

(Without Reference to File)

## CONCURRENCE IN SENATE AMENDMENTS

AB 713 (Mullin)

As Amended August 28, 2020

2/3 vote. Urgency

### SUMMARY:

This urgency measure would establish new exemptions from the California Consumer Privacy Act (CCPA) with regard to certain types of medical information, including medical information collected as part of regulated research activities, and for business associates of covered entities subject to the Health Insurance Portability and Accountability Act (HIPAA).

### The Senate Amendments:

Removed the prior contents of the bill related to the Early Psychosis and Mood Disorder Detection and Intervention Fund, and inserted the provisions amending the CCPA described above.

### COMMENTS:

- 1) *New exemptions to the CCPA:* Despite existing exemptions that apply specifically to their industries, the health care and medical research industries have expressed concern that the exemptions contained in the CCPA do not adequately permit their respective activities or would otherwise subject their industries to duplicative or unduly burdensome regulation. In support of AB 713, a coalition of health care, research, and commercial organizations write that this bill is necessary to "protect vital medical research and streamline health care operations, reducing waste in our health care system[.]"

*Business Associates:* The CCPA currently exempts both medical information/PHI and health care providers from its provisions. This bill would additionally exempt business associates of health care providers, so long as they treat any PI in question in the same manner as medical information or PHI under CMIA and HIPAA, respectively.

Staff notes that any medical information or PHI handled by business associates is already exempt from the CCPA. (*See* Civ. Code Sec. 1798.145(c)(1)(A).) Nonetheless, proponents of this bill seek a broader exemption for business associates more generally, arguing that "HIPAA-regulated Business Associates provide services to Covered Entities (doctors, nurses and other providers) and are extensively regulated under HIPAA and under Business Associate Agreement contracts. Subjecting Business Associates to CCPA regulation is another recipe for waste in our health care system and millions lost to compliance and litigation costs that will be passed on to taxpayers. Business Associates are heavily regulated today and do not require additional privacy obligations, especially during the ongoing crisis."

From a public policy perspective, the business associates exemption in the bill is narrow and ensures that consumers' PI is treated in a privacy protective manner, either under medical privacy laws (HIPAA and CMIA) or under the CCPA. Both the medical privacy schemes and the CCPA offer consumers remedies in the event of data breach and require strict data security. While a business associate might not be subject to medical privacy laws in every situation, the bill in print ensures that a consumer's PI must be handled as though it was

governed by those laws in order for the exemption from the CCPA to apply. As a practical matter, this ensures that in the event the PI is mishandled or a data breach occurs, a robust privacy scheme with remedies should always apply, be it HIPAA, CMIA, or the CCPA.

*Medical Research subject to the Common Rule:* As noted above, the CCPA already exempts information collected as part of a clinical trial subject to the Federal Policy for the Protection of Human Subjects, also known as the Common Rule. This bill would include a similar exemption in a new code section, and expand it to exclude any information collected, *used*, or *disclosed* in *research*, including but not limited to a clinical trial, *conducted in accordance with applicable ethics, confidentiality, privacy, and security rules of the Common Rule.* (Emphasis added.)

While a clear expansion of the original research exemption, this provision recognizes that research is not confined to clinical trials and that there are multiple ways that researchers can obtain, use, and disclose the information that is the subject of their studies without compromising patient or individual privacy.

*Patient information deidentified pursuant to HIPAA:* The CCPA already excludes from the definition of PI "deidentified" information, defined as "information that cannot reasonably identify, relate to, describe, or be linked, directly or indirectly, to a particular consumer," and requires a business that uses deidentified information to implement technical safeguards that prohibit reidentification, implement business processes that specifically prohibit reidentification, and implement business processes to prevent inadvertent release of deidentified information. (Civ. Code Sec. 1798.140 (h)).

Similarly, under HIPAA, health information that "does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual" is not individually identifiable health information. HIPAA permits a covered entity to determine that health information is not individually identifiable only if one of the following two deidentification methods are used: the expert determination method, or the safe harbor method.

