SUMMARY OF THE 42 CFR PART 2 REVISIONS BY SAMHSA

SAMHSA Friday posted the long-awaited revisions to the 42 CFR Part 2 regulations governing confidentiality and disclosures of patient records for patients of substance abuse treatment programs. The regulations do little to make it easier for providers to share patient records, as had been hoped by NASMHPD and other mental health organizations, but rather strengthen the protections already available.

Comments to SAMHSA are due within 60 days of publication (on or about April 9).

NASMHPD, the Medicaid Directors, and a number of other stakeholders had recommended aligning the 42 CFR Part 2 protections with protections afforded under privacy provisions of the Health Insurance Portability and Accountability Act (HIPAA), but SAMHSA dismisses that request summarily in the preamble to the regulations, stating that due to its targeted population, Part 2 provides more stringent federal protections than most other health privacy laws, including HIPAA.

SAMHSA says it is mindful of the intent of the governing statute (42 U.S.C. 290dd-2) and regulations, which is to protect the confidentiality of substance abuse patient records so as not to make an individual receiving treatment for a substance use disorder in a Part 2 program more vulnerable by virtue of seeking treatment than an individual with a substance use disorder who does not seek treatment. At the same time, SAMHSA says it is striving to facilitate information exchange within new and emerging health and health care models, which promote integrated care and patient safety, while respecting the legitimate privacy concerns of patients seeking treatment.

SAMHSA also says it decided not to address issues pertaining to e-prescribing and prescription drug monitoring programs (PDMPs) in the proposed regulations because the Part 2 program e-prescribing and PDMPs are not ripe for rulemaking at this time due to the state of technology and because the majority of Part 2 programs are not prescribing controlled substances electronically.

One change that may make the exchange of information somewhat easier is the use of a new defined term, “treating provider relationship.” The existence of a “treating provider relationship” would permit a patient to consent to disclosures of protected information using a more general description of the individuals or entities to which a disclosure may be made, if the individuals or entities have a treating provider relationship with the patient whose information is being disclosed. Absent such a relationship, consents to disclose would have to specifically name the individuals or entities to which disclosure may be made.

Because SAMHSA wants to ensure that patient identifying information is only disclosed to those individuals and entities on the health care team with a need to know this sensitive information, SAMHSA is limiting a general designation to those individuals or entities with a treating provider relationship. Patients may further designate their treating providers as “past,” “current,” and/or “future” treating providers. In addition, a patient may designate, by name, one or more individuals on their health care team with whom they do not have a treating provider relationship.

Under the definition, a treating provider relationship begins when an individual seeks health-related assistance from an individual or entity who may provide assistance. However, the relationship is clearly established when the individual or entity agrees to undertake diagnosis, evaluation and/or treatment of the patient, or consultation with the patient, and the patient agrees to be treated, *whether or not* there has been an actual in-person encounter between the individual or entity and patient.

A “treating provider relationship” exists, regardless of whether there has been an actual in-person encounter when:

- A patient agrees to be diagnosed, evaluated and/or treated for any condition by an individual or entity, and

- The individual or entity agrees to undertake diagnosis, evaluation and/or treatment of the patient, or consultation with the patient, for any condition.

SAMHSA considers an entity (not an individual, previously designated in the regulation as an "organization") to have a treating provider relationship with a patient if the entity employs or privileges one or more individuals who have a treating provider relationship with the patient.

The term "agrees" as used in the definition does not necessarily imply a formal written agreement. An agreement might be evidenced by, among other things, making an appointment or seeking a telephone consultation.

In the case of an entity that has a treating provider relationship with the patient whose information is being disclosed, SAMHSA is proposing to permit the designation of the name of the entity without requiring any further designations (as is required for an entity that does not have a treating provider relationship with the patient whose information is being disclosed). For example, the consent form could specify any of the following names of entities: Lakeview County Hospital, ABC Health Care Clinic, or Jane Doe & Associates Medical Practice.

In the case of an entity that is a third-party payer but does not have a treating provider relationship with the patient whose information is being disclosed that requires patient identifying information for the purpose of reimbursement for services rendered to the patient by the Part 2 program, SAMHSA proposes to permit the designation of the name of the entity (e.g., Medicare).

