2. Does Executive Order 13175 apply to this proposed rule?

This action does not have tribal implications, as specified in Executive Order 13175. Proposing a site to the NPL does not impose any costs on a tribe or require a tribe to take remedial action. Thus, Executive Order 13175 does not apply to this proposed rule.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

1. What is Executive Order 13045?

Executive Order 13045: "Protection of Children From Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997) applies to any rule that: (1) Is determined to be "economically significant" as defined under Executive Order 12866, and (2) concerns an environmental health or safety risk that the EPA has reason to believe may have a disproportionate effect on children. If the regulatory action meets both criteria, the agency must evaluate the environmental health or safety effects of the planned rule on children, and explain why the planned regulation is preferable to other potentially effective and reasonably feasible alternatives considered by the agency.

2. Does Executive Order 13045 apply to this proposed rule?

This proposed rule is not subject to Executive Order 13045 because it is not an economically significant rule as defined by Executive Order 12866, and because the agency does not have reason to believe the environmental health or safety risks addressed by this proposed rule present a disproportionate risk to children.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

1. What is Executive Order 13211?

Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use," (66 FR 28355, May 22, 2001) requires federal agencies to prepare a "Statement of Energy Effects" when undertaking certain regulatory actions. A Statement of Energy Effects describes the adverse effects of a "significant energy action" on energy supply, distribution and use, reasonable alternatives to the action and the expected effects of the alternatives on energy supply, distribution and use.

2. Does Executive Order 13211 apply to this proposed rule?

This action is not a "significant energy action" as defined in Executive Order 13211, because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. Further, the agency has concluded that this rule is not likely to have any adverse energy impacts because proposing a site to the NPL does not require an entity to conduct any action that would require energy use, let alone that which would significantly affect energy supply, distribution or usage. Thus, Executive Order 13211 does not apply to this action.

I. National Technology Transfer and Advancement Act

1. What is the National Technology Transfer and Advancement Act?

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note), directs the EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., materials specifications, test methods, sampling procedures and business practices) that are developed or adopted by voluntary consensus standards bodies. The NTTAA directs the EPA to provide Congress, through OMB, explanations when the agency decides not to use available and applicable voluntary consensus standards.

2. Does the National Technology Transfer and Advancement Act apply to this proposed rule?

No. This proposed rulemaking does not involve technical standards. Therefore, the EPA did not consider the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

1. What is Executive Order 12898?

Executive Order (EO) 12898 (59 FR 7629, Feb. 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies and activities on minority populations and low-income populations in the United States.

2. Does Executive Order 12898 apply to this proposed rule?

The EPA has determined that this proposed rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. As this rule does not impose any enforceable duty upon state, tribal or local governments, this rule will neither increase nor decrease environmental protection.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Natural resources, Oil pollution, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Dated: May 1, 2014.

Barry Breen,

Principal Deputy Assistant Administrator, Office of Solid Waste and Emergency Response.

[FR Doc. 2014–10832 Filed 5–9–14; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

42 CFR Part 2

Confidentiality of Alcohol and Drug Abuse Patient Records

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice of Public Listening Session.

SUMMARY: The Substance Abuse and Mental Health Services Administration (SAMHSA) announces that it will hold a public listening session on Wednesday, June 11, 2014, to solicit information concerning the Confidentiality of Alcohol and Drug Abuse Patient Records Regulations, 42 CFR Part 2. This session will be held in Rockville, MD, to obtain direct input from stakeholders on updating the regulations. The scheduled listening session provides an opportunity for SAMHSA to seek public input on potential changes to the regulations.

DATES: The listening session will be held on Wednesday, June 11, 2014, from 9:30 a.m. to 4:30 p.m.

ADDRESSES: *Participation:* The listening session will be held at the Substance Abuse and Mental Health Services Administration at 1 Choke Cherry Road, Rockville, MD 20857, Lobby-level Sugarloaf Conference Room.

SAMHSA will post the agenda and logistical information on how to participate via the phone or internet on the SAMHSA Web site at *http://www.samhsa.gov/healthprivacy* in advance of the listening session.