The expert determination method requires a person with appropriate knowledge of and experience with generally accepted statistical principles and methods for rendering information not individually identifiable to determine that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify the individual. The expert is required to document the methods and results of the analysis that justify such a determination. Under the safe harbor method, a long list of identifiers of the individual, relatives, employers, and household members of the individual are removed, including all geographic subdivisions smaller than a state except for the initial three digits of a zip code, all elements of dates directly related to an individual, device identifiers and serial numbers, and health plan beneficiary numbers, among others.

HIPAA and the CCPA thus have arguably compatible standards for deidentification, but because the specific language in the CCPA is different than the deidentification language in HIPAA, proponents of this bill are concerned that PI deidentified under HIPAA might not meet the standard under the CCPA. Such a discrepancy could subject deidentified patient information to various obligations and liabilities under the CCPA. Accordingly, this bill would expressly exempt patient information that has been deidentified under HIPAA.

However, as an additional safeguard, discussed more in Comment 5 below, the bill would also require any business that discloses or sells deidentified patient information to disclose on its online privacy policy its practice of disclosing deidentified patient information and which of the two relevant HIPAA deidentification methods it used.

- 2) *Prohibition on reidentification of deidentified patient information:* This bill would prohibit a person from reidentifying, or attempting to reidentify, deidentified patient information, subject to limited exceptions. Notably, the bill would provide that any patient information that is reidentified, including for the purposes above, be subject to applicable federal and state data privacy and security laws including, but not limited to, the HIPAA, CMIA, and the CCPA. Proponents of this bill argue that this provision is "a first-in-the-nation prohibition on reidentifying patient records outside of a medical context, significantly advancing privacy."

Staff notes, however, that the CCPA already exempts deidentified information from its provisions, and subjects any business that attempts to reidentify information once again to the CCPA. (*See* Civ. Code Sec. 1798.140(h).) The CCPA also limits remedies for violations of its provisions. With the exception of data breaches of consumers' nonencrypted and nonredacted PI resulting from failure to follow specified provisions of the Act, the CCPA is exclusively enforced by the Attorney General, who is required to give businesses 30 days to cure any violations prior to bringing a law suit. (*See* Civ. Code Secs. 1798.150 and 1798.155.) In other words, while this bill's prohibition on the reidentification of patient information is, on its face, an arguably more robust protection of privacy than what is included in the CCPA, violations of this prohibition would be subject to the limited enforcement.

- 3) *Interaction with Proposition 24 on this November's ballot:* The proponents of this measure have posited in conversations with staff that its urgency is largely based on the prospect of Proposition 24, a ballot initiative amending the CCPA, being approved by the voters this November. Of relevance to this bill, that initiative would amend various provisions of the CCPA, including the provisions containing the existing exemptions, discussed in the comments above. If passed, Proposition 24 would completely replace the language of those various code sections, nullifying any bills amending language in those sections that may be signed into law this year. Notably, the Proposition would also provide that the California Privacy Rights and Enforcement Act (CPRA) (which would replace the CCPA, should the ballot initiative pass) may only be amended by the Legislature "to enhance privacy and [that] are consistent with and further the purposes and intent of this Act." This particular provision has generated concern amongst various industries that any expansion of exemptions within the CPRA would generally be impermissible. Seeking to ensure that various research permitted by federal law continues to be legal in California regardless of the outcome of Proposition 24 in November, the author of AB 713 elected to create a new section in the CCPA that would include nearly duplicative exemptions as those found in the CCPA along with the new exemptions discussed above.

While this approach may help assure that the new exemptions provided by this bill are not eliminated should Proposition 24 pass, it creates a statutory scheme that is at best confusing and likely unworkable for the courts. Specifically, this bill would create two exemptions in the CCPA for providers of healthcare that are nearly identical, save several words. It would also create two identical exemptions, in different code sections, for medical information or PHI, and an additional duplicative exemption for research. It would be difficult, to say the

least, to determine which of these exemptions to apply and if they should be interpreted differently. Accordingly, the Author and Committee should take note that cleanup legislation will be necessary in 2021. Any such legislation could harmonize these provisions and eliminate duplicity where necessary, ensuring that the protections of the CCPA are applied without confusion.

