



June 25, 2014  
Cathy J. Friedman  
SAMHSA Public Health Analyst  
Substance Abuse and Mental Health Services Administration  
1 Choke Cherry Road  
Room 5-1011  
Rockville, MD 20857

Re: FR Document 2014-10913. Applicability of 42 CFR Part 2, Confidentiality and Drug Abuse Patient Records

[PrivacyRegulations@SAMHSA.hhs.gov](mailto:PrivacyRegulations@SAMHSA.hhs.gov)  
<http://www.samhsa.gov/healthprivacy/>

Dear Ms. Friedman:

The American Health Information Management Association (AHIMA) is pleased to submit the following comments on Substance Abuse and Mental Health Services Administration: Applicability of 42 CFR Part 2, Confidentiality of Alcohol and Drug Abuse Patient Records. AHIMA represents more than 71,000 educated health information management and health informatics professionals in the United States and around the world. AHIMA is committed to promoting and advocating for high quality research, best practices and effective standards in health information and to actively contributing to the development and advancement of health information professionals worldwide. AHIMA's enduring goal is quality healthcare through quality information ([www.ahima.org](http://www.ahima.org)). The discussion below provides AHIMA's responses to several of SAMSHA's questions.

### **Applicability of 42 CFR Part 2**

- *How would redefining the applicability of 42 CFR Part 2 impact patients, health care provider organizations, HIEs, CCOs, HIT vendors, etc.?*

The current regulations apply to 42 CFR Part 2, Confidentiality of Alcohol and Drug Abuse Patient Records. The proposed information gathering seeks to obtain direct input from stakeholders on updating the regulations. As noted by SAMSHA listening session participants, AHIMA agrees that more substance abuse treatment occurs in general healthcare settings and integrated care settings, which are typically not covered under the current regulations. For example, in *Behavioral Consultation and Primary Care: A Guide to Integrating Services* (2006), Robinson and Reiter estimate that more than two-thirds of primary care visits are related to psychosocial issues. Evidence also points to the sizeable presence in various mainstream general healthcare settings of persons with substance use conditions—both unidentified and identified. More than 1.5 million visits for treatment at hospital emergency departments in 2008 were found to be associated with some form of substance misuse or abuse (Drug Abuse Warning Network, 2008). Drug or alcohol disorders in 2006 were associated with about 3 percent of hospital stays in the United States, accounting for an estimated \$12 billion in costs (Russo and Elixhauser, 2006; Kassed, Levit, and Hambrick, 2007). Significant increases have also been noted recently in the number of mental health and substance abuse visits to federally qualified health centers (FQHCs)—increasing almost 45 percent between 2001 and 2007 (Bureau of Primary Care, n.d.). FQHC staff

deal with important health issues with their patients, sometimes including discussions related to the use of alcohol and tobacco (Carlson et al., 2001).

Redefining the applicability of 42 CFR Part 2 would bring a greater consistency to the access, use, and disclosure of alcohol and drug abuse patient records. A greater consistency in managing this patient information would address multiple challenges faced by healthcare professionals managing data regardless of media, including increased administrative expenses that are the result of complying with current disparate regulations. AHIMA believes that SAMHSA should consider limiting the changes to information related to current medications, medication history, diagnosis, patient encounters, and allergies. Without this limitation, AHIMA believes that the proposed definition based on services could negatively impact providers, as it would expand the current definition to providers and facilities that provide services but do not meet current facility definitions. There are two primary concerns with basing the definition on “service”:

1. If the definition is too broad or vague, it could have the unintended effects of including providers and entities that were not meant to be covered, and
2. If the definition is too defined or specific, it could quickly become outdated by not keeping up with changes in the marketplace.