The session is open to the public and the entire day's proceedings will be webcast, recorded, and made publicly available. Interested parties may participate in person or via webcast. Capacity is limited and registration is required. To register, go to *http://42cfrpart2-listeningsession.eventbrite.com.* Registration will be open until we meet maximum capacity. In addition to attending the session in person and joining via webinar, the Agency offers several ways to provide comments, as enumerated below. The forum will begin with opening remarks from the SAMHSA official charged with moderating the session. The session location is accessible to persons with disabilities.

You may submit comments using any of the following methods:

- Mail: The Substance Abuse and Mental Health Services Administration, 1 Choke Cherry Road, Rockville, MD 20857, Room 5–1011.
- Hand Delivery or Courier: 1 Choke Cherry Road, Rockville, MD 20857, Room 5–1011 between 9 a.m. and 5 p.m., ET, Monday through Friday, except federal holidays.
- Email: *PrivacyRegulations@SAMHSA.hhs.gov.*
- Fax: 1–240–276–2900.

Each submission must include the Agency name and the docket number for this notice. Comments must be received by 5:00 p.m. ET on Wednesday June 25, 2014.

FOR FURTHER INFORMATION CONTACT: For information concerning the listening session or the live webcast, please contact Kate Tipping, Public Health Advisor, SAMHSA, 1 Choke Cherry Road, Rockville, MD 20857, Room 5–1011, (240) 276–1652 or email *PrivacyRegulations@SAMHSA.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The federal statute (United States Code, Title 42, section 290dd–2) governing the confidentiality of substance abuse treatment information guarantees the confidentiality of information for persons receiving substance abuse treatment services from federally assisted programs. Under the statute, a federally assisted substance abuse program generally may only release identifiable information related to substance abuse treatment services with the individual's express consent. The federal regulations that implement this law—Title 42 of the Code of Federal Regulations Part 2 (42 CFR Part 2)—were last updated in 1987. Over the last 25 years, significant changes have occurred within the U.S. health care system that were not envisioned by these regulations, including new models of integrated care that are built on a foundation of information sharing to support coordination of patient care, the development of an electronic infrastructure for managing and exchanging patient data, the development of prescription drug monitoring programs and a new focus on performance measurement within the health care system. When the regulations were written, substance abuse treatment was primarily conducted by specialty treatment providers, and as a result, the impact on coordination of care was not raised as a core issue.

SAMHSA has heard from stakeholders that some of the current consent requirements make it difficult for these new health care organizations including health information exchange organizations (HIEs), Accountable Care Organizations (ACOs), and others to share substance abuse treatment information. A number of organizations across the country are excluding substance abuse treatment data due to the difficulty and expense of implementing the functionality and workflow changes necessary to comply with current regulations. In these instances, patients are prevented from fully participating in integrated care efforts even if they are willing to provide consent.

Behavioral health is essential to overall health and the costs of untreated substance abuse disorders, both personal and societal, are enormous. However, treatment for substance abuse disorders is still associated with discrimination. In addition, there may be potential serious civil and criminal consequences for the disclosure of this information beyond the health care context. There continues to be a need for confidentiality protections that encourage patients to seek treatment without fear of compromising their privacy. SAMHSA strives to facilitate information exchange while respecting the legitimate privacy concerns of patients due to the potential for discrimination and legal consequences. We hope to clarify the requirements associated with information exchange in these new models and reduce burdens associated with specific consent requirements that do not serve to protect patient privacy.

In consideration of the concerns raised regarding the application of 42 CFR Part 2 to new health care models and the continued need for confidentiality protections, the Agency will conduct a public listening session to provide all interested parties the opportunity to share their views on the subject prior to the initiation of rulemaking. Members of the public are invited to attend and view the proceedings, with space available on a first-come, first-served basis (based on registration). Written comments may also be submitted at the session or through the process described above.

SAMHSA asks listening session participants to consider the following questions in preparing to make comments at the listening session. Listening session attendees will also be provided with a list of these questions at the forum site:

a. Applicability of 42 CFR Part 2

42 CFR Part 2 currently applies to federally funded individuals or entities that "hold themselves out as providing, and provide, alcohol or drug abuse diagnosis, treatment or treatment referral" including units within a general medical facility that hold themselves out as providing diagnosis, treatment or treatment referral (§ 2.11 Definitions, Program). The U.S. health care system is changing and more substance abuse treatment is occurring in general health care and integrated care settings which are typically not covered under the current regulations. It has also posed difficulties for identifying which providers are covered by Part 2; whether a provider or organization is covered by Part 2 can change depending on whether they advertise their substance abuse treatment services (i.e. 'hold themselves out'), which can change over time.

