SAMHSA Listening Session – June 11, 2014

On June 11, 2014, the Substance Abuse and Mental Health Services Administration (SAMHSA) held a public listening session for the purpose of soliciting input from stakeholders on updating 42 C.F.R. Part 2. Commonly referred to as Part 2, these regulations govern the use and disclosure of substance abuse treatment records. The following topics were addressed in the listening session:

1. Applicability of 42 CFR Part 2
2. Consent Requirements
3. Redisclosure
4. Medical Emergency
5. Qualified Service Organization (QSO)
6. Research
7. Addressing Potential Issues with Electronic Prescribing and Prescription Drug Monitoring Programs (PDMPs)

Individuals were pre-selected to make comments based on the order of their request to SAMHSA and the stakeholder group represented. In sessions where there was time remaining, non-selected individuals were also permitted to make comments. The listening session was led by Maureen Boyle (Lead Public Health Advisor, Health Information Technology) and Kate Tipping (Public Health Advisor, Health Information Technology Privacy) of SAMHSA. SAMHSA also accepted written comments until June 25, 2014.

The full Notice of Public Listening Session is available here. An agenda of the listening session can be found here. The listening session is also available to watch on You Tube here.

The text and a summary of the 42 CFR Part 2 regulations can be found here.

Ms. Tipping's Introductory Statements

The 42 CFR Part 2 regulations that prohibit disclosure of substance abuse treatment records with very few exceptions were originally intended to encourage patients to seek out treatment without fear that their privacy would be compromised. Part 2 was authorized by both the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 and the Drug Abuse Prevention, Treatment, and Rehabilitation Act of 1972 with the most recent substantial update to the regulation in 1987. The healthcare delivery system has changed in ways that were not anticipated by the regulation, such as the use of electronic health records (EHRs) and development of health information exchanges (HIEs). SAMHSA has received feedback that the current regulations pose a barrier to the integration of behavioral health and general healthcare delivery. However, there is also fear that an erosion of the privacy protections

provided by Part 2 will discourage patients from seeking substance abuse treatment. SAMHSA is considering updating the regulations to take into account these new healthcare models, while also maintaining strong privacy protections for substance abuse treatment patients.

DISCUSSION TOPICS

1. Applicability of 42 CFR Part 2

a. Redefining applicability of Part 2 beyond entities that "hold themselves out as providing alcohol or drug abuse diagnosis." Impact on patients, providers, HIEs, ACOs, and HIT vendors?

b. Redefining what information is covered under Part 2 to include the substance abuse treatment services being provided rather than being defined by the type of facility providing the services.

Comments

- Impact of current law: Many commenters reflected the sentiment that the current law promotes stigma and leads to subpar care for those with substance abuse issues. Commenters recommended legislative change that would protect patient privacy, but enable coordinated care. For example, commenters generally supported sharing of substance abuse records through EHRs in order to enhance integration with a patient's medical record and enable more coordinated care. In addition, many commenters supported having substance abuse treatment records available only pursuant to a court order, and not to the police.
- Avoiding negative treatment consequences: Eric Goplerud, Senior Vice President and Director of Substance Abuse, Mental Health and Criminal Justice Studies at NORC, noted that in order to avoid the likelihood of negative treatment consequences, a patient's prior substance abuse treatment information is needed by subsequent providers. He views Part 2 as a disincentive to seeking treatment as evidenced by the fact that only 10% of addicts go to treatment and recommends legislative action to eliminate the barriers Part 2 imposes on quality of care delivery. In general, he suggested that basic information related to diagnosis and treatment should be shared to avoid preventable negative treatment consequences.
- Harmonize Part 2 regulations with HIPAA Privacy Rule: A number of commenters representing HIEs and behavioral health providers also suggested harmonizing Part 2 with HIPAA's privacy requirements. More specifically, commenters stated that Part 2 should not be limited to substance abuse and behavioral health providers but should be expanded to include entities also covered under the HIPAA Privacy Rule. Commenters, including representatives from the Legal Action Center (LAC), suggested that the current definition of who is covered by Part 2 needs clarification. LAC recommends that SAMHSA should look at the service provided and not how the service provider holds himself or herself out. If the focus is to be on patients, because the current Part 2 regulations do not allow records to be shared, integrated care models suffer. However, Jim Pyles, a representative of the American Psychoanalytic Association stated that if SAMHSA allowed Part 2 to be harmonized with HIPAA, there would be a breach of trust of substance abuse patients. Substance abuse records should only be allowed to be disclosed by the patient. Patients should be able to determine whether they want their information shared.

