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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Calif. Privacy Law's 3 Limited Exemptions For Health Cos.

By **Jason Linder and Libby Jelinek**
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Jason Linder


Libby Jelinek

On June 28, 2018, Gov. Jerry Brown signed into law the California Consumer Privacy Act, ushering in a new era of consumer privacy protections in California. The CCPA goes into effect on Jan. 1, 2020. Clarifying regulations from the California attorney general's office are expected in draft form by the fall of 2019, to be finalized by July 1, 2020. Nevertheless, businesses are wise to begin preparations now.

Health and life sciences companies risk being lulled into a false sense of security by certain CCPA exemptions related to the Confidentiality of Medical Information Act, the Health Insurance Portability and Accountability Act of 1996 and clinical trials. So that health and life sciences companies can better determine whether the information they collect is subject to the CCPA, this article addresses the scope of those exemptions and identifies the main areas of ambiguity that could be clarified by the attorney general's forthcoming regulations.

A Brief Overview of the CCPA

The CCPA imposes new data protection obligations on "businesses," defined as (1) for-profit entities (2) doing business in California (3) that either (a) have over $25 million in gross annual revenue; (b) annually buy, receive for commercial purposes, sell or share for commercial purposes the personal information of 50,000 or more California consumers, households, or devices; or (c) derive 50% or more of their annual revenues from selling California consumers' personal information.[1] Notably, the CCPA does not apply to not-for-profit organizations or government agencies.

The CCPA also grants consumers three main buckets of privacy rights: the right to (1) request that a business disclose the categories and specific pieces of the consumer's personal information that the business has collected, the business' sources, and the third parties with whom the business shares personal information;[2] (2) request that a business delete any of the consumer's personal information that the business has collected[3] and (3) opt-out by directing a business that sells the consumer's personal information to stop doing so.[4]

In general, the CCPA protects consumers' "personal information," which is broadly defined as information that identifies, relates to, describes, is capable of being associated with or could reasonably

be linked, directly or indirectly, with a particular consumer household.[5] Examples include the consumers' name, address, Social Security number or biometric information.

In addition to government enforcement, the CCPA provides a private cause of action, with the possibility of statutory damages, for certain data breaches caused by inadequate security policies and procedures.[6]

Potential CCPA Exemptions for Health and Life Sciences Companies

The CCPA expressly exempts certain types of information, including information that is already subject to the Confidentiality of Medical Information Act, HIPAA or the federal policy for the protection of human subjects, also known as the common rule, for clinical trials. Specifically, Section 1798.145(c) provides that the CCPA does not apply to the following categories of information:

1. Medical information governed by the CMIA, or patient information maintained by a provider of health care in the same manner as medical information under the CMIA;[7]

2. Protected health information collected by a covered entity or business associate governed by HIPAA or patient information maintained by a covered entity in the same manner as protected health information under HIPAA;[8] and

3. Information collected as part of a clinical trial subject to the common rule, pursuant to the International Council for Harmonisation good clinical practice guidelines or pursuant to U.S. Food and Drug Administration's human subject protection requirements.[9]

These exemptions are limited. Most importantly, businesses must understand that they exempt types of information from CCPA compliance, not health and life sciences companies as a whole. The following explanations identify what questions health and life sciences companies must answer to determine whether the CMIA, HIPAA or clinical trial exemptions apply.

Medical Information Under the CMIA

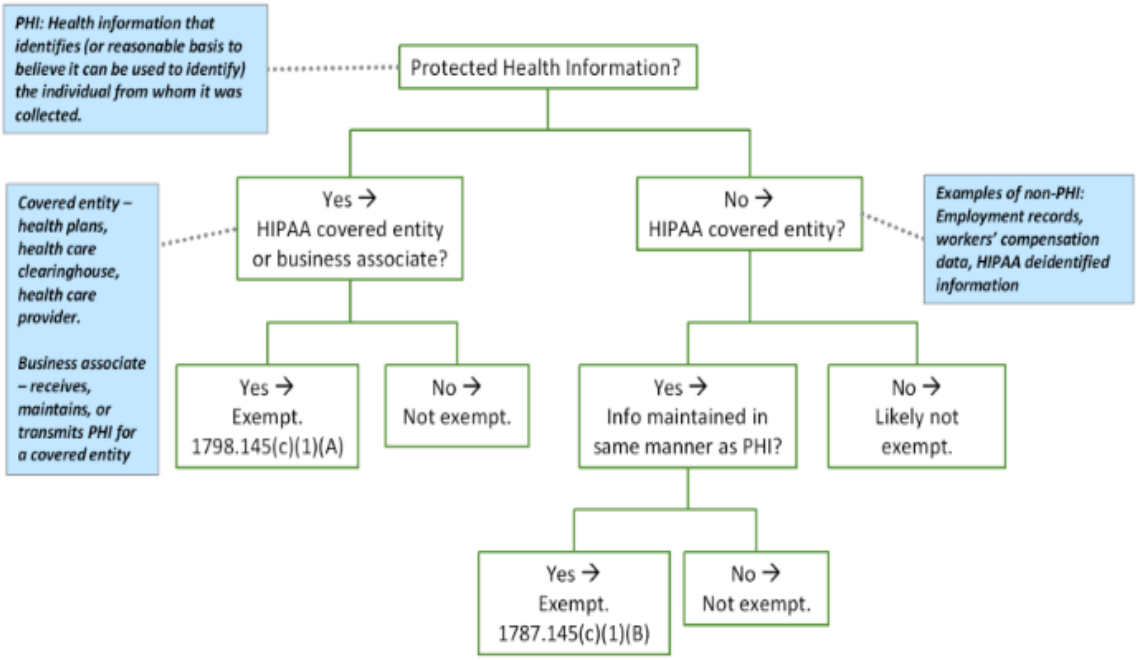
To determine whether this exemption applies, businesses should consider whether they maintain medical information governed by the CMIA. Medical information can be thought of as a subset of personally identifying information.