SAMHSA is considering options for defining what information is covered under 42 CFR Part 2. Covered information could be defined based on what substance abuse treatment services are provided instead of being defined by the type of facility providing the services. For example, the regulations could be applied to any federally assisted health care provider that provides a patient with specialty substance abuse treatment services. In

this scenario, providers would not be covered if they provided only substance abuse screening, brief intervention, or other similar pre-treatment substance abuse services.

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

• Would this change address stakeholder concerns?

• Would this change raise any new concerns?

b. Consent Requirements

SAMHSA has heard a number of concerns from individuals and stakeholders regarding the current consent requirements of 42 CFR Part 2. 42 CFR 2.31 requires the written consent to include the name or title of the individual or the name of the organization to which the disclosure is to be made. This is commonly referred to as the "To Whom" consent requirement. Some stakeholders have reported that this requirement makes it difficult to include programs covered by 42 CFR Part 2 in HIEs, health homes, ACOs and CCOs. These organizations have a large and growing number of member providers and they generally do not have sophisticated consent management capabilities. Currently, a Part 2 compliant consent cannot include future un-named providers which requires the collection of updated consent forms whenever new providers join these organizations. As a result, many of these organizations are currently not including substance abuse treatment information in their systems.

While technical solutions for managing consent collection are possible, SAMHSA is examining the consent requirements in § 2.31 to explore options for facilitating the flow of information within the health care context while ensuring the patient is fully informed and the necessary protections are in place. Specifically, we are analyzing the current requirements and considering the impact of adapting them to:

1. Allow the consent to include a more general description of the individual, organization, or health care entity to which disclosure is to be made.

2. Require 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.

3. Require the consent to name the individual or health care entity permitted to make the disclosure.

4. Require that if the health care entity permitted to make the disclosure is made up of multiple independent units or organizations that the unit, organization, or provider releasing substance abuse related information be specifically named.

5. Require that the consent form explicitly describe the substance abuse treatment information that may be disclosed.

SAMHSA welcomes comments on patient privacy concerns as well as the anticipated impact of the consent requirements on integration of substance abuse treatment data into HIEs, health homes, ACOs, and CCOs.

• Would these changes maintain the privacy protections for patients?

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

• Would these changes raise any new concerns?

c. Redisclosure

SAMHSA has also heard numerous concerns regarding the prohibition on redisclosure (§ 2.32). Currently most EHRs don't support data segmentation. Without this functionality, EHR systems must either keep alcohol and drug abuse patient records separate from the rest of the patient's medical record or apply the 42 CFR Part 2 protections to the patient's entire medical record if such record contains information that is subject to 42 CFR Part 2.

SAMHSA is considering revising the redisclosure provision to clarify that the prohibition on redisclosure only applies to information that would identify an individual as a substance abuser, and allows other health-related information shared by the Part 2 program to be redisclosed, if legally permissible. This would allow HIT systems to more easily identify information that is subject to the prohibition on redisclosure enabling them to utilize other technological approaches to manage redisclosure. If data are associated with information about where the data were collected (data provenance) which reveals that the data were collected by a practice that exclusively treats addiction, the data would still be protected under the proposed change.

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

• Would these changes maintain the privacy protections for patients?

d. Medical Emergency

SAMHSA has heard concerns 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 is considering adapting the medical emergency exception to make it more in-line with the statutory language and to give providers more discretion as to when a bona fide emergency exists. For example, amending this standard to allow providers to use the medical emergency provision to prevent emergencies or to share information with a detoxification center when a patient is unable to provide informed consent due to their level of intoxication.

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

• Are there specific use cases SAMHSA should take into consideration?

• Are there patient concerns about the impact of this change on their privacy?

e. Qualified Service Organization (QSO)

SAMHSA has also heard concerns from payers and health management organizations related to disclosing information that is subject to 42 CFR Part 2 to health care entities (ACOs/CCOs) for the purpose of care coordination and population health management; helping them to identify patients with chronic conditions in need of more intensive outreach. Under the current regulations, substance abuse information may not be shared for these purposes without consent.

