THE PARTNERSHIP TO AMEND

42 CFR PART 2

January 8, 2021

Re: 42 CFR Part 2 – Recommendations for Next Rule

Dear Nominee Becerra,

The Partnership to Amend 42 CFR Part 2 (Partnership), writes to provide recommendations for the U.S. Department of Health and Human Services (HHS) to consider when drafting the new rule for the 42 CFR Part 2 (Part 2) provisions in the Coronavirus Aid, Relief, and Economic Security Act (CARES Act).

The Partnership is a coalition of nearly 50 organizations committed to aligning Part 2 with the disclosure requirements of the Health Insurance Portability and Accountability Act (HIPAA) for the purposes of treatment, payment, and health care operations (TPO).

First and foremost, we want to take this opportunity to thank you for your past engagement on this important issue, especially the letter you signed while serving as Attorney General for California, which urged Congress to remove the roadblocks created by Part 2. In that letter, you and your colleagues astutely recognized that substance use disorders (SUDs) are an epidemic and highlighted several key reasons why Part 2 is problematic. Specifically, the letter cites the confusing requirements of Part 2, how Part 2 hinders access to medication-assisted treatment, and the stigma of SUDs as urgent reasons for ultimately aligning Part 2 with HIPAA.

You will take the helm of HHS at a time of unprecedented urgency. First, the Centers for Disease Control and Prevention's preliminary estimate is that more than 81,000 Americans died of drug overdose in 2020. Second, a recent article in *Politico* states that federal health officials believe the drug crisis is only being amplified by months of social isolation, high unemployment, and diversion of public health resources all a result of the COVID-19 pandemic.[1] Given this alarming correlation, an important part of responding to the COVID-19 pandemic will be to simplify coordination of care for SUDs, which ultimately will prevent gaps and expand access to care. Furthermore, we anticipate SUDs may continue to rise even after the COVID-19 pandemic is over, reflecting the extreme toll it has taken on Americans. As such, we believe quickly issuing the proposed rulemaking, as required by section 3221 of the CARES Act, will both help curb the SUD epidemic and also strongly supports the incoming Biden-Harris Administration's Build Back Better strategy.

As you are aware, the publication of the next Part 2 proposed rule, pursuant to the CARES Act, has a deadline of March 27, 2021, which falls within the Biden-Harris Administration's

[1] Dan Goldberg and Brianna Ehley, *Biden's other health crisis: A resurgent drug epidemic,* Politico, Nov. 28, 2020.

first 100 days and has serious implications for patient care related to SUDs. Prior requirements in the Part 2 regulation led to segmented data, interrupted flow of that data, and ultimately hindered informed diagnosis, treatment, and implementation of an individual's care plan and access to care. The CARES Act takes great strides to remedy these issues by promoting partial alignment between Part 2 and HIPAA, though the two privacy frameworks remain distinct, particularly for consent purposes. Nevertheless, the law clearly strives to bring Part 2 in line with HIPAA, a fact being embraced by industry thought leaders. For example, the Medicaid and CHIP Payment and Access Commission (MACPAC) noted during its December 2020 meeting that the CARES Act "[p]ermanently aligns 42 CFR Part 2 and HIPAA".[2]

Additionally, and most importantly, the Partnership staunchly supports patient privacy. We are acutely aware that even if the sharing of information is made easier, it has limited utility without continued strong protections for patient privacy. Without trust, patients may not seek the care they need to treat SUDs. We are also aware that individuals may be concerned that SUD records will be used against them by law enforcement.

These are significant concerns. However, the CARES Act protects patient rights in two important ways. First, it allows an individual to revoke his or her consent to sharing SUDs records, giving patients control over their information.[3] Second, SUD records are expressly prohibited by law from being used in civil, criminal, administrative, or legislative proceedings against a patient by any government authority (unless authorized by court order or patient consent). Furthermore, SUD records specifically cannot: (a) be entered into evidence in criminal prosecutions or civil actions; (b) form part of the record for a decision or otherwise be taken into account in government agency proceedings; (c) be used by a governmental agency for law enforcement purposes or investigations; or (d) be used in a warrant application.[4] As such, we believe the changes made to Part 2 by the CARES Act will allow for smoother care coordination while simultaneously strengthening patient privacy.