- Patient choice/Management of disclosures: Commenters representing health information technology vendors supported enabling patients to choose to whom information may be shared (like HIPAA) effectively giving patients control of their own privacy protections and also allowing disclosure of substance abuse information for treatment, payment and operations (similar to the HIPAA disclosure provisions related to treatment, payment, and operations).
- Concerns with data segmentation: Several commenters raised concerns with impact on patient safety when information is segmented (e.g., substance abuse information is extracted from a record prior to disclosure).
- Sharing of substance abuse information electronically: Commenters suggested that Part 2 should be restructured to allow substance abuse information to be shared electronically for care coordination and information sharing via HIT tools. EHRs and HIEs can keep information secure and enable sharing of information that will positively impact care. Currently HIEs and ACOs do not have access to substance abuse treatment information, due to Part 2 restrictions, so commenters suggested that these restrictions lead to subpar, lower quality care. Commenters from the LAC and other consumer advocacy groups stated that patients should retain control of substance abuse records, even for treatment and payment purposes due to the stigma and discriminatory conduct. Other commenters from LAC supported including substance abuse information in HIEs, but noted that Part 2's most stringent provisions must be maintained to allow patients to freely seek care, and that HIPAA's lower threshold should not be adopted. Patient groups also commented that Part 2 should be updated to allow for integrated care but the privacy requirements should be maintained due to discrimination faced by those receiving treatment for substance abuse.
- Application of Part 2 to providers: Commenters suggested that Part 2 should apply to information and not providers. If a provider holds substance abuse information, explicit patient consent should be required to disclose it. Commenters suggested that Part 2 may be a financial barrier because providers in medical homes do not have the financial incentives to participate. Large systems of care should fall under Part 2 because of care referrals. Information should not be subject to consents and re-consents for team-based care in ACOs and medical homes.
- Care Integration: Commenters representing health plans noted that their plans must integrate care to achieve the triple aim of health care reform, which includes improving health care quality, improving population health, and lowering costs, but are limited by Part 2. Additionally, a commenter from Maine Health stated that Part 2 should be repealed because it is a barrier to integrated care. There should be free exchange of information for ACOs to provide whole-person care.

2. Consent Requirements

a. "To whom" requirement: Part 2 requires written consent to disclose information to include name of individual or organization to whom disclosure is to be made. Should the consent be modified to include a more general description of the individual or organization (for HIEs, ACOs, etc). Currently, a Part 2 consent may not include unnamed future providers, so HIEs, ACOs, health homes, and other such entities do not contain substance abuse treatment information.

b. Should the patient be provided with a list of providers or organizations that may access their information, and be notified regularly of changes to the list?

c. Should the consent be required to name the individual or provider allowed to make the disclosure?

d. Should a health care entity made up of multiple units or organizations that is allowed to make a disclosure be required to specifically name the unit, organization or health care provider releasing substance abuse related information?

e. Should the consent form explicitly describe the substance abuse treatment information that may be disclosed?

Comments

- Flexibility of "to whom" standard for HIEs and HIOs: Renee Popovitz, an attorney and general counsel to behavioral health providers and Health Information Organizations (HIOs), stated that the current Part 2 consent requirements are a roadblock to inclusive care. Specifically, she commented that the Part 2 consent requirements should be relaxed by allowing the "To whom" requirements to allow consent to future providers in HIEs, HIOs, and ACOs. Commenters also addressed allowing consent to any provider, aligning consent requirements with HIPAA, and allowing re-disclosure for treatment, payment, and operations. A commenter representing Massachusetts' All-Payer Claims Database (APCD), the Center for Health Information Analysis, suggested allowing APCDs as an entity where substance abuse information could be disclosed because such information would be helpful to evaluate quality of substance abuse treatment and care.
- Access by law enforcement: Commenters representing consumer advocates expressed concern that any change to the consent requirements not allow law enforcement to have access to substance abuse records, which would deter patients from seeking treatment for fear that they could be prosecuted. Some commenters suggested having a specific court order for the release of substance abuse information to law enforcement.
- Patient consent for disclosure of substance abuse treatment information: There seemed to be a broad consensus among commenters that patients should know where their substance abuse information is going, and that they be notified if the information is accessed. Consumer advocates suggested that the consent form explain how patient information will be used, and be specific if multiple people or a care team will have access to the information. Comments from the LAC suggested that patients should have the right to decide where their information gets disclosed through patient consent management options. In addition the LAC suggested that the "To whom" provisions were too narrow and that disclosures to future providers be allowed with consent. Commenters representing health plans advocated for having an audit trail available to patients so they can see who has accessed their substance abuse treatment information. Commenters representing HIEs stated that the Part 2 consent form should allow data to be governed by HIPAA so patients can opt in to participate in an integrated health system. Patients can be kept updated as to who has accessed their substance abuse information through a website. Commenters also suggested that behavioral records be integrated into medical records for enhanced care coordination, which will reduce medical errors and enhance patient safety. Deborah Peel, founder of Patients Privacy Rights, commented that data segmentation should be required in EHRs, and that accounting for disclosures should be required.