In the case of an entity that does not have a treating provider relationship with the patient whose information is being disclosed and is not a third-party payer, SAMHSA proposes to permit the designation of the name(s) of the entity(-ies) and at least one of the following: (1) the name(s) of an individual participant(s); (2) the name(s) of an entity participant(s) that has a treating provider relationship with the patient whose information is being disclosed; or (3) a general designation of an individual or entity participant(s) or a class of participants that must be limited to those participants who have a treating provider relationship with the patient whose information is being disclosed.

Examples of an entity without a treating provider relationship include an entity that facilitates the exchange of health information (e.g., HIE) or a research institution. The consent form could designate the HIE (an entity that does not have a treating provider relationship with the patient whose information is being disclosed) and Drs. Jones and Smith, and County Memorial Hospital (all participants in the HIE with a treating provider relationship with that same patient). Likewise, the consent form could designate the HIE (an entity that does not have a treating provider relationship with the patient whose information is being disclosed) and "my treating providers" (a general designation of a class of individual and/or entity participants with a treating provider relationship with that same patient). The consent form could not include the general function "HIE" without specifying the name of the HIE entity used by the treating provider. Merely listing a function is not sufficient for consent because it would not sufficiently identify the recipient of the patient identifying information.

If a general designation is used, the entity must have a mechanism in place to determine whether a treating provider relationship exists with the patient whose information is being disclosed. SAMHSA encourages innovative approaches. For example, the HIE in the aforementioned example could have a policy in place requiring their participating providers to attest to having a treating provider relationship with the patient. Likewise, the HIE could provide a patient portal that permits patients to designate treating providers as members of "my health care team" or "my treating providers."

In all instances, patient-identifying information should only be disclosed to those individuals and organizations in accordance with the purpose stated by the patient on the signed consent form and only to those individuals with a need to know this sensitive information. SAMHSA is proposing to require the consent form to explicitly describe the substance use disorder-related information to be disclosed. The types of information that might be requested include diagnostic information, medications and dosages, lab

tests, allergies, substance use history summaries, trauma history summary, employment information, living situation and social supports, and claims/encounter data. The designation of the “Amount and Kind” of information to be disclosed must have sufficient specificity to allow the disclosing program or other entity to comply with the request. For example, the description may include: “medications and dosages, including substance use disorder-related medications,” or “all of my substance use disorder-related claims/encounter data.” An example of an unacceptable description would be “all of my records.”

SAMHSA also is proposing to require a Part 2 program or other lawful holder of patient-identifying information to obtain written confirmation from the patient that they understand both the terms of their consent and, when using a general designation in the “To Whom” section of the consent form, that they have the right to obtain, on request, a list of entities to which their information has been disclosed pursuant to the general designation.

Lists of Disclosures

Patients who have included a general designation in the “To Whom” section of their consent form must be provided, by the entity without a treating provider relationship that serves as an intermediary a list of entities to which their information has been disclosed pursuant to the general designation (“List of Disclosures”). If entities that are required to comply with the List of Disclosures requirement wish to include the names individuals on the list of disclosures, nothing in the proposed rule prohibits it. Patients who wish to know the names of individuals to whom their information is disclosed may ask the entity on the List of Disclosures to provide that information, but 42 CFR Part 2 would not require the entity to comply with the patient’s request.

SAMHSA is proposing that entities named on the consent form that disclose information to their participants under the general designation (entities without a treating provider relationship that serve as intermediaries) must respond to requests for a list of disclosures in 30 or fewer calendar. The response must include the name of the entity to which each disclosure was made, the date of the disclosure, and a brief description of the information disclosed. The brief description of the information disclosed must have sufficient specificity to be understandable to the patient. The requirement to provide a list of disclosures cannot be satisfied by providing patients with a list (or web address) of entities that potentially could receive their patient identifying information.

Responses sent to the patient electronically may be sent by encrypted transmission (e.g., email), or by unencrypted email at the request of the patient, so long as the patient has been informed of the potential risks associated with unsecured transmission—that there may be some level of risk that the information in an unencrypted email could be read by a third party. If patients are notified of the risks and still prefer unencrypted email, the patient has the right to receive the information in that way, and entities are not responsible for unauthorized access in transmission. Before using an unsecured method to respond to a request for a list of disclosures, an entity would be expected to take precautions, such as checking an email address for accuracy before sending it or sending an email alert to the patient for address confirmation.