As you begin drafting the next Part 2 rule, we submit the following for your consideration:

Original Consent Process. While the Confidentiality of Substance Use Disorder Patient Records Final Rule (final rule) issued in July 2020 takes an important step forward to address the issue of patient consent, we believe more needs to be done in this regard. The final rule allows an entity, instead of an individual, to be specified as the recipient of Part 2 records, which broadens the scope of the consent and incrementally relieves the burden on patients and providers. However, this is not enough because a new patient consent is needed each time there is a new entity where the Part 2 record needs to be disclosed. Fortunately, the CARES Act further simplifies the process by requiring only one consent,

---

[2] Aaron Pervin and Erin McMullen, Promoting Behavioral and Physical Clinical Integration Through EHRs, 2020. https://www.citethisforme.com/guides/bluebook-law-review/how-to-cite-a-presentation, last visited December 30, 2020.
[3] Coronavirus Aid, Relief, and Economic Security Act (CARES Act), Pub. L. No. 116-136, Sec. 3221(b)(1)(C).
[4] Id. at Sec.3221(e).

after which the Part 2 record can be used or disclosed by a covered entity or business associate for the purposes of TPO in accordance with the HIPAA regulations.

Additionally, please note that although the initial consent requirement was amended under section 3221 of the CARES Act to allow a general designation (instead of a specific practice), there still remains a roadblock in practice: the list of disclosures requirement in Part 2. Specifically, section 2.31 of Part 2 mandates that "upon request, patients who have consented to disclose their patient identifying information using a general designation *must be provided a list of entities to which their information has been disclosed pursuant to the general designation*" (emphasis added). Due to the list of disclosures requirement, practitioners are often uncomfortable attempting to use the general designation in the consent.

Recommendation: Ensure that the consent requirements in the next rule are simple and straightforward so additional administrative processes are not imposed on patients, providers, or payers (including health plans and their subcontractors). The consent process should be easily folded into existing HIPAA compliance processes, preferably with the patient's acknowledgement of HIPAA practices and the patient's Part 2 consent incorporated into the same document at intake where feasible. Furthermore, include language to address the conflict with Part 2's list of disclosures requirement.

Transmission and Retransmission of Data. The CARES Act plainly states that once written consent is obtained, a Part 2 record may be transmitted and retransmitted for TPO in accordance with HIPAA regulations. No further consent should be required for TPO unless the patient revokes consent.

Recommendation: Include specific language directing covered entities and business associates to disclose and redisclose data in accordance with HIPAA regulations.

The final rule also requires physically separating records with Part 2 data. However, such physical separation is difficult once the data is transmitted, as very few integrated systems or Health Information Exchanges (HIEs) can manage the consent process for a completely separate database for Part 2 records. The separation of data not only creates an administrative burden, but also makes the data difficult to obtain by subsequent treating providers, ultimately hindering patient care. For example, we have heard anecdotes of physicians physically carrying two separate laptops for the purposes of compliance with the data segregation requirements.

Recommendation: Specify that once Part 2 data is transmitted or retransmitted with patient consent, there is no requirement to segregate a patient's Part 2 data from the rest of a HIPAA database, with the regulatory requirement for data segmentation terminating upon transmission or retransmission.

Revocation of Consent Provisions. The patient's ability to revoke consent is an important privacy protection supported by the Partnership. However, serious administrative issues arise when there is an expectation that a revocation be retroactively effective. Specifically,

practices are now required, under the *Promoting Interoperability* program, to incorporate information from outside sources for medications, allergies, and other problems. If revocation is mandated to be retroactive, there is technically no way to go back and isolate this data from a patient's overall clinical record.

Furthermore, it is critical that the responsibility for managing the revocation remain with a designated entity. We believe that the management of the consent revocation should be the responsibility of the Part 2 treatment entity that contributed that data and that program would be responsible for seeing that the Part 2 data is not being transmitted either to another covered entity or business associate.