#### **According to the Author:**

This bill is an important measure to protect patient care in the health care system and limit unintended consequences for health care research and operations related to implementation of the CCPA. California is currently home to the largest, most innovative and productive life sciences ecosystem in the world. California's life sciences now include over 3,000 companies that directly and indirectly employ almost 900,000 people and generate \$147.7 billion in revenue. The innovations produced in California are saving lives and transforming health care through earlier disease detection, less invasive procedures and more effective treatments. This bill would provide an important clarification to the law by harmonizing the law with certain areas of health care information already covered under existing medical privacy and confidentiality regulations. Additional clarification is needed for the de-identification standards under HIPAA for the purpose of biomedical research, business associates that handle protected health information, human subject research that falls outside of the area clinical trials, and FDA product and patient safety standards. This bill will provide the necessary clarification in these areas to ensure that California's life science industry and biomedical research are not adversely affected by the rollout of new privacy standards established by the CCPA.

#### **Arguments in Support:**

In support of AB 713, a coalition of health care, research, and commercial organizations write that they have "identified important areas for cleanup in the CCPA that will protect vital medical research and streamline health care operations, reducing waste in our health care system during this critical moment as we respond to the COVID-19 epidemic. The amendments below clarify existing provisions in the CCPA and will save our health care system and the State of California millions in avoided, duplicative compliance costs while protecting critical medical research from legal uncertainty during this important stage of our response. [...] The amendments in AB 713 are ultimately about avoiding waste and promoting efficiency in our health care system and in medical research. We have rules that have worked for over a decade and it is unreasonable to subject these hard-working professionals to an additional layer of duplicative regulation."

#### **Arguments in Opposition:**

None on file.

#### **FISCAL COMMENTS:**

The Senate Appropriations Committee found, pursuant to Senate Rule 28.8, that any additional state costs are not significant, and do not and will not require the appropriation of additional state funds, and that the bill will cause no significant reduction in revenues.

#### **VOTES:**

##### **ASM HEALTH: 15-0-0**

**YES:** Wood, Mayes, Aguiar-Curry, Bigelow, Bonta, Burke, Carrillo, Flora, Limón, McCarty, Nazarian, Ramos, Rodriguez, Santiago, Waldron

**ASM APPROPRIATIONS: 18-0-0**

**YES:** Gonzalez, Bigelow, Bloom, Bonta, Brough, Calderon, Carrillo, Chau, Diep, Eggman, Fong, Gabriel, Eduardo Garcia, Maienschein, Obermolte, Petrie-Norris, Quirk, Robert Rivas

**ASSEMBLY FLOOR: 74-0-6**

**YES:** Aguiar-Curry, Arambula, Bauer-Kahan, Berman, Bigelow, Bloom, Boerner Horvath, Bonta, Brough, Burke, Calderon, Carrillo, Cervantes, Chau, Chen, Chiu, Choi, Chu, Cooper, Cunningham, Dahle, Daly, Diep, Flora, Fong, Frazier, Friedman, Gabriel, Gallagher, Cristina Garcia, Gipson, Gloria, Gonzalez, Grayson, Holden, Irwin, Jones-Sawyer, Kalra, Kamlager-Dove, Kiley, Lackey, Levine, Limón, Low, Maienschein, Mathis, Mayes, McCarty, Medina, Melendez, Mullin, Muratsuchi, Nazarian, O'Donnell, Obermolte, Patterson, Petrie-Norris, Quirk, Quirk-Silva, Ramos, Reyes, Luz Rivas, Robert Rivas, Rodriguez, Salas, Santiago, Smith, Mark Stone, Voepel, Waldron, Weber, Wicks, Wood, Rendon

**ABS, ABST OR NV:** Cooley, Eggman, Eduardo Garcia, Gray, Blanca Rubio, Ting

**UPDATED:**

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CONSULTANT: Nichole Rocha / P. & C.P. / (916) 319-2200

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