Patients could also request that the entity communicate with them by an alternative means or at an alternative location. Responses sent by mail may be sent by United States Postal Service first class mail, an equivalent service, or a service with additional security features (e.g., tracking).

To allow time to develop, test, and implement advanced technology to more efficiently comply with this requirement, SAMHSA is proposing that the List of Disclosures requirement would not become effective until two years after the effective date of the final rule. It does note that some entities may be able to comply with this requirement without developing and implementing new technologies. In addition, entities that use and disclose primarily paper records could easily implement a system, if one does not already exist, such as a sign-out/sign-in log that could be used to generate such a list. SAMHSA anticipates that

there will be few requests based on the relatively small number of accounting requests that most covered entities have received under the HIPAA Accounting for Disclosures rule.

SAMHSA is proposing that patient requests for a list of entities to which their information has been disclosed must be in writing and limited to disclosures made within the past two years. "Written" includes either paper or electronic documentation. A request letter addressed to the entity that disclosed the information might include language such as: "I am writing to request a list of the entities to which my information has been disclosed within the past two years.

Other Definitional Changes

Other new or revised definitions within the proposed regulations serve to broaden, rather than narrow or make more practical, the protections afforded patients. For instance, to emphasize that the term "**patient**" refers to both current and former patients, SAMHSA proposes to revise the definition to provide that a patient is any individual who has applied for or been given diagnosis, treatment, or referral for treatment for a substance use disorder at a Part 2 program. "Patient" would also include any individual who, after arrest on a criminal charge, is identified as an individual with a substance use disorder in order to determine that individual's eligibility to participate in a Part 2 program.

SAMHSA notes that more substance use disorder treatment services are occurring in general health care and integrated care settings, which are typically not covered under the current regulations. Providers who in the past offered only general or specialized health care services (other than substance use disorder services) now, on occasion, provide substance use disorder treatment services, but only as incident to the provision of general health care.

To clarify the regulations' application only to specialized programs, "**Part 2 program**" would now be defined as follows:

1. If a provider is not a general medical facility or general medical practice, then the provider meets the Part 2 definition of a "program" if it is an individual or entity who holds itself out as providing, and provides substance use disorder diagnosis, treatment, or referral for treatment.

2. If the provider is an identified unit within a general medical facility or general medical practice, it is a "program" if it holds itself out as providing, and provides, substance use disorder diagnosis, treatment or referral for treatment.

3. If the provider consists of medical personnel or other staff in a general medical facility or general medical practice, it is a "program" if its primary function is the provision of substance use disorder diagnosis, treatment, or referral for treatment and is identified as such specialized medical personnel or other staff by the general medical facility or general medical practice.

While the term "general medical facility" is not defined, SAMHSA states that hospitals, trauma centers, or federally qualified health centers would all be considered "general medical facilities." Primary care providers who work in such facilities would be covered if: (1) they work in an identified unit within such general medical facility that holds itself out as providing, and provides, substance use disorder diagnosis, treatment or referral for treatment, or (2) the primary function of the providers is substance use disorder diagnosis, treatment or referral for treatment and they are identified as providers of such services by the general medical facility.

In addition, a practice comprised of primary care providers could be considered a "general medical practice." As such, an identified unit within that general medical practice that holds itself out as providing and provides substance use disorder diagnosis, treatment, or referral for treatment would be considered a "program" as defined in these proposed regulations.

While **"holds itself out"** is not defined within the regulations, SAMHSA says a previously published guidance relative to the term provides sufficient definition. Under that guidance, "holds itself out" means

any activity that would lead one to reasonably conclude that the individual or entity provides substance use disorder diagnosis, treatment, or referral for treatment including but not limited to:

- Authorization by the state or federal government (e.g. licensed, certified, registered) to provide, and provides, such services;
- Advertisements, notices, or statements relative to such services; or
- Consultation activities relative to such services.

Consistent with the goal of modernizing the regulations, SAMHSA proposes to revise the definition of **"records"** to include any information, whether recorded or not, received or acquired by a Part 2 program relating to a patient. For the purpose of these regulations, records include both paper and electronic records.

A **"lawful holder"** of patient identifying information is an individual or entity who has received such information as the result of a Part 2-compliant patient consent (with a re-disclosure notice) or as a result of one of the limited exceptions to the consent requirements specified in the regulations and, therefore, is bound by 42 CFR Part 2. Examples of such "lawful holders" of patient identifying information include a patient's treating provider, a hospital emergency room, an insurance company, an individual or entity performing an audit or evaluation, or an individual or entity conducting scientific research.