3. **Redisclosure and Medical Emergency**
   a. **Part 2 prohibits redisclosure and EHRs do not allow for data segmentation so either substance abuse records and separate from medical records of the entire medical record is subject to Part 2.**
   b. **SAMHSA is considering revising the redisclosure requirements to apply the prohibition on redisclosure only to information that identifies an individual as a substance abuser, and allows other health related information to be redisclosed. Does this change allow for technical solutions for EHRs and HIEs to comply with Part 2? Do these changes maintain privacy protections for patients?**
   c. **Part 2 has a medical emergency exception that allows information to be disclosed to treat a condition that poses an immediate threat to an individual to the extent necessary for treatment.**
   d. **What factors should be taken into account to determine whether a bona fide medical emergency exists? Should providers have greater discretion in determining whether an emergency exists, and can they use the emergency exception to prevent emergencies or share information? How will this impact patient privacy?**

Comments

- Patient consent for redisclosure: Commenters representing providers stated that patients should provide informed consent to allow redisclosure of substance abuse information for treatment, payment, and operations like HIPAA. Deborah Peel stated that there are no technical changes needed to Part 2. She also stated that patients should have to consent to redisclosure,and that the data should remain in the patients' control.
- Abstract key data elements: Other commenters suggested that discrete data elements, such as medications, allergies, and other non-sensitive information, be abstracted to the summary of care record in the EHR which would be useful to patient care.
- Substance abuse information in emergencies: Commenters from HIEs stated that providers may need substance abuse information for medical emergencies, but currently this information is not contained in the HIE.
- Sharing of mental health and substance abuse information: Eric Goplerud commented that health care and mental health/substance abuse information should be freely shared, and raising anxiety about information sharing is not productive. There is no difference between treatment in community health centers and in substance abuse treatment centers. There should not be different levels of protection based on place of treatment. Substance abuse records should be like the Genetic Information Nondiscrimination Act GINA, where general information can be shared for treatment.[1] Jim Pyles from the American Psychoanalytic Association commented that HIPAA should not be applied to substance abuse information. Providers cannot treat a patient without consent, and should not get information without consent. He noted that since it is not clear whether ACOs or medical homes will work, patients should be in charge of their information.

[1] Genetic Information Nondiscrimination Act of 2008, Pub. L. 110-223, 122 Stat. 881, Title II codified at 42 U.S.C. 2000ff *et seq.* (2008) (*available at* http://www.gpo.gov/fdsys/pkg/PLAW-110publ233/pdf/PLAW-110publ233.pdf).

4. Quality Service Organizations (QSO)

a. Allow Part 2 data to flow to health care entities for care coordination and population management while maintaining patient protections, so the definition of a QSO can be expanded to include care coordination services and allow a QSO Agreement (QSOA) to be executed between the entity that stores the Part 2 information and a service provider.

b. Are there use cases? Are there patient concerns on privacy?

Comments

- Disclosure pursuant to patient consent: LAC commented that the QSOA should not allow disclosure without consent because it would lead to discrimination. Others commented that QSOAs support disclosure pursuant to patient consent. If providers are allowed to participate as QSOs, it would decrease barriers to care coordination. There were also comments referring to discrimination from provider to provider based on substance abuse treatment.
- QSOA between two providers: Comments also included a request that SAMHSA clarify whether a QSOA could be entered into between two substance abuse providers. There was also a request to clarify whether a payer could contract with a QSO, and to allow for flexibility in determining how a QSO is defined.
- Release of Part 2 data to other entities: Commenters representing the Massachusetts Executive Office of Health and Human Services stated that Part 2 should be amended to allow third party payer release of substance abuse information to a QSO. Additional comments included amending consent to include disclosure to QSOs/HIEs.