Recommendation: Specifically state that the revocation of consent for Part 2 data transmission is effective only from the point of revocation going forward and that responsibility for the revocation should be limited to those who are so notified by the patient and their respective actions.

Scope of Part 2 Consent Process. The Department of Health and Human Services (HHS) and the Substance Abuse and Mental Health Services Administration (SAMHSA) guidance seem to indicate that a Part 2 consent should not impede the transmission of behavioral health data that does not originate with a Part 2 program. However, this is very different in practice as there is much confusion on how to handle behavioral health data. Providers hesitate to share behavioral health data because they are concerned that they may be violating Part 2 requirements related to consent.

Recommendation: HHS and SAMHSA should explore, in partnership with stakeholders, how to exclude behavioral health data from the Part 2 data and incorporate the findings into the rule and any subsequent frequently asked questions or guidance. Similarly, HHS and SAMHSA should explore, in conjunction with the States and stakeholders, policy mechanisms for promoting the use of behavioral health data for care coordination purposes when state privacy laws may impose restrictions beyond both Part 2 and HIPAA.

Research. The final rule permits disclosures for the purposes of research under Part 2 by a HIPAA covered entity or business associate to non-HIPAA covered individuals and organizations. However, the CARES Act does not specifically address disclosures for the purpose of research.

Recommendation: Include a provision in the next rule, consistent with the last rule, to ensure that disclosures for the purposes of research from a HIPAA covered entity to a non-HIPAA covered entity are permissible.

Patient Rights. The final rule does not address patient rights. However, in Section 422(j) of the CARES Act, it is stated that nothing in that section can be construed to limit patient rights related to privacy protections for protected health information as defined under Section 164.522 of the HIPAA Privacy Rule.

Recommendation: Include specific language to ensure that patient privacy rights are protected in accordance with the CARES Act and HIPAA.

Claims Data Access. HHS provides patients' claims data through various initiatives, including to organizations participating in alternative payment models. Accountable care organizations, for example, are provided claims data at least monthly, and sometimes weekly. But these data lack SUD-related information because of limits of Part 2.

Recommendation: We urge HHS to start providing SUD-related claims data to providers practicing in alternative payment models to help support their work in population health management.

Please feel free to contact Deepti Loharikar, Director of Regulatory Affairs, Association for Behavioral Health and Wellness, at loharikar@abhw.org or (202) 505-1834 with any questions.

Sincerely,

Maeghan Gilmore

Maeghan Gilmore, MPH
Chairperson, Partnership to Amend 42 CFR Part 2

Members of the Partnership

Academy of Managed Care Pharmacy · Alliance of Community Health Plans · American Association on Health and Disability · American Health Information Management Association · American Hospital Association · American Psychiatric Association · American Society of Addiction Medicine · American Society of Anesthesiologists · America's Essential Hospitals · America's Health Insurance Plans · AMGA · Association for Ambulatory Behavioral Healthcare · Association for Behavioral Health and Wellness · Association for Community Affiliated Plans · Association of Clinicians for the Underserved · Blue Cross Blue Shield Association · The Catholic Health Association of the United States · Centerstone · College of Healthcare Information Management Executives · Confidentiality Coalition · Employee Assistance Professionals Association · Global Alliance for Behavioral Health and Social Justice · Hazelden Betty Ford Foundation · Healthcare Leadership Council · InfoMC · The Joint Commission · The Kennedy Forum · Medicaid Health Plans of America · Mental Health America · National Alliance on Mental Illness · National Association for Behavioral Healthcare · National Association for Rural Mental Health · National Association of ACOs · National Association of Addiction Treatment Providers · National Association of Counties · National Association of County Behavioral Health and Development Disability Directors · National Association of State Mental Health Program Directors · National Rural Health Association · Netsmart · OCHIN · Opioid Safety Alliance · Otsuka America Pharmaceutical, Inc. · Primary Care Collaborative · Pharmaceutical Care Management Association · Premier Healthcare Alliance · Population Health Alliance · Smiths Medical · Strategic Health Information Exchange Collaborative