. *Neurology. Clinical practice, 13(1), e200110*. <https://doi.org/10.1212/CPJ.0000000000200110>.

10. Larson, T. C., Kaye, W., Mehta, P., & Horton, D. K. (2018). *Amyotrophic Lateral Sclerosis Mortality in the United States, 2011-2014*. *Neuroepidemiology, 51(1-2), 96–103*, <https://doi.org/10.1159/000488891>.

11. Massachusetts Department of Public Health, *Letter to Practice Manager, Physician, or Keeper of Medical Records, download (mass.gov)* <https://www.mass.gov/doc/request-letter-and-instructions-for-reporting-als-cases/download>.

12. MDinteractive, *2022 MIPS Measure #386: Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences | MDinteractive* <https://mdinteractive.com/mips_quality_measure/2022-mips-quality-measure-386>.

13. National Center for Health Statistics -Centers for Disease Control and Prevention -ICD-10-CM, https://icd10cmtool.cdc.gov/?fy=FY2024&query=Amyotrophic

14. Social Security Program Operations Manual System (POMS), *DI 23022.100 - Amyotrophic Lateral Sclerosis (ALS) – ADULT*, (2022), <https://secure.ssa.gov/apps10/poms.nsf/lnx/0423022100>.

15. Yoon, S. Y., Kim, H. K., Kim, M. J., Suh, J. H., & Leigh, J. H. (2021). Factors associated with assisted ventilation use in amyotrophic lateral sclerosis: a nationwide population-based study in Korea. Scientific reports, 11(1), 19682. <https://doi.org/10.1038/s41598-021-98990-x>.

Multiple Sclerosis Citations:

1. Al-Sakran LH, Marrie RA, Blackburn DF, Knox KB, Evans CD. *Establishing the Incidence and Prevalence of Multiple Sclerosis in Saskatchewan*. Canadian

Journal of Neurological Sciences / Journal Canadien des Sciences Neurologiques. 2018;45(3):295-303. <https://www.cambridge.org/core/journals/canadian-journal-of-neurological-sciences/article/establishing-the-incidence-and-prevalence-of-multiple-sclerosis-in-saskatchewan/5B4BBCD6E2F717849918658D646D649C>.

2. BlueCross BlueShield, *The Health Impact of Multiple Sclerosis October 2019*,

27. <https://www.bcbs.com/about-us/association-news/blue-cross-blue-shield-association-reports-americans-multiple-sclerosis-are-three>.

3. *Chronic Conditions Data Warehouse, Other Chronic Health, Mental Health, and Potentially Disabling Chronic Conditions Algorithms: MBSF_OTCC_{YYYY} File other-condition-algorithms.pdf.* 2024. <file://phtmsisilon00.tmspfile.cdphintra.ca.gov/PVDI-Redir/PROFILES-VDI/PMunoz/Documents/other-condition-algorithms.pdf>.

4. National Institutes of Health, Website, *Multiple Sclerosis*, <https://www.nccih.nih.gov/health/multiple-sclerosis>.

5. Williamson, D.M., Noonan, C., Henry, J., Wagner, L., Indian, R., Lynch, S., Neuberger, J., Schiffer, R., Trottier, J., Marie, R. (2010) *The prevalence of multiple sclerosis in 3 US communities*. Preventing Chronic Diseases, 7(1): A12. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2811507/

Parkinson's Disease Citations:

1. Health and Safety Code section 103870, 103870.1, 103870.2, 2017, Ch. 52, Sec. 12., CHAPTER 1.6. Richard Paul Hemann Parkinson's Disease Program, *California Code, HSC 103870* <https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?sectionNum=103870&lawCode=HSC>.

2. Szumski NR, Cheng EM. *Optimizing algorithms to identify Parkinson's disease cases within an administrative database*. Mov Disord. 2009 Jan 15;24(1):51-6. PMID: 18816696; PMCID: PMC2647991. <https://pmc.ncbi.nlm.nih.gov/articles/PMC2647991/>.