On the other hand, a patient who has obtained a copy of their records or a family member who has received such information from a patient would ***not*** be considered a "lawful holder of patient identifying information", because the regulations do not prohibit a Part 2 program from giving a patient access to his or her own records or allowing a patient to inspect and copy his or her own records. Nor is the Part 2 program required to obtain a patient's written consent or other authorization in order to provide access to the patient's legal representative.

One modified definitional term could create confusion where confusion did not previously exist, and is likely to engender opposition from some providers. SAMHSA proposes to refer to alcohol abuse and drug abuse collectively as **"substance use disorder"**, and to use the term "substance use disorder" to be consistent with recognized classification manuals, current diagnostic lexicon, and commonly used descriptive terminology. SAMHSA proposes to define the term "Substance use disorder to cover substance use disorders that can be associated with altered mental status that has the potential to lead to risky and/or socially prohibited behaviors, including, but not limited to, substances such as, alcohol, cannabis, hallucinogens, inhalants, opioids, sedatives, hypnotics, anxiolytics, and stimulants. In addition, SAMHSA proposes to clarify that, for the purposes of these regulations, the definition excludes both tobacco and caffeine.

Other Changes of Note

Confirming that an Individual is not a Patient No Longer Permitted

SAMHSA is proposing to remove the blanket permission granted under the existing regulations to disclose that an identified individual is not and never has been a patient. SAMHSA says that confirming the identity of an individual who is not and has never been a patient while remaining silent on the identity of an actual patient could, by inference, compromise patient privacy if the individuals are of a small group of individuals. In confirming the identity of an individual who is not and never has been a patient, caution should be used so as not to make an inadvertent disclosure with respect to one or more other individuals. This proposed rule does not prohibit entities that receive a request for information about an individual from refusing to disclose any information regardless of whether the individual is or ever has been a patient(s).

Security of Written Records

SAMHSA clarifies that both Part 2 programs and other lawful holders of patient-identifying information must have in place formal policies and procedures for the security of both paper and electronic records. The formal policies and procedures must address, among other things, the sanitization of hard copy and electronic media. Suggested resources for Part 2 programs and other lawful holders developing formal policies and procedures include materials from the HHS Office for Civil Rights (e.g., *Guidance Regarding Methods for De-identification of Protected Health Information in Accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule*), and the National Institute of Standards and Technology (NIST) (e.g., the most current version of the *Special Publication 800-88, Guidelines for Media Sanitization*).

Disposition of Records by Discontinued Programs

SAMHSA proposes to modernize this section to address the disposition of both paper and electronic records by discontinued programs, and add requirements for "sanitizing" paper and electronic media—rendering the data stored on the media non-retrievable. SAMHSA notes that sanitizing electronic media is distinctly different from deleting electronic records and may involve clearing (using software or hardware products to overwrite media with non-sensitive data) or purging (degaussing or exposing the media to a strong magnetic field in order to disrupt the recorded magnetic domains) the information from the electronic media. If circumstances warrant the destruction of the electronic media prior to disposal, destruction methods may include disintegrating, pulverizing, melting, incinerating, or shredding the media.

Because failure to ensure total destruction of patient identifying information may lead to the unauthorized disclosure of sensitive information regarding a patient's substance use disorder history, SAMHSA says it expects the process of sanitizing paper (including printer and FAX ribbons, drums, etc.) or electronic media to be permanent and irreversible, so that there is no reasonable risk the information may be recovered.

Notice of Federal Protections

SAMHSA proposes to continue to require that patients be given a summary in writing of the federal law and regulations. SAMHSA would permit the notice to patients to be either on paper or in an electronic format. SAMHSA also proposes to require the statement regarding the reporting of violations to include contact information for the appropriate authorities. The reporting of any violation of the regulations could be directed to the U.S. Attorney for the judicial district in which the violation occurs and the report of any violation of these regulations by an opioid treatment program could also be directed to the SAMHSA office responsible for opioid treatment program oversight. (This replaces the previous requirement that notice be given to the Food and Drug Administration.) SAMHSA is considering whether to issue guidance at a later date that includes a sample notice.

Although it is not a proposed requirement, SAMHSA encourages programs to be sensitive to the cultural composition of its patient population when considering whether the notice should also be provided in a language(s) other than English (e.g., Spanish).