SAMHSA is analyzing the regulations to identify options for allowing Part 2 data to flow to health care entities for the purpose of care coordination and population management while maintaining patient protections. One potential solution includes expanding the definition of a qualified service organization (QSO; § 2.11) to explicitly include care coordination services and to allow a QSO Agreement (QSOA) to be executed between an entity that stores Part 2 information, such as a payer or an ACO that is not itself a Part 2 program, and a service provider.

• Are there other use cases we should be taking into consideration?

• Are there specific patient concerns about the impact of this change on their privacy?

f. Research

Under the current regulations, the Part 2 "program director" has to authorize the release of information for scientific research purposes. This issue has been brought to SAMHSA's attention from organizations that store patient health data, including data that are subject to Part 2, which may be used for research (e.g. health management organizations). Under the current regulatory framework, absent consent, these organizations do not have the authority to disclose Part 2 data for scientific research purposes to qualified researchers or research organizations. This issue can be addressed by expanding the authority for releasing data to qualified researchers/research organizations to other health care entities that receive and store Part 2 data, including third-party payers, HIEs, and care coordination organizations for the purposes of research, audit, or evaluation.

SAMHSA is considering expanding the authority for releasing data to qualified researchers/research organizations to health care entities that receive and store Part 2 data, including third-party payers, health management organizations, HIEs, and care coordination organizations.

- 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?
- Would this change address concerns related to research?
- Are there specific privacy concerns associated with expanding the authority or releasing data to qualified researchers/research organizations in this way?
- Are there additional use cases that should be considered in the research context?

g. Addressing Potential Issues With Electronic Prescribing and Prescription Drug Monitoring Programs (PDMPs)

Part 2 protections include a prohibition on the redisclosure of information received directly from a Part 2 program. A pharmacy that receives electronic prescription information directly from a Part 2 program must obtain patient consent to send that information to a PDMP, and patient consent is also required for the PDMP to redisclose that information to those with access to the PDMP. Pharmacy data systems do not currently have mechanisms for managing patient consent or segregating data that are subject to Part 2 and preventing the data from reaching the PDMP. Pharmacy systems also lack the ability to identify which providers are subject to Part 2, making it difficult to prevent the Part 2 data from reaching the PDMP.

If a patient does not consent to sharing their data via e-prescribing, their only option for filling their prescription is to bring a paper prescription to the pharmacy. In this instance, since the information is given by the patient, it is not protected by 42 CFR Part 2. They, therefore, cannot prevent the information from reaching the PDMP which in some states is accessible by law enforcement and has the potential to lead to investigation/arrest and other forms of discrimination.

- How do pharmacy information system vendors anticipate addressing this issue? Are there specific technology barriers SAMHSA should take into consideration?
- Are there other concerns regarding 42 CFR Part 2 and PDMPs? Please describe relevant use cases and provide recommendations on how to address the concerns.
- Are there patient concerns about the impact of e-prescribing and PDMPs on their privacy?

Draft Agenda for the June 11, 2014 Public Listening Session

—Welcome and Introductions—9:30 a.m.–9:45 a.m.
—Applicability of 42 CFR Part 2—9:45 a.m.–10:45 a.m.
—Consent requirements—10:45 a.m.–11:45 a.m.
—Redisclosure and Medical emergency provisions—11:45 a.m.–12:45 p.m.
—LUNCH (on your own)—12:45 p.m.–1:15 p.m.
—Quality Service Organization (QSO) provision—1:15 p.m.–1:45 p.m.
—Research—1:45 p.m.–2:45 p.m.
—Electronic prescribing and prescription drug monitoring programs (PDMPs)—2:45 p.m.–3:30 p.m.
—Open Comment Period—3:30 p.m.–4:30 p.m.

The agenda will be strictly followed; participants may attend all or part of the listening session as relevant. The updated agenda will be posted on the SAMHSA Web site at *http://www.samhsa.gov/healthprivacy* in advance of the listening session.

Cathy J. Friedman,
SAMHSA Public Health Analyst.

[FR Doc. 2014–10913 Filed 5–9–14; 8:45 am]
BILLING CODE 4162–20–P