
PARTNERSHIP TO AMEND 42 CFR PART 2

A COALITION OF NEARLY 50 HEALTH CARE STAKEHOLDERS COMMITTED TO ALIGNING 42 CFR PART 2 (PART 2) WITH HIPAA FOR TREATMENT, PAYMENT, AND HEALTH CARE OPERATIONS (TPO) TO ALLOW APPROPRIATE ACCESS TO PATIENT INFORMATION THAT IS ESSENTIAL FOR PROVIDING WHOLE-PERSON CARE.

January 28, 2019

Don Rucker, M.D.
National Coordinator
Office of the National Coordinator for Health Information Technology
330 C Street, SW
Floor 7
Washington, DC 20201

Re: Draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs

Dear Dr. Rucker,

On behalf of the Partnership to Amend 42 CFR Part 2 (Partnership), I appreciate the opportunity to submit comments on the draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs.

The Partnership is a coalition of nearly 50 national health care organizations representing a range of stakeholders, including patients, clinicians, hospitals, biopharmaceutical companies, pharmacists, electronic health record (EHR) vendors, and insurance providers. The Partnership is committed to aligning 42 CFR Part 2 (Part 2) with the Health Insurance Portability and Accountability Act (HIPAA) for the purposes of treatment, payment, and health care operations (TPO) to allow appropriate access to patient information that is essential for providing whole-person care while protecting patient privacy. See attached position paper for more information and a full list of Partnership members.

As the draft strategy indicates, “state and federal regulators have established narrower rules pertaining to sensitive categories of health information” than HIPAA. One such rule is 42 CFR Part 2 (Part 2), Federal Confidentiality of Substance Use Disorder Patient Records. These outdated regulations set requirements limiting the use and disclosure of patients’ substance use records from certain substance use treatment programs. Patients must submit written consent prior to the disclosure of their substance use disorder (SUD) record. Obtaining multiple consents from the patient is burdensome and creates barriers to whole-person, integrated approaches to care, which are part of our current health care framework. In situations where the patient does not give consent, Part 2 regulations may lead to a doctor treating a patient and writing prescriptions for opioid pain medication for that individual without knowing the person has a SUD. Separation of a patient’s addiction record from the rest of that person’s medical record creates challenges and prevents patients from receiving safe, effective, high quality substance use treatment and coordinated care.

Part 2 was created to reduce stigma associated with SUDs and encourage people to seek treatment without fear of prosecution by law enforcement. While important goals, Part 2 is not compatible with the way health care is delivered in the 21st Century. Part 2 presents enormous barriers to patient safety and coordinated care, and it

creates a clinical burden for physicians. When a patient's written consent is not available to a provider, a great administrative burden exists when trying to physically locate a patient to obtain that consent. If a provider does not ultimately receive written consent from the patient to access his or her addiction record, the inability to see a patient's entire medical record hinders patient safety. This inhibits the electronic exchange of health information, reducing the effectiveness of clinical reports to physicians, and delaying data transmission to providers.

The draft strategy recommendation in this area suggests that the Department of Health and Human Services (HHS) provide additional guidance about HIPAA privacy requirements and Part 2 requirements. We agree that additional guidance is necessary. We strongly recommend that new guidance changes current regulations so that Part 2 is aligned with HIPAA to allow for the transmission of Part 2 records without written consent for the purposes of treatment, payment, and health care operations. This will promote integrated care and enhance patient safety. Additionally, it will provide health care professionals with one federal privacy standard for all of medicine. This reduces the complexity of providers trying to determine which federal privacy law is applicable to each situation and whether or not a written consent is necessary.

42 CFR Part 2 is one regulation the Department of Health and Human Services can, and should, reevaluate to achieve ONC's goal of reducing health-IT related burden and enhancing care coordination. Aligning Part 2 with HIPAA would reduce the burden on physicians and improve care for patients with SUD. Thank you for considering our recommendations. If you have any questions, please contact me at (202) 449-7660 or klein@abhw.org.

Sincerely,

A handwritten signature in dark ink, reading "Rebecca Murow Klein". The signature is written in a cursive, flowing style.

Rebecca Murow Klein, Chair
Partnership to Amend 42 CFR Part 2

Attachment: Partnership to Amend 42 CFR Part 2

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A COALITION OF NEARLY 50 HEALTH CARE STAKEHOLDERS COMMITTED TO ALIGNING 42 CFR PART 2 (PART 2) WITH HIPAA FOR TREATMENT, PAYMENT, AND HEALTH CARE OPERATIONS (TPO) TO ALLOW APPROPRIATE ACCESS TO PATIENT INFORMATION THAT IS ESSENTIAL FOR PROVIDING WHOLE-PERSON CARE.

The undersigned organizations agree on the following:

- Part 2 provisions are not compatible with the way health care is delivered currently.
- Access to a patient's entire medical record, including addiction records, ensures that health care professionals have all the information necessary for safe, effective, high quality treatment and care coordination that addresses all of a patient's health needs.
- Failure to integrate services and supports can lead to risks and dangers to individual patients, such as contraindicated prescription medicines and problems related to medication adherence.
- Obtaining multiple consents from a patient is challenging and creates barriers to whole-person, integrated approaches to care that have proven to produce the best outcomes for our patients.
- Part 2 requirements should be aligned fully with the HIPAA requirements that allow the use and disclosure of patient information for **treatment, payment, and health care operations (TPO)**.
- Health care professionals, insurers, and others who receive basic health information through a health information exchange or a shared electronic health record should not use this information to discriminate against patients regarding quality of care, payment of covered services, or access to care.
- Part 2 information should not be disclosed for non-treatment purposes to law enforcement, employers, divorce attorneys, or others seeking to use the information against the patient, which the HIPAA privacy framework already easily accommodates. Existing penalties for unauthorized release and use of confidential medical information should apply.
- In the 115th Congress, we supported H.R. 6082, the Overdose Prevention and Patient Safety Act (OPPS Act), which passed the House of Representatives by a bipartisan vote of 357-57. H.R. 6082 would align Part 2 with HIPAA for the purposes of TPO, while strengthening protections against the use of addiction records in criminal proceedings.

Academy of Managed Care Pharmacy · Alliance of Community Health Plans · American Association on Health and Disability · American Dance Therapy Association · 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 · Corporation for Supportive Housing · Employee Assistance Professionals Association · Global Alliance for Behavioral Health and Social Justice · Hazelden Betty Ford Foundation · Health IT Now · 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 of Addiction Treatment Providers · National Association for Behavioral Healthcare · National Association for Rural Mental Health · National Association of ACOs · 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 · Otsuka America · Patient-Centered Primary Care Collaborative · Pharmaceutical, Inc. · Pharmaceutical Care Management Association · Premier Healthcare Alliance · Smiths Medical · Strategic Health Information Exchange Collaborative