Prohibitions against Redisclosure

SAMHSA proposes to clarify that the prohibition against re-disclosure only applies to information that would identify, directly or indirectly, an individual as having been diagnosed, treated, or referred for treatment for a substance use disorder, such as indicated through standard medical codes, descriptive language, or both. Other health-related information shared by the Part 2 program could be re-disclosed, if permissible under other applicable law. For example, if an individual receives substance use disorder treatment from a Part 2 program and also receives treatment for a health condition such as high blood pressure, the individual's record would include information unrelated to their substance use disorder (i.e., high blood pressure). Part 2 does not prohibit re-disclosure of the information related to the high blood pressure as long as it does not include information that would identify the individual as having or having had a substance use disorder.

However, illnesses that are brought about by drug or alcohol abuse may reveal that a patient has a substance use disorder. For example, cirrhosis of the liver or pancreatitis could reveal a substance use disorder. Also, if a prescription for a medication used for substance use disorder treatment is revealed without further clarification of a non-substance disorder use (e.g., methadone used for the treatment of cancer), it would suggest that the individual has a substance use disorder and disclosure of that information also would be prohibited.

SAMHSA also proposes to reiterate that the federal rules restrict any use of the information to criminally investigate or prosecute any patient with a substance use disorder.

Medical Emergencies

SAMHSA proposes aligning the regulatory language with the statutory language regarding the medical emergency exception of 42 CFR part 2 (§2.51). The current regulations state that information may be disclosed without consent for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intervention. The statute, however, states that records may be disclosed "to medical personnel to the extent necessary to meet a bona fide medical emergency."

SAMHSA proposes to adapt the medical emergency exception to give providers more discretion to determine when a "bona fide medical emergency" exists. The proposed language states that patient identifying information may be disclosed to medical personnel to the extent necessary to meet a bona fide medical emergency, in which the patient's prior informed consent cannot be obtained.

SAMHSA proposes to continue to require the part 2 program to immediately document, in writing, specific information related to the medical emergency. Before a Part 2 program enters into an affiliation with an HIE, it should consider whether the HIE has the capability to immediately notify the Part 2 program when its records have been disclosed pursuant to a medical emergency. To promote compliance, SAMHSA recommends that the notification include all the information that the Part 2 program is required to document in the patient's records (e.g., date and time of disclosure, the nature of the emergency). Similarly, SAMHSA recommends that the Part 2 program consider whether the HIE has the technology, rules, and procedures to appropriately protect patient-identifying information.

Research Activities

SAMHSA also proposes to revise the research exception to permit data to be disclosed to qualified personnel for the purpose of conducting scientific research by a Part 2 program or any other individual or entity that is in lawful possession of Part 2. SAMHSA is proposing to allow patient-identifying information to be disclosed for purposes of scientific research:

1) if the researcher is a HIPAA covered entity or business associate and provides documentation that the researcher obtained research participants' authorization, or a waiver of research participants' authorization by an Institutional Review Board (IRB) or privacy board, for use or disclosure of information about them for research purposes consistent with the HIPAA Privacy Rule, (45 CFR 164.512(i)); or
2) if the researcher is subject to the HHS Common Rule (45 CFR part 46, subpart A) and provides documentation that the researcher is in compliance with the requirements of the HHS Common Rule, including requirements relating to informed consent or a waiver of consent (45 CFR 46.111 and 46.116); or
3) if the researcher is both a HIPAA covered entity or business associate and subject to the HHS Common Rule, the researcher has met the requirements of both (1) and (2).

SAMHSA also is proposing to address data linkages because the process of linking two or more streams of data opens up new research opportunities. It proposes to permit researchers to request to link data sets that include patient identifying information if: (1) the data linkage uses data from a federal data

repository; and (2) the project, including a data protection plan, is reviewed and approved by an IRB registered with the Office for Human Research Protections (OHRP). This permissible disclosure would allow a researcher to disclose patient-identifying information to a federal data repository and permit the federal data repository to link the patient-identifying information to data held by that repository and return the linked data file back to the researcher. It would also ensure that patient privacy is considered, that the disclosure and use of identifiable data is justified, and that the research protocol includes an appropriate data protection plan.