5. Research

a. Consideration of expanding the authority for releasing information from only the "program director" to qualified researchers/research organizations to health care entities that receive and store Part 2 data, including 3rd party payers, HIEs, and other care coordination organizations.

b. Factors to consider when looking at how health care entities are set up? Privacy concerns with expanding the authority?

Comments

- Application to All-Payer Claims Databases: State mandated APCDs are explicitly authorized to disclose Part 2 data to researchers or qualified entities for approved research projects with privacy protections.
- Two tiered system for substance abuse patients: Commenters representing Medicaid managed care organizations stated that there is a tiered system of care and that substance abuse patients are left out of research projects. Having two systems of care may perpetuate the stigma. Commenters also suggested conducting educational outreach programs for consistent application. However, Deborah Peel stated that privacy concerns over how healthcare entities act as research organizations should be examined. She also commented that patients should be educated about consent and data sharing.
- Negative effects of segmentation of Part 2 data: Others commented that HIPAA protects all records and that Part 2 exacerbates the stigma of substance abuse, and segmentation of

EHRs will marginalize these populations. There should be strong enforcement of inappropriate release of this information.

6. E-Prescribing/Prescription Drug Monitoring Programs (PDMPs)

a. E-prescriptions filled by pharmacies must obtain patient consent if received directly from a Part 2 provider, before sending the information to a PDMP, but pharmacies lack the ability to manage patient consents and segregating the Part 2 data. It is also difficult to identify which providers are subject to Part 2.

b. If patients do not consent to sharing data through e-prescribing, they must use paper prescriptions, and not protected by Part 2, and can sometimes be accessed by the PDMP and by law enforcement in some cases.

c. Are there technology barriers?

d. Patient concerns?

Comments

- Part 2 creates obstacles to patient care: Commenters stated that Part 2 places obstacles to e-prescribing, and creates barriers to patient care because providers do not see all of the medications a person is taking. Sharing of information should be allowed among members of a treatment team.
- Lack of privacy of e-prescribing: Deborah Peel commented that e-prescribing makes it hard to keep prescription information private, and leads to patients not taking the medication they need.
- Access to prescription information by law enforcement: LAC commented that unless a Part 2 court order is obtained, law enforcement should not have access to prescription information. Other commenters suggested that Prescription Drug Monitoring Programs (PDMPs) allow doctors to know if a patient is doctor shopping in order to obtain illegal substances, therefore, law enforcement should be restricted from accessing this information, but providers should be allowed access. There should be strong penalties, including making the evidence excludable if illegally obtained.

7. Open Comment Period: Reflects comments not related to any other topic or additional comments by interested parties

Comments

- Part 2 creates barriers to care: Commenters suggested that Part 2's requirement of naming specific providers in the consent creates barriers to the exchange of information and integrated care. Part 2 information should flow freely to allow for integrated care.
- Alignment with HIPAA: Some commenters wanted Part 2 to align more closely with HIPAA and allow information to be released without patient authorization. These comments also suggested that the Part 2 provisions do not allow for whole person care.
- American Health Lawyers Association (AHLA) comments: The AHLA discussed that revisions to the "to whom" provision, and the redisclosure prohibition were needed, and

suggested establishing a convenor session to establish a neutral forum for differing perspectives.

- Comments from substance abuse groups supporting the current Part 2 provisions: Some substance abuse groups suggested that loosening Part 2's protections would reduce patient trust and lead to less treatment. Others commented that patients should decide what information to share because they have an expectation of privacy.
- Comments from health providers/HIT Vendors: Experts suggested that the health system is 3-7 years away from data segmentation. The "to whom" requirement should be expanded and allow patients to designate HIEs, and allow an opt-out from doing so. There should also be mandatory exclusion for criminal or civil proceedings of substance abuse information. Others agreed with an opt-in or opt-out process for the disclosure of substance abuse records.
- Comments from the National Advocates of Pregnant Women: Commenters suggested that because Part 2 provides no private right of action, providers can disclose substance abuse information to the police. Pregnant women are not protected from seeking substance abuse treatment.
- Comments from Renee Popovitz: Eighty percent surveyed support revising Part 2. HHS/SAMHSA should issue subregulatory guidance to include treatment providers. Part 2 needs revision to address patient safety issues. SAMHSA should coordinate with CMS (Medicaid, ACOs, etc) so that such guidance is consistent across health care agencies.