- *Would this change address stakeholder concerns?*

AHIMA believes that the proposed changes would provide more consistent guidance to healthcare organizations and reduce inconsistent interpretations of the regulations. AHIMA believes that these changes would foster better care coordination because of greater consistencies in how the information is managed. However, considering the long history and established culture surrounding the current regulations, many stakeholders will react with concerns regarding confidentiality, security, and privacy. The changes will likely result in the need for the training and education of an array of stakeholders, including clinicians, health information management, patients, and others. Therefore, time and resources will be needed to clarify the new consent process. AHIMA believes that SAMSHA should work with public partners (such as the Office of Civil Rights (OCR) and the Centers for Medicare and Medicaid Services (CMS) to provide such stakeholder education and training. Additionally, AHIMA believes that it will be critical for consumers and patients to understand the new consent requirements and urges SAMSHA to help assure that consumers, patients and their caregivers are appropriately informed. Furthermore, AHIMA urges the Department of Health and Human Services to harmonize terms, definitions, and requirements relating to confidentiality, security and privacy of health information across Federal agencies and programs, including HIPAA.

- *How would this change raise any new concerns?*

Redefining the applicability of 42 CFR Part 2 may not result in the desired outcome of making these types of records easier to access. The change could result in unintended outcomes such as diminished information workflow or new barriers to health information exchange, because of the potential impact on providers not currently defined under 42 CFR Part 2. This could create complications with electronic health record (EHR) design, development, and configuration as currently substance abuse records are typically partitioned from the rest of EHR data.

## **Consent Requirements**

- *Would these changes maintain the privacy protections for patients?*

AHIMA believes that the privacy protections for patients would be maintained. The proposed changes would likely streamline provider communications with their patients while the information itself will remain protected health information and will be protected as such under 42 CFR Part 2. AHIMA recommends that SAMSHA work with its federal partners to further explore and study encryption for this type of data.

- *Would these changes address the concerns of HIEs, health homes, ACOs, and CCOs?*

AHIMA believes that these changes would address some concerns expressed by stakeholders such as of HIEs, health homes, ACOs, and CCOs. The proposed changes may not provide the level of relief sought by these entities, but they will encourage patients and providers to work together to share health data electronically and in real time.

- *Would these changes raise any new concerns?*

Alcohol and drug abuse patient records have received elevated levels of protection. AHIMA believes that the proposal to modify the current requirements will raise confidentiality, privacy, and security concerns from healthcare industry stakeholders. Moving forward with facilitating the flow of information in this context does raise some concerns and questions, such as:

- How difficult would it be to manage the consent and revocation process?
- Could patients provide a general consent to release information to others in a specific institution or would the consent require a list of specific individuals to whom the information could be released?
- Would the consent form require a description of the specific information to be disclosed? If so, how would this happen with patient-level data such as problem lists and medications?

It is difficult to address the refusal or revocation of consent in cases of the EHR for an entire health system. If the primary care physician, as a member of a health system, has access to that health system's EHR, then it becomes difficult and even impossible to prevent complete access to patient's record. This could hold true for health information exchanges in the 1:1 denial of access. The 42 CFR Part 2 changes will need to be implemented with transparency and education. In addition, all patient consent requests must be made in advance of the planned health information exchange and the information used will be commensurate with the circumstances for why health data is exchanged. Patients should be made aware that their consent to share health information is revocable at any time and that any access, use, or disclosure of patient information will not be used for discriminatory purposes or as a condition for receiving medical treatment.

### **Redisclosure**

- *Would this type of change facilitate technical solutions for complying with 42 CFR Part 2 in an EHR or HIE environment?*

AHIMA believes that efforts are under way to facilitate technical solutions, although uncertainty exists about widespread availability and implementation of specific functionality of solutions, such as the ability of a system to segregate specific types of data.

- *Would these changes maintain the privacy protections for patients?*

AHIMA believes that the effectiveness of the security protections depends upon the industry's ability to come to consensus on effective standards, policies, processes, and workflows. In addition, overall success is dependent upon the stakeholders' ability to consistently implement privacy safeguards. If there are not consistent implementation of standards, policies, processes, and workflows, PHI likely will be at a greater risk of exposure.

Additionally, AHIMA believes that application of this law to only information that identifies an individual as substance abuser, needs further definition to exclude (at the very least) medications. Using SAMSHA's proposed definition, medication used to treat substance abuse would be an identifier by its very nature. AHIMA is concerned that excluding this data from redisclosure would be a patient safety issue preventing the sharing of drug-to-drug interaction and related information.