In general, medical information is information held by a health care provider, health care service plan, pharmaceutical company or contractor (1) regarding a patient's medical history, condition or treatment and (2) containing an element that identifies the patient, like the patient's name, address, email, phone number or Social Security number.[10]

Businesses should next consider whether they are a providers of health care under the CMIA. If so, other patient information maintained in the same manner as medical information is also exempt. A provider of health care includes any of several people and entities listed in California Civil Code §56.05, including doctors, therapists, psychologists, pharmacies and many health care facilities and home health entities.

Importantly, a business that maintains patient information on behalf of a provider of health care, but that does not itself qualify as a provider of health care, still must comply with the CCPA. The CCPA does not separately define patient information.

Health and life sciences companies should look for clarification on compliance obligations regarding affiliates of health care providers and the scope of patient information in the forthcoming attorney general regulations.[11]



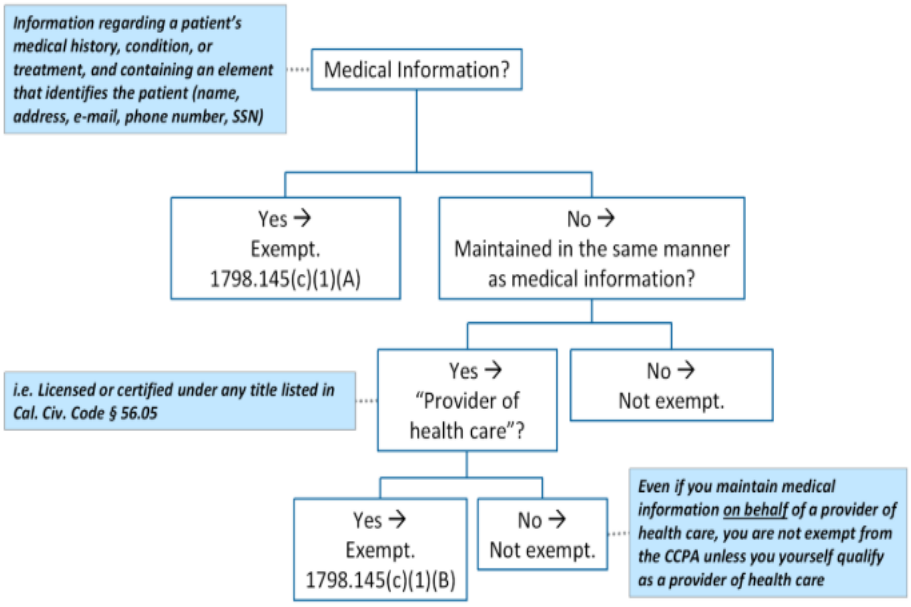
Protected Health Information Under HIPAA

To determine whether this exemption applies, businesses should first consider whether they maintain protected health information or other patient information maintained in the same manner as PHI. In brief, PHI is health information created or received by a HIPAA-covered entity that identifies (or for which there is a reasonable basis to believe it can be used to identify) the individual from whom it was collected.[12]

Common types of non-PHI are workers' compensation data and information in employment records. The CCPA is ambiguous as to whether information that is de-identified under HIPAA (and therefore non-PHI) is considered "personal information" under the CCPA, which has separate, arguably more narrow, de-identification requirements. Public comments submitted to the attorney general have requested clarification on this issue.[13]

Second, businesses should consider whether they qualify as a covered entity or business associate under HIPAA. A covered entity is a health plan, health care clearinghouse or health care provider.[14] A business associate receives, maintains or transmits PHI for a covered entity in connection with performing certain services or functions for the covered entity, including claims processing or administration, consulting or data aggregation.[15]

Read strictly, the exemption for non-PHI patient information maintained in the same manner as PHI applies only to covered entities, not business associates. Commenters have requested that the attorney general's forthcoming regulations clarify whether the exception does in fact extend to business associates.[16]