SAMHSA is proposing to limit the data repositories from which a researcher may request data for data linkages purposes to federal data repositories because federal agencies that maintain data repositories have policies and procedures in place to protect the security and confidentiality of the patient identifying information that must be submitted by a researcher in order to link the data sets. For example, in addition to meeting requirements under the HIPAA Rules and/or the HHS Common Rule, as applicable, requests for "research identifiable files" data from CMS require a Data Use Agreement and are reviewed by CMS's Privacy Board. CMS also has internal policies to protect the privacy and security of data received from the researcher, including the retention and destruction of that data. In addition, all federal agencies must comply with directives that protect sensitive data such as *Office of Management and Budget Circular No. A-130, Appendix III--Security of Federal Automated Information and NIST Federal Information Processing Standard 200 entitled Minimum Security Requirements for Federal Information and Information Systems*.

SAMHSA is soliciting public input regarding whether to expand the data linkages provision beyond federal data repositories, what confidentiality, privacy, and security safeguards are in place for those non-federal data repositories, and whether those safeguards are sufficient to protect the security and confidentiality of the patient identifying information. It invites stakeholders to provide input and recommendations on the specific policies, procedures, and other safeguards that non-federal data repositories should have in place including, but not limited to:

1. Data use agreements (e.g., a data use agreement or contract between the researcher and the data repository with written provisions to uphold security and confidentiality of the data and provide for sanctions or penalties for breaches of confidentiality);

2. A review by a privacy board or other regulatory body(-ies);

3. Internal security and privacy protections (both physical and electronic) for the confidentiality and security of data, including the retention and destruction of data received for data linkage purposes (e.g., a requirement to destroy, in a manner to render the data nonretrievable, all patient identifying information provided by the researcher for data linkage purposes after performing the match).

4. Security and privacy protections (both physical and electronic) for receiving and linking data (e.g., a requirement that transmission of data between the researcher and the data repository must occur through the use of secure methods and use the most current encryption technology, such as the most current version of the Advanced Encryption Standard (NIST Federal Information Processing Standards (FIPS 197)).

5. Internal confidentiality agreements for staff members who have access to patient identifying information and other confidential data;

6. Laws and regulations governing functions and operations, including those that address security and privacy;

7. Capability to perform data linkages according to recognized standards; and

8. Other relevant safeguards.

SAMHSA also is requesting public comment on the following sets of questions:

(1) First, should state government, local government, private, and/or other non-federal data repositories that meet the criteria above be permitted to conduct data linkages?

(2) Second, are there additional or alternative criteria that should be included in the list above? Are there specific categories of data repositories that are already required to provide similar safeguards? When providing categories of data repositories, what are the safeguards that are already in place for those entities?

(3) Third, how could it be ensured that data repositories providing data linkages are in compliance with criteria or standards concerning confidentiality, privacy, and security safeguards? Are there any regulatory or oversight bodies (including non-governmental and governmental) that currently oversee compliance with criteria or standards concerning confidentiality, privacy, and security safeguards of data in non-federal repositories?

Finally, SAMHSA is proposing to require any individual or entity conducting scientific research using patient-identifying information to resist in judicial proceedings any efforts to obtain access to patient records except as permitted by these regulations. This requirement means that researchers involved in a judicial proceeding are only required to disclose patient identifying information pursuant to a subpoena that is accompanied by a court order.

Audits and Evaluations

Under the current Medicare or Medicaid audit or evaluation section of the regulations, an audit or evaluation is limited to a civil investigation or administrative remedy by any federal, state, or local agency responsible for oversight of the Medicare or Medicaid program. It also includes administrative enforcement, against the program by the agency, or any remedy authorized by law to be imposed as a result of the findings of the investigation.

SAMHSA proposes to modernize this section to include both paper and electronic patient records. In addition, it proposes to update the Medicare or Medicaid audit or evaluation subsection title to include CHIP. SAMHSA also proposes to permit the Part 2 program, not just the Part 2 program director, to determine who is qualified to conduct an audit or evaluation.

Finally, SAMHSA proposes to permit an audit or evaluation necessary to meet the requirements of a CMS-regulated ACO or similar CMS-regulated organization (including a CMS-regulated Qualified Entity (QE)), if the auditing entity has a signed Participation Agreement with CMS that requires the CMS-regulated ACO or similar CMS-regulated organization (including a CMS-regulated QE) to comply with all applicable provisions of 42 U.S.C 290dd-2 and 42 CFR Part 2.