Health Data Privacy Regulatory Requirements Adjusted, Public Health Interests Prioritized, During COVID-19 Nationwide Public Health Emergency

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As the COVID-19 crisis intensified, social distancing measures were implemented nationwide, resulting in electronic delivery of healthcare services. Expedient sharing of health data became a critical aspect of the public health response. Accordingly, regulatory privacy protections of health data are being adjusted to prioritize the mobilization of new care delivery technologies in healthcare settings and the implementation of more simplified patient data sharing to alleviate administrative burdens attendant to providing care in a rapidly changing healthcare landscape. Adjusting regulatory requirements during the pandemic balances the protection of individuals from COVID-19 with minimal disruption to healthcare services delivery during a public health crisis.

Aligned with other COVID-19 response-related initiatives, the U.S. Department of Health and Human Services (HHS) issued several Notices of Enforcement Discretion to inform the public that HHS is exercising its discretionary application of the Privacy, Security, and Breach Notification Rules under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) during the COVID-19 nationwide public health emergency. Ordinarily, under the HIPAA Privacy Rule, a covered entity or business associate may not use or disclose protected health information ( PHI ) without an individual’s authorization except for limited purposes, such as for treatment, payment, and health care operations. However, HHS determined that for the duration of the COVID-19 national emergency, provided an entity demonstrates good faith HIPAA compliance efforts, HHS will not impose potential penalties for violations of certain HIPAA Privacy Rule provisions against:

- covered entities or their business associates for uses and disclosures attendant to COVID-19 response efforts under the Privacy Rule provisions 45 C.F.R. § 164.502(a)(3) (Permitted Uses and Disclosures by

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1 The views expressed here are solely those of the author in her private capacity and do not in any way represent the views of the California Department of Justice.
3 45 C.F.R. § 164.502(a)(1).
Business Associates), 45 C.F.R. § 164.502(e)(2) (Standards for Disclosures to Business Associates), 45 C.F.R. § 164.504(e)(1) (Business Associate Contracts), and 45 C.F.R. § 164.504(e)(5) (Business Associate Contracts with Subcontractors), subject to certain other requirements;

- covered entities or their business associates in connection with the good faith participation in the operation of community-based testing sites; and

- covered entities in connection with the good faith provision of telehealth using non-public facing audio or video communication products, regardless of whether the telehealth service is related to the diagnosis and treatment of health conditions related to COVID-19.

Additionally, in furtherance of COVID-19 response efforts, the Coronavirus Aid, Relief, and Economic Security (CARES) Act amended 42 U.S.C. §§ 290dd-2 and its implementing regulations at 42 C.F.R. Part 2 (Part 2) to enable providers to better coordinate patient care and to expediently receive and share vital information, specifically as related to patients with substance use disorder. Part 2 protects the confidentiality of health records of persons who have applied for or been given a diagnosis or treatment for alcohol or drug abuse at a federally assisted program.4

Previously, subject to exceptions, Part 2 prohibited the use or disclosure of patient information relating to substance use disorder treatment absent written patient consent.5 Most substance abuse treatment programs were also subject to HIPAA requirements if they transmitted electronic health information in connection with transactions for which HHS has adopted a HIPAA standard in 45 C.F.R. Part 162.6 And so, in addition to complying with the data privacy requirements of Part 2, the substance abuse treatment programs, under 45 C.F.R. § 164.502(a) of the HIPAA Privacy Rule, could not disclose patient data that qualified as PHI without the patient’s authorization except for limited purposes.7 The CARES Act amended Part 2 so that once the patient’s prior written consent is obtained, the health records related to substance use disorder may be used or disclosed by a covered entity, business associate, or qualifying program for permissible purposes under HIPAA until the patient revokes the consent in writing.8 Removing the administrative burden of requiring providers to obtain prior written patient consent for each subsequent permissible use and disclosure allows these entities to share patient data more efficiently with other providers in the care continuum, enhancing care coordination.

It is vital during a public health emergency, such as the COVID-19 Nationwide Public Health Emergency, to prioritize protecting individuals while also ensuring that any disruption to healthcare services delivery is minimized. Numerous strategies may be adopted. Relaxing regulatory restrictions for the duration of the emergency, as the HHS has done with certain HIPAA provisions, and amending existing laws, as the CARES Act did with sharing substance use disorder records, are two strategies that may further initiatives to combat a nationwide public health crisis.

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4 42 C.F.R. § 2.11.
6 45 C.F.R. § 160.103.
7 45 C.F.R. § 164.502(a)(1).