Information Collected as Part of a Clinical Trial

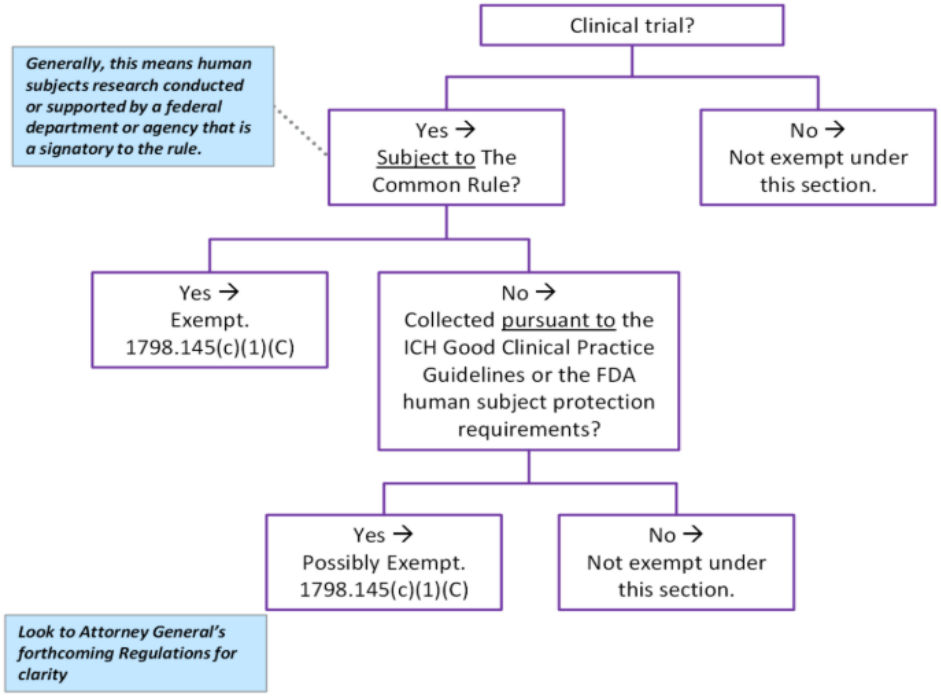
Businesses should consider whether any clinical trial that it conducts is subject to or otherwise complies with the common rule, the International Council for Harmonisation good clinical practice guidelines or the FDA human subject protection requirements.

The common rule provides ethical standards for human subjects research and generally applies to clinical trials conducted or funded by a federal agency.[17] Privately funded research is not required to comply with the Common Rule. The ICH good clinical practice guidelines set forth international ethical standards for human subject research, including guidance for preventing unauthorized access to data.[18] The FDA human subject protection requirements conform to and implement the common rule.[19]

Public comments submitted to the attorney general dispute whether this section exempts only clinical trials that are subject to the common rule or whether it also exempts clinical trials that are conducted pursuant to the common rule voluntarily, pursuant to the good clinical practice guidelines, or pursuant to the FDA human subject protection requirements.[20]

Privately funded organizations that voluntarily comply with the common rule but are not in fact required to follow its standards should therefore err on the side of caution. Public comment also discusses a related issue: the CCPA may still apply to research data collected outside of the clinical trial context, such as the personal information of the administrators of the trial, surveys conducted to select trial

participants or studies based on sources other than clinical trials.[21] The attorney general's forthcoming regulations should provide much-needed clarity on these issues.



Jason Linder is a partner at Irell & Manella LLP. He is a former senior U.S. Department of Justice prosecutor and assistant U.S. attorney.

Libby Jelinek is an associate at the firm.

[1] CCPA, §1978.140(c).

[2] CCPA, §1798.100.

[3] CCPA, §1798.105.

[4] CCPA, §1798.120.

[5] CCPA, §1798.140(o).

[6] CCPA, §1798.150.

[7] CCPA §1798.145(c)(1)(A)-(B).

[8] CCPA §1798.145(c)(1)(A)-(B).

[9] CCPA §1798.145(c)(1)(C).

[10] Cal. Civ. Code §56.05.

[11] See, e.g., Public Comments, CCPA00000301–02, https://www.oag.ca.gov/privacy/ccpa.

[12] 45 CFR 160.103.

[13] See, e.g., Public Comments, CCPA00000961, https://www.oag.ca.gov/privacy/ccpa.

[14] 45 CFR 160.103.

[15] 45 CFR 160.103.

[16] See, e.g., Public Comments, CCPA00000449, https://www.oag.ca.gov/privacy/ccpa.

[17] 45 CFR 46.

[18] See ICH E6 GCP, https://ichgcp.net/.

[19] 21 CFR 50.

[20] See, e.g., Public Comments, CCPA00000414, https://www.oag.ca.gov/privacy/ccpa.

[21] See, e.g., Public Comments, CCPA00000444–45, CCPA00000450, https://www.oag.ca.gov/privacy/ccpa.