## **Medical Emergency**

- *What factors should providers take into consideration in determining whether a medical emergency exists?*

AHIMA believes that the current law/regulation should be revisited. To parse out certain data based upon a service is unwieldy and unmanageable. It creates patient safety issues, such as the lack of access to a patient's complete data, and can be technically difficult to accomplish. AHIMA believes that consideration should be given to make applicability, consent, redisclosure, and emergency access to be consistent with current psychiatric record protections. AHIMA recommends applying the appropriate (industry recognized) clinical and legal criteria and definitions for a medical emergency, which includes life/death situations, medical allergies, mental status and other situations that require immediate medical attention.

- *Are there specific use cases SAMHSA should take into consideration?*
- *Are there patient concerns about the impact of this change on their privacy?*

AHIMA believes that this is currently a contentious and complex issue and will remain one in the future. Deciding what information to make available for a medical emergency is a delicate question, as emergencies may be viewed differently by different people and what may be viewed as an emergency in "real time" may not be viewed as an emergency after some time elapses. This may result in additional risk for unintentional disclosures of information that may not be medically necessary, but when considering the situation in real time, it is more beneficial to have more information than not enough so that the appropriate quality care can be provided. For example, providing access to substance abuse medications is intended to address patient safety issues. However, access, use and disclosure to knowledge of the patient's substance abuse medications could have other unintended consequences and negative outcomes with regard to privacy, confidentiality, and security. Safeguards must be in place to ensure that access is limited to the "minimum necessary" and "need to know" guidelines.

## **Research**

- *Are there factors that should be considered related to how current health care entities are organized, how they function or how legal duties and responsibilities attach to entities that make up an umbrella organization?*

AHIMA believes that issues with regard to responsibility for the process would need to be addressed. Any solution would need, at a minimum, to mirror the current process with regard to safeguards, controls, responsibility, and authority to take action.

- *Would this change address concerns related to research?*

AHIMA believes that if properly designed and implemented, these changes would facilitate research opportunities.

- *Are there specific privacy concerns associated with expanding the authority or releasing data to qualified researchers/research organizations in this way?*

AHIMA believes that data under 42 CFR part 2 is still considered to have “extra” protections. Since this is considered “sensitive” information and is afforded extra protections by law, it appears that any research conducted will still require authorization from the patient prior to release. Expanding authority and allowing for greater distribution of data would most likely introduce new privacy challenges. AHIMA suggests that SAMSHA work with public and private sectors partners to fully explore the potential

## Conclusion

Thank you for providing AHIMA the opportunity to comment on these important questions. AHIMA has developed several publicly available resources<sup>1, 2, 3, 4, 5</sup> about privacy, confidentiality and security of health records and health information and would be pleased to provide additional information to SAMSHA and its Federal partners on these critical topics. We look forward to continuing our work with you to advance our nation’s healthcare system. If you have any comments or questions, please do not hesitate to contact me or Meryl Bloomrosen, AHIMA’s Vice President of Public Policy and Government Relations at [Meryl.Bloomrosen@ahima.org](mailto:Meryl.Bloomrosen@ahima.org) or at 202-659-9440.

Sincerely,



Lynne Thomas Gordon, MBA, RHIA, CAE, FACHE, FAHIMA  
CEO

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<sup>1</sup> Laws and Regulations Governing the Disclosure of Health Information (Updated)

[http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1\\_050565.hcsp?dDocName=bok1\\_050565](http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_050565.hcsp?dDocName=bok1_050565)

<sup>2</sup> Authorization Requirements for the Disclosure of Protected Health Information (Updated)

[http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1\\_050486.hcsp?dDocName=bok1\\_050486](http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_050486.hcsp?dDocName=bok1_050486)

<sup>3</sup> Rediscovery of Patient Health Information (Updated)

[http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1\\_050541.hcsp?dDocName=bok1\\_050541](http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_050541.hcsp?dDocName=bok1_050541)

<sup>4</sup> Patient Access and Amendment to Health Records (Updated)

[http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1\\_050401.hcsp?dDocName=bok1\\_050401](http://library.ahima.org/xpedio/groups/public/documents/ahima/bok1_050401.hcsp?dDocName=bok1_050401)

<sup>5</sup> Gorton, Elisa R. "A New Age for Mental and Substance Abuse Health Records: Considerations for Protecting Highly Sensitive Records in Electronic Systems." *Journal of AHIMA* 83, no.4 (April 2012): 42-43.