3. The Micheal J. Fox Foundation, Report *Economic Burden and Future Impact of Parkinson's Disease Final Report*. <https://www.michaeljfox.org/sites/default/files/media/document/2019%20Parkinson%27s%20Economic%20Burden%20Study%20-%20FINAL.pdf>.

Mandated Use of Specific Technologies, Equipment, Actions, or Procedures

The Department has approved two technologies for the submission of case reports by mandatory reporters under Article 3 Technical Requirements. The first method is Secure File Transfer Protocol (SFTP), and the second method is Simple Object Access Protocol (SOAP). Both technologies comply with the Health Level Seven International (HL7) format standards for secure data exchange between hospitals and facilities and the Department. Mandatory reporters have the option to either automatically upload case files or to manually submit the information via the Direct Data Entry Web Portal. These technologies are commonly used across the industry for reporting data to the Department, other agencies, and other healthcare facilities. Submitting the case reports via these two approved technologies must be required for all mandatory reporters in order to comply with the Department's privacy and information security policies when handling a patient's confidential information and health data. Mandatory reporters will be able to comply with these technical requirements using their current equipment and personnel.

Economic Impact Analysis

The Department has determined that the regulations will have no impact on:

1. **The creation or elimination of jobs within the State of California.**

These regulations establish the standards and technical requirements for mandatory reporters who must submit cases of Parkinson's disease and neurodegenerative disease to the registries. Because case reporting is limited to a hospital, facility, physician and surgeon, or other health care provider diagnosing or providing treatment for a patient with a neurodegenerative disease, the Department's proposed regulatory action would have no significant economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states, nor would the proposed regulations result in the creation or elimination of jobs within the state.

2. **The creation of new businesses or the elimination of existing businesses within the State of California.**

   These regulations establish the standards and technical requirements for mandatory reporters who must submit cases of Parkinson's disease and neurodegenerative disease to the registries. Because case reporting is limited to a hospital, facility, physician and surgeon, or other health care provider diagnosing or providing treatment for a patient with a neurodegenerative disease, the proposed regulatory action would not result in the creation of new businesses or the elimination of existing businesses in the state.

3. **Expansion of businesses currently doing business in the state.**

   These regulations establish the standards and technical requirements for mandatory reporters who must submit cases of Parkinson's disease and neurodegenerative disease to the registries. Because case reporting is limited to a hospital, facility, physician and surgeon, or other health care provider diagnosing or providing treatment for a patient with a neurodegenerative disease, the proposed regulatory action would not result in the expansion of businesses currently doing business in the state.

4. **Benefits of the Regulations to the Health and Welfare of California Residents, Worker Safety, and the State's Environment.**

The proposed regulations will not improve worker safety or the state's environment, but may benefit the health and welfare of California's residents by improving patient experiences for individuals whose data is reported to the registries.

Evidence Supporting No Significant Economic Impact on Business

Because case reporting is limited to a hospital, facility, physician and surgeon, or other health care provider diagnosing or providing treatment for a patient with a neurodegenerative disease, the Department's proposed regulatory action would have no significant economic impact on California business enterprises and individuals, including the ability of California businesses to compete with businesses in other states.

Additionally, the proposed regulatory action will not create a cost to local, state, and federal entities. This conclusion is further supported because the Department has been using the same administrative framework, submission standards and technical requirements to collect PD information since 2018 and continued to use this system in July 2023 to collect MS information. The Department anticipates using the same administrative framework, submission standards and technical requirements to collect Alzheimer's disease and ALS information.

To comply with reporting requirements some hospitals and facilities may need to update their health information technology. That cost may vary from $1,000 - $250,000 per facility depending on the type of information technology adopted. Health and Safety Code 103870 and 103871 already require hospitals and facilities diagnosing or providing treatment for a patient with neurodegenerative diseases to report each case of a neurodegenerative disease to the Department in a format as prescribed. Based on what is known of these entities, the Department does not anticipate that many would need to engage in such an upgrade based on the fact that many hospitals and facilities may already be submitting other